



ANNUAL REPORT 2019

With the successful clinical proof of concept in our lead program we believe Initiator Pharma has an exciting future ahead.

20 19

TABLE OF CONTENTS

Initiator Pharma	3
2019 in Brief	4
Milestones	5
Financial Highlights	5
CEO letter	6
Goals, strategy & business model	8
Project portfolio	9
The Initiator Pharma share	12
Report from the Board of Directors and the Chief Executive Officer	13
The board of directors and Auditor	14
Management	15
Profit & Loss Statement	16
Balance Sheet	17
Statement of changes in equity for 2019	18
Statement of cash flow	18
Accounting policies	19
Notes to the financial statements	21
Signatories to the Annual Report	23
Independent Auditor's Report	24
Glossary	26
Shareholder information	27



Initiator Pharma A/S

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Initiator Pharma



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.

Our 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. In March we reported the final data from a Phase 2a clinical proof of concept study for IPED2015, documenting statistically and clinically significant effects on patients with severe ED.

Furthermore, in March this year we expanded our pipeline of clinical phase projects by exercising an option to in-license IP2018 from Saniona and filed a CTA for a Phase 2a clinical proof of concept study in patients with depression-induced ED to be initiated later this year.

Initiator Pharma is a pharmaceutical company based in Aarhus, Denmark. Our shares are listed on Spotlight Stockmarket (SS:INIT), and as of Dec 31, 2019 we had approx 3,900 shareholders.

“The positive read-out of the IPED2015 Phase IIa trial is constituting a significant milestone and a clear validation of Initiator Pharma's cost effective performance model as a value-creating biotech company. 2020 will be an exhilarating year with a series of upcoming value inflection points in the near to mid-term future.”

Claus Elsborg Olesen
CEO, Initiator Pharma A/S

2019 IN BRIEF

- **On April 29th** we called for the Annual General Assembly that was held on May 23rd and released our annual report for 2018.
- **On May 23rd** we released our Q1 report.
- **On June 10th** we announced that we had successfully completed the Phase 1 for IPED2015.
- **On June 25th** we announced the start of dosing of IPED2015 in the Phase 2a proof-of-concept clinical trial in erectile dysfunction patients.

- **On October 18th** we announced that we had received an extension of the option agreement for the IP2018 drug candidate from Saniona until 31 March 2020 and furthermore opt to pay back the 5 MSEK bridge loan obtained earlier this year.
- **On November 22nd** we released our Q3 report.
- **On December 5th** we announced that the Phase 2a proof of concept study for IPED2015 had achieved statistically significant results on key efficacy endpoints in severe ED patients after a single administration of IPED2015. Moreover, no observations of critical adverse events were recorded.
- **On December 23rd** we announced that individuals in the board and management exercised a total of 434 197 warrants for subscription of new shares, raising approx 1,9 SEK in proceeds to the company.

Q1

- **On Febr 22nd** we released our full year report for 2018.

Q2

- **On July 5th** we announced that the incentive program in Initiator Pharma, approved by the AGM on May 23rd had been fully subscribed. If all warrants are exercised the company will issue a total of 434.197 new shares, representing 1.9% of issued shares, with par value of DKK 0.105 and with an exercise price of SEK 8,40.
- **On Aug 13th** we provided a status update on the ongoing Phase 2a study in patients with Erectile Dysfunction.
- **On Aug 13th** we announced that the company has secured bridge financing of SEK 5 million with the aim of preparing the company's other candidate drug IP2018 for the start of a clinical phase 2a trial. With this bridge financing, the company is able to conduct activities for added value before seeking more long-term funding. The clinical phase 2a trial regarding IP2018 is expected to begin in early 2020.
- **On Aug 23rd** we released our first half report.
- **On September 3rd** we announced that we had been awarded a grant from Innovation Fund Denmark of up to DKK 2 mill to support the ongoing clinical development program for IPED2015.
- **On September 27th** we announced that the dosing of the last patients in clinical Phase 2a Proof-of-Concept trial with IPED2015 had started, with anticipated release of draft data from the study expected during December 2019.

Q3

Q4

SIGNIFICANT EVENTS AFTER YEAR END

- **On March 15th** we reported the final data from the company's Phase IIa study with IPED2015, demonstrating statistically significant and clinically relevant results on key efficacy endpoints in patients with sED after a single administration of IPED2015. As previously reported, the Phase IIa study was completed satisfactorily with no observations of critical adverse events.
- **On March 31st** we announced that we have filed a Phase 2a Clinical Trial Application (CTA) to MHRA, UK, for our candidate drug IP2018. Through the submission of the CTA, we also exercised our option agreement with Saniona for IP2018.
- **On April 27th** we announced that we have completed a SEK 3 direct share issue with warrants to Formue Nord, a Danish investment fund, and also announced a proposal to the Annual General Meeting for a SEK 7 rights issue with warrants that has been fully guaranteed. The warrant program connected to the share issues will raise another SEK 16.5 if fully utilized.

Q1

Milestones and Financial Highlights

Milestones

Milestones achieved during 2019

- Completed Phase 1 study for IPED2015 demonstrating that IPED2015 in general is safe and well tolerated
- Completed Phase 2a proof of concept study for IPED2015 in patients with severe Erectile Dysfunction and reported preliminary results showing statistically significant results on key efficacy endpoints

Upcoming milestones

- File Clinical Trial Application (CTA) for a Phase 2a proof of concept study for IP2018
- Exercise option to in-license IP2018
- Initiate the Phase 2a for IP2018
- IPED2015 business development and dealmaking e.g. partnership or trade sale

Key Figures

Income Statement, TDKK	2019	2018	2017
Operating profit/loss	-9 339	-12 609	-9 561
Profit/loss before tax	-9 975	-12 703	-10 362
Profit/loss for the year	-8 288	-10 297	-8 582

Balance Sheet, TDKK	2019	2018	2017
Fixed assets	37	125	212
Current receivables	3 839	2 713	1 917
Cash and cash equivalents	7 562	14 491	7 169
Total assets	11 438	17 328	9 298
Equity	9 908	16 571	5 964
Current liabilities	1 530	758	3 334
Total equity and liabilities	11 438	17 328	9 298

Cash flow, TDKK	2019	2018	2017
Cash flow from operating activities	-8 553	-13 583	-7 784
Cash flow for the year	-6 929	7 321	7 002

Key figures, %	2019	2018	2017
Liquidity ratio	745%	2270%	273%
Equity ratio	87%	96%	64%

Share data, DKK	2019	2018	2017
Diluted earnings per share	-0,34	-0,51	-1,04
Equity per share	0,42	0,72	0,69
Dividend	0	0	0
Cash flow per share	-0,29	0,32	0,81

Share data, #	2019	2018	2017
Shares outstanding	23 591 375	23 157 178	8 683 943
Diluted shares outstanding	24 459 769	24 025 572	9 118 140



CEO letter

Initiator Pharma ended 2019 on a very positive note as we in December announced positive topline data from the IPED2015 phase 2a clinical trial in erectile dysfunction. This strengthens our conviction that our candidate drug IPED2015 has strong potential to become the medical treatment of erectile dysfunction for the PDE5i non-responders. The positive data also support our ambition to position Initiator Pharma as a recognized and cost-effective biotech company adding significant value to drug candidates through well designed and well conducted Proof-of-Concept clinical trials.



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

Overall, 2019 represented a transformational period for Initiator Pharma as we completed the Phase 1 trial and subsequently initiated the critical Phase 2a trial for IPED2015. We have advanced our portfolio, and Initiator Pharma is today a clinical-stage biotech company. We have successfully completed our Phase 2a clinical trial with positive results. The data and learning from the PoC study enables us to create a more detailed plan that outlines the clinical and regulatory pathway going forwards, e.g., the pivotal study that constitutes a cornerstone in the final NDA (New drug application in the US). This roadmap represents an essential tool in our Business Development effort, aiming at ensuring the continued development of IPED2015 for the benefit of the patients and our shareholders.

At the JP Morgan conference in San Francisco in January, we experienced a keen interest in Initiator Pharma and IPED2015. The general response is an acknowledgment of the unmet medical need and of Initiator Pharma on how we, with a completely novel mechanism of action (MoA), has created an effective and safe solution for the treatment of PDE5i non-responders. We will continue the ongoing interactions with potential acquirers or partners, while keep exploring new opportunities that, due to COVID-19 pandemic, for the time being, is reduced to virtual meetings. Nevertheless, we still have high confidence in a future deal or partnership for Initiator Pharma.

In parallel with the IPED2015 activities in the last quarter of 2019, we also continued the development of IP2018. We filed a CTA on the 31st of March this year, triggering the exercise of the option agreement with Saniona and allowing us to integrate IP2018 fully into the Initiator Pharma pipeline.

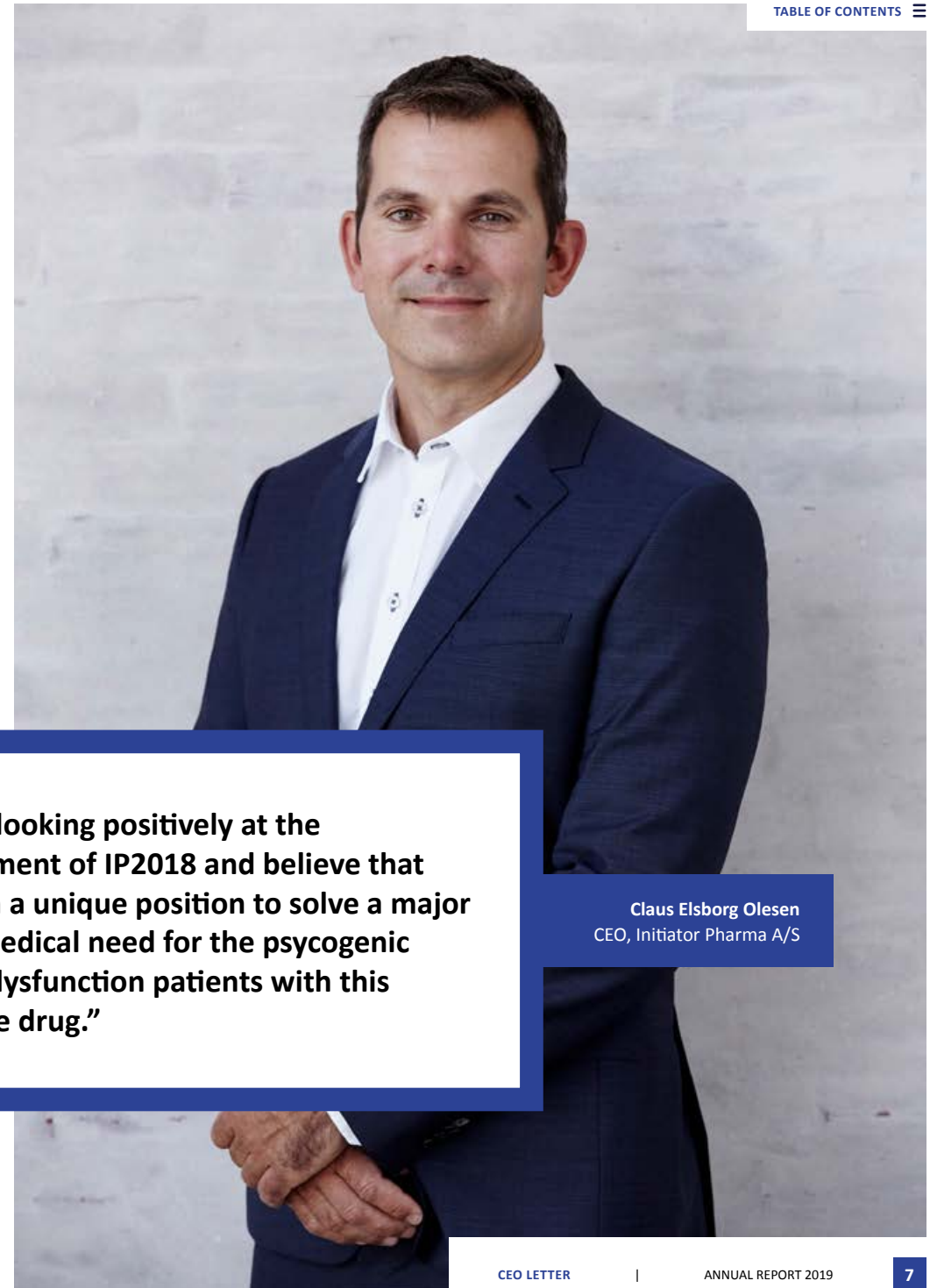
“Initiator Pharma has proven its ability to deliver candidate drugs that provide a solution to a very serious medical problem that affects a lot of people.”

IP2018 is a candidate drug for the combined treatment of depression and erectile dysfunction, which is a clear differentiation from other antidepressants on the market today. In the planned clinical phase 2a trial, Initiator Pharma intends to primarily confirm the effect of IP2018 on the erectile function of patients, and after that, 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.

In addition to the progress we made in 2019, I see good reasons for Initiator Pharma’s ability to create value going forward. Firstly, with IPED2015 we are addressing a major unmet need targeting a segment where a large number of patients, the PDEi non-responders, currently lack an effective treatment. Secondly, 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. I look forward to Initiator Pharma’s future progression and have high confidence in our programs.

With these words, I would like to thank all existing shareholders and welcome new shareholders to become part of an exciting future together with a biotech company with two clinical Phase 2 assets in development.

Claus Elsborg Olesen
CEO, Initiator Pharma A/S



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

Claus Elsborg Olesen
CEO, Initiator Pharma A/S



Goals



Strategy



Business model

“With current treatment, sexual dysfunction is still a significant problem in depression. IP2018 has a unique profile by having effects on both erection and depression in preclinical studies. Along with the good safety profile in clinical phase I trials, I consider it a promising candidate for treating sexual dysfunction in patients with depression.”

Ulf Simonsen
Professor and CMO



Goals

Initiator Pharma’s goal is to progress novel drug candidates toward the market in a cost and time effective way, for the benefit of both patients in need of new or improved medical therapies and for our shareholders.



Strategy

Our strategy is to identify promising drug candidates in late preclinical and early clinical development that target medical indications with clearly defined unmet medical needs and with attractive commercial opportunities, and rapidly progress these candidates through clinical Proof-of-Concept studies to the point where we expect to enter partnerships for late-stage clinical development.



Business model

The company aims to commercialize its research efforts through the following 2 business models:

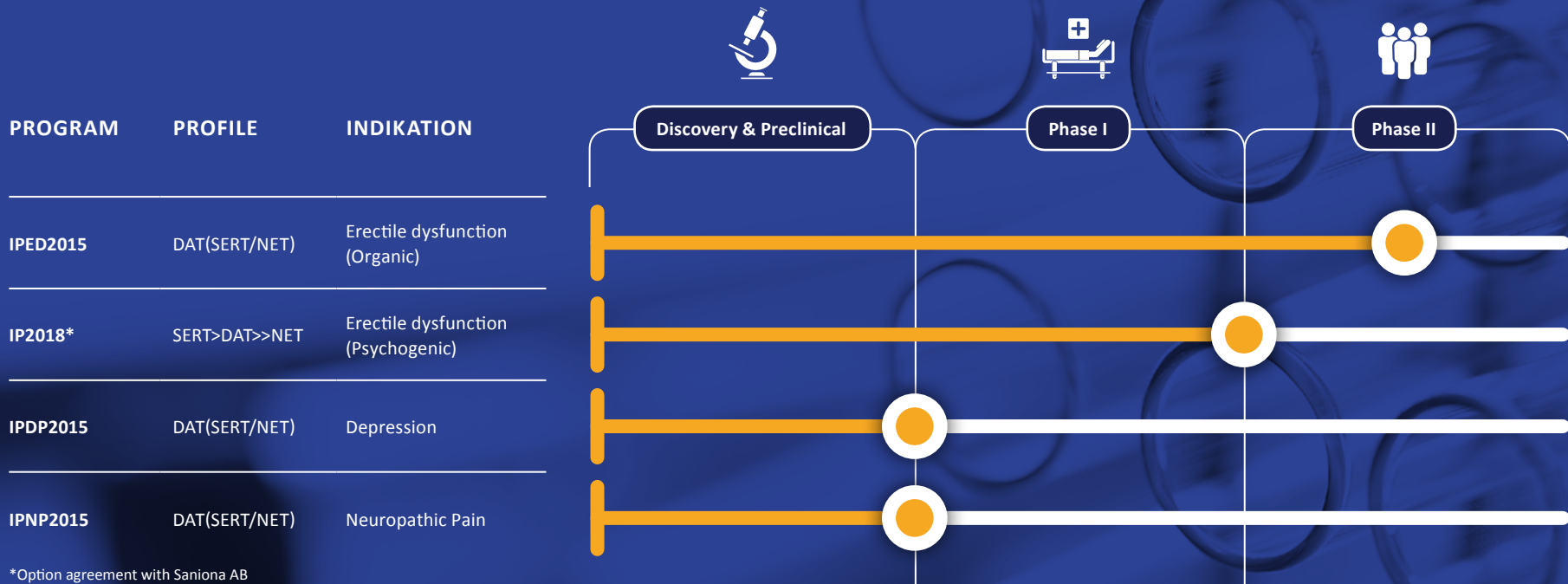
- By internal development of selected programs through the early phases of drug development before out-licensing to pharmaceutical companies who will take over the further development of Initiator Pharma’s programs and typical with upfront payments, milestone and royalty payments on product sales to 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.

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

Initiator Pharma is employing a virtual organization model in order to maximize speed and flexibility while minimizing development costs. 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.

Project portfolio

Initiator Pharma currently has a portfolio of four projects, of which two are in clinical development and two are in preclinical development.



All four drug candidates belong to the drug class known as monoamine reuptake inhibitors (MRIs). Molecules in this class act as reuptake inhibitors 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. This in turn results in an increase in the synaptic concentrations of one or more of these neurotransmitters and therefore an increase in monoaminergic neurotransmission.

IPED2015

Initiator Pharma's most progressed asset is IPED2015, in clinical development as a novel treatment paradigm for erectile dysfunction (ED). The aim is to improve the quality of life for a growing number of patients and their partners that do not respond to, or cannot be treated with, current marketed medication (PDE5 inhibitors) for sexual dysfunction. Conservatively estimated this represents more than 15 million men in the US and EU. In early June 2019 Initiator Pharma announced a successful conclusion of the Company's Phase 1 Safety and Tolerability study in IPED2015 and in December 2019 we reported positive preliminary efficacy data from a Phase 2a proof of concept study.

Phase 2a clinical proof of concept study

During 2019 Initiator Pharma completed a Phase 2a Proof-of-Concept study for IPED2015, and reported positive preliminary efficacy data on December 5th. The study included twelve patients suffering from severe Erectile Dysfunction (sED) with scores below 12 on the IIEF-5 scale, meaning that it was not possible to treat the condition with currently available treatment. The patients 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 (visual sexual stimulation) 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.

Important endpoints of the study were the effect on the clinically relevant ability to increase and maintain the rigidity of the erection measured with RigiScan. The effect of IPED2015

(n=12) was significant vs. placebo (n=12) on penis stiffness measured as 80-100% rigidity (P<0.05). There was also a significant effect of IPED2015 (n=12) versus placebo (n=12) on Rigidity Activity Units (base of penis: 3.50 vs. 0.83 and tip of the penis: 3.25 vs. 0.33, P<0.05), and Tumescence Activity Units (base of penis: 2.83 vs. 0.58, P<0.05 and tip of the penis: 2.17 vs. 0.42). The average events of tumescence were not different in IPED2015 versus the placebo group (base of penis: 3.49 vs. 2.80 and tip of the penis: 3.33 vs. 2.55). Thus, in the study, IPED2015 demonstrated statistically and clinically significant efficacy data on ED. The positive effects on the erectile function that were observed were closely related to the plasma concentrations and were seen in a total of 25% of the patients.

Taking the exploratory nature of the study and the clinical endpoint assessment setting (Rigiscan device application and visual sexual stimulation) and the severity of ED into account, the study findings are considered very promising. In conclusion, this supports the aim of the further development of an oral formulation of IPED2015 for the treatment of moderate and severe ED in patients not responding to current therapies.

Erectile Dysfunction (ED) Market

The current number of ED patients is estimated to about 150 mio men worldwide and a number that is estimated to increase to more than 300 mio by 2025. About 30-40% of these patients will not respond to the current treatment and represent a significant unmet medical need. This is exactly our primary target group and will clearly distinguish us from the PDE5i drugs, where patent expiry results in increasing price pressure from generics. In 2015 the ED market generated about 4 bn USD and Initiator Pharma strongly believes that targeting the PDE5i non-responders will allow us to receive premium pricing for IPED2015 and thereby generate substantial commercial value for Initiator Pharma.

IP2018

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.
- 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 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 younger depressed 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.

Anti-depression Market

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.

IPNP2015

Chronic neuropathic pain is a highly devastating condition and affects millions of patients worldwide and is estimated to have market valuation of USD 8 billion It is a multifactorial disease. Recommended first-line treatments include selected antidepressants (i.e., tricyclic antidepressants and dual reuptake inhibitors of both serotonin and noradrenaline), calcium channel alpha2-delta ligands (i.e., gabapentin and pregabalin), and topical lidocaine. Opioid analgesics and tramadol are generally recommended as second-line treatments that can be considered for first-line use in specific clinical circumstances. Despite this apparent wealth of treatment options, less than 50% of patients experience meaningful pain relief in clinical trials examining pharmacotherapy. Lack of efficacy as well as safety concerns remain areas of high-unmet need and provide a window of opportunity for developing novel treatments.

IPNP2015 is a proprietary triple reuptake inhibitor of 5-HT, NA and DA. Initiator Pharma has tested IPNP2015 in rodent models of persistent and neuropathic pain. IPNP2015 possesses superior antinociceptive efficacy compared with the dual monoamine reuptake inhibitor duloxetine, and it is an attractive new drug candidate for the treatment of chronic pain. Therefore, Initiator Pharma develops IPNP2105 for treatment of chronic neuropathic pain.

IPDP2015

IPDP2015 is active in the mouse FST (forced swim test), a model predictive for antidepressant-like activity in the clinic following acute drug administration. In agreement with both in vitro and in vivo measures of the ability to inhibit DA transporter function, IPDP2015 induced slow-on/slowoff increases in locomotor activity, indicating no abuse liability. As such it represents an attractive new drug candidate for the treatment of depression.

Major depression disorder also known as depression is a severe disorder with serious consequences. Some treatments are available; however, in clinical trials the majority of the patients fail to achieve a full therapeutic response. Furthermore, impairment from the disorder continues essentially unchanged in patients who are treated but do not fully remit. Clearly, alternatives are needed to manage this common clinical condition. Combination studies with SSRI’s and Bupropion improved treatment in antidepressant-resistant patients (reduction in the number & severity of symptoms), and reduced sideeffects/ adverse events (including reduction in sexual dysfunction).

IPDP2015 also worked well in rat models of persistent and neuropathic pain. Depression in patients with pain is associated with more pain complaints and greater impairment. Depression and pain share biological pathways and neurotransmitters, which has implications for the treatment of both concurrently. Treatment of depression and pain simultaneously is necessary for improved outcomes.

The Initiator Pharma share

The share, share capital and ownership structure

Initiator Pharma is listed on Spotlight Stockmarket in Sweden, under the ticker code INIT. At December 31, 2019, the number of shares outstanding amounted to 23,591,375. The company has as of December 31 a total of 868,394 outstanding warrants, representing 3.7% of the number of issued shares.

The closing share price on December 31 was SEK 7.96, up +147% for the year. The market capitalization of the company on December 31 was approx SEK 188 million. During 2019 the average daily trading volume was 78,500 shares, and for the full year the traded volume was 19.6 million shares or 85% of the issued shares.

At December 31, 2019 the company had around 3,900 shareholders, with the 25 largest shareholders holding 44,8% of all outstanding shares:

Top 10 shareholders as of December 31, 2019

Shareholder	Number of shares	Shares %
Försäkringsaktiebolaget, Avanza Pension	1 360 498	5,77%
BNY Mellon SA/NV (Former BNY)	1 031 127	4,37%
Ålandsbanken i ägares ställe	1 004 398	4,26%
Claus Olesen Holding APS	692 738	2,94%
UBS Switzerland AG	639 535	2,71%
Nordnet Pensionsförsäkring AB	602 545	2,55%
DanPet AB	537 438	2,28%
Mikael Södergård Thomsen APS	505 946	2,14%
Lars Hendriksen A/S	489 717	2,08%
Peters, Dan	451 511	1,91%
Other shareholders	15 841 725	68,41%
Total	23 157 178	100,00%

NB: The above table does not include the exercise of 434,197 warrants that wer registered in VPC on January 2nd, 2020.

Shareholdings per size and per country

Shareholding	Number of shareholders	Number of shares	Shares (%)
1 - 500	2 081	307 207	1,33%
501 - 1,000	488	380 483	1,64%
1,001 - 5,000	845	2 065 978	8,92%
5,001 - 10,000	218	1 617 386	6,98%
10,001 - 15,000	103	1 280 152	5,53%
15,001 - 20,000	37	659 755	2,85%
20,001 -	165	16 870 788	72,85%
Total	3 937	23 157 178	100,00%

Shareholders by geography

Shareholders by country	Number of shareholders	Number of shares	Share of votes
Sweden	3 105	14 370 079	62,05%
Nordics, excl Sweden	766	5 686 756	24,56%
Europe, excl Nordics	49	2 676 804	11,56%
USA	3	65 229	0,28%
Other	15	358 310	1,55%
Total	3 938	23 157 178	100,00%

Initiator Pharma share price 2019



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 2019.

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 Stockmarket 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[®], Cialis[®] and Levitra[®]. In December 2019 we reported positive clinical proof of concept data for IPED2015 in a clinical Phase 2a study.

After the close of the year we announced the filing of a Clinical Trial Application and the exercise of an in-licensing option with Saniona for IP2018, a Phase 2 ready compound targeting Depression and Erectile Dysfunction.

FINANCIAL DEVELOPMENT IN 2019

Revenue and results of operation

As a development Company Initiator Pharma generated no revenues in the financial year 2019, unchanged from 2018. The company recognized an operating loss of DKDK 9,339 for the full year 2019, compared to DKDK 12,609 for 2018.

The reduction in operating costs for the full year reflects the progression of IPED2015 through the preclinical program and the start-up of the clinical phase 1 in 2018, as well as TDKK 928 in recognized grant in Q4:2019.

External R&D costs in 2019 amounted to to TDKK 6,259, compared to 8,666 in the same period in 2018.

Financial position

The equity as of December 31, 2019 was TDKK 9,908. Cash and cash equivalents amounted to TDKK 7,562 as of December 31, 2019. Total assets as of December 31, 2019, were TDKK 11,438.

Cash flow

The operating cash flow for the financial year 2019 was TDKK -8,554, incl a negative change in working capital of TDKK 1,072. Cash flow from investment activities was TDKK 0 and cash flow from financing activities was TDKK 1,625 reflecting the full exercise of incentive warrants under the Warrant 2017 program.

POTENTIAL FINANCIAL IMPACT OF COVID-19

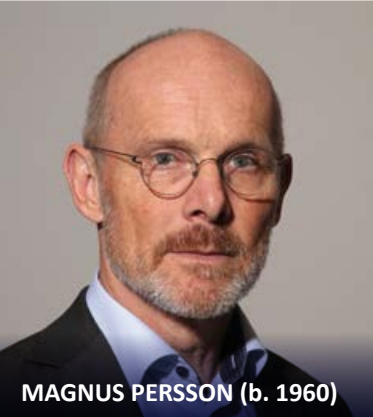
The board and management have carefully reviewed the potential impact of the covid-19 pandemic on Initiator Pharma's ongoing operations and financial outlook. As of April 2020 the board and management do not expect material impact on the financial position of the company. This is related to the fact that the company currently have no ongoing clinical development activities. However, depending on the length and severity of the covid-19 pandemic the board and management believe future risks are related to:

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

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

The company expects to have sufficient capital to fund the planned development activities through 2020.

The Board of Directors and Auditor



MAGNUS PERSSON (b. 1960)

Chairman and member of the Board of Directors since 2016

Education: Medical doctor and Ph.D. from the Karolinska Institute

No. of shares held: 120 036

Warrants held: 147 627



PETER HOLM (b. 1974)

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



HENRIK MOLTKE (b. 1958)

Member of the Board of Directors since 2016

Education: Master's degree in international economics and strategic management from the Copenhagen Business School

No. of shares held: 59 248

Warrants held: 39 077



CLAUS OLESEN (b. 1974)

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 : 779 579

Warrants held: 178 019

Auditor: Deloitte Statsautoriseret Revisionspartnerselskab.

Auditor in charge: Jens Sejer Pedersen. **Address:** Deloitte Statsautoriseret Revisionspartnerselskab, Weidekampsgade 6, 2300 Copenhagen S, Denmark

Management



TORGEIR VAAGE (b. 1964)

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: 161 701

Warrants held: 151 967



ULF SIMONSEN (b. 1963)

CMO of Initiator Pharma A/S since 2016 and co-founder 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: 585 200

Warrants held: 104 208




MIKAEL THOMSEN (b. 1968)

CSO of Initiator Pharma A/S since 2016 and co-founder 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: 618 191

Warrants held: 169 334



DAN PETERS (b. 1961)

CTO of Initiator Pharma since 2016 and co-founder 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: 1 036 711 personal and via company controlled by Dan Peters

Warrants held: 78 162

Financial reports

Profit & Loss Statement

(TDKK)	Notes	2019	2018
Gross loss		-8 366	-11 438
Staff costs	1	-886	-1 085
Depreciation and write-downs	2	-87	-87
Operating profit/loss		-9 339	-12 609
Other financial expenses		-636	-94
Profit after financial items		-9 975	-12 703
Tax	2	1 687	2 406
Profit/loss for the year	3	-8 288	-10 297
<i>No of shares, issued</i>		23 591 375	23 157 178
<i>No of shares, diluted</i>		24 459 769	24 025 572
Weighted average number of shares		24 242 671	20 081 616

Balance Sheet on December 31, 2019

ASSETS

(TDKK)	Notes	2019	2018
Patents, acquired rights		34	56
Intangible assets	5	34	56
Other fixtures and fittings, tools and equipment		4	69
Property, plant and equipment	6	4	68
Fixed assets		37	125
Other receivables		1 286	307
Income Tax receivable		1 687	2 406
Contributed capital in arrears		866	
Current receivables		3 839	2 713
Cash and cash equivalents	7	7 562	14 491
Current assets		11 401	17 204
Assets		11 438	17 328

EQUITY AND LIABILITIES

(TDKK)	Notes	2019	2018
Contributed capital	8	2 477	2 432
Retained earnings		7 431	14 139
Equity		9 908	16 571
Trade payables		1 141	239
Other payables		389	520
Current liabilities other than provisions		1 530	758
Liabilities other than provisions		1 530	758
Equity and liabilities		11 438	17 328
Contingent liabilities	10		

Statement of changes in equity for 2019

(TDKK)	Contributed capital	Retained earnings	Total
January 1, 2019	2 432	14 140	16 571
Increase of capital	46	1 306	1 351
Issue of warrants		273	273
Profit/loss for the year		-8 288	-8 288
December 31, 2019	2 477	7 431	9 908

Statement of cash flow

(TDKK)	Notes	2019	2018
Operating profit/loss		-9 339	-12 611
Amortisation, depreciation and impairment losses		87	88
Changes in working capital	9	-1 072	-2 701
Cash flow from ordinary operating activities before financial items		-10 323	-15 224
Interest income paid		-636	-93
Income tax refunded/(paid)		2 406	1 735
Cash flow from operating activities		-8 553	-13 583
Investing activities			
Investments in intangible assets		0	0
Cash flow from investing activities		0	0
Financing activities			
New share issue		1 351	20 760
Issue of warrants		273	144
Cash flow from financing activities		1 625	20 904
Increase/decrease in cash and cash equivalents		-6 929	7 321
Cash and cash equivalents at the end of period		7 562	14 491

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 operating income

Other operating income comprises income of a secondary nature as viewed in relation to the Entity's primary activities, including rental income and gains from the sale of intangible assets and property, plant and equipment.

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	2019 (TDKK)	2018 (TDKK)
Wages and salaries	882	1 068
Other social security costs	1	3
Other staff costs	3	14
Staff costs	886	1 085
Average number of employees	1	1
	Remuneration of management 2019 (TDKK)	Remuneration of management 2018 (TDKK)
Total amount for management categories	921	1 021
Staff costs	921	1 021

Note 2 - Depreciation, amortisation and impairment losses	2019 (TDKK)	2018 (TDKK)
Amortisation of intangible assets	22	22
Depreciation of property, plant and equipment	65	65
Depreciation and write-downs	87	87

Note 3 - Tax on profit/loss for the year	2019 (TDKK)	2018 (TDKK)
Tax on current year taxable income	-1 687	-2 406
Adjustment concerning previous years	-1	0
	-1 686	-2 406

Note 4 - Proposed distribution of profit/loss	2019 (TDKK)	2018 (TDKK)
Retained earnings	-8 288	-10 298
	-8 288	-10 298

Note 5 - Intangible assets (TDKK)	Acquired rights
Cost beginning of year	112
Cost end of year	112
Amortisation and impairment losses beginning of year	-56
Amortisation for the year	-22
Amortisation and impairment losses end of year	-78
Carrying amount end of year	34

Note 6 - Property, plant and equipment (TDKK)	Other fixtures and fittings, tools and equipment
Cost beginning of year	196
Cost end of year	196
Depreciation and impairment losses beginning of the year	-128
Depreciation for the year	-65
Depreciation and impairment losses end of the year	-193
Carrying amount end of year	4

Note 7 - Contributed capital in arrears

A number of shareholders has on December 23, 2019 exercised their warrants. Full payment has taken place in the beginning of January 2020.

Note 8 - Cash

Total cash funds amounts to 7.562 TDKK, of which 200 t.kr is pledged as security for the guarantee provided by the Company's bank.

Note 9 - Contributed capital	Number	Nominal value (TDKK)
Shares	23 591 375	2 477
	23 591 375	2 477

The company has an established a warrant program, approved by the AGM in 2018 and in 2019. 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 868 394 warrants representing 3.7% of outstanding shares:

Year approved	Number of warrants	Subscription price	Pct of issued shares	Exercise price	Exercise deadline
AGM 2018	434 197	SEK 0.47	1.9%	SEK 3.99	Dec 31, 2020
AGM 2019	434 197	SEK 0.89	1.9%	SEK 8.40	Dec 31, 2021
Total	868 394		3.7%		

The warrants are subject to vesting conditions.

Note 10 - Change in working capital	2019 (TDKK)	2018 (TDKK)
Increase/decrease in receivables	-1 844	-125
Increase/decrease in trade payables etc	772	-2 577
Change in working capital	-1 072	-2 702

Note 11 - Contingent liabilities

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

Statement by Management on 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 01/01/2019 - 12/31/2019.

The annual report is presented in accordance with the Danish Financial Statements Act.

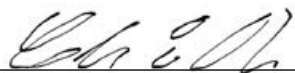
In our opinion, the financial statements give a true and fair view of the entity's financial position at 12/31/2019 and of the results of its operations and cash flows for the fiscal year 01/01/2019 - 12/31/2019.

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, 27/04/2020

Executive Board



Claus Elsborg Olesen

Board of Directors



Gunnar Magnus Severus Modée Persson
Chairman



Peter Joakim Holm



Henrik Kristian Moltke



Claus Elsborg Olesen

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 01.01.2019 - 31.12.2019, 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 31.12.2019 and of the results of its operations and cash flows for the financial year 01.01.2019 - 31.12.2019 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 statements 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 exists. 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, April 27th, 2020

Deloitte

Statsautoriseret Revisionspartnerselskab
Central Business Registration No: 33963556

Jens Sejer Pedersen

State Authorised Public Accountant
Identification number (MNE) mne14986

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®, 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®, Cialis® and Levitra® 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.

Shareholder information

FINANCIAL CALENDAR

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

CONTACT INFORMATION

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