ERIK PENSER BANK

Penser Access | Pharmaceuticals: Major | Sweden | 7 December 2020

Initiator Pharma

On the rise

The small company with big ambitions

Initiator Pharma develops drugs for central nervous system (CNS) indications. The company is conducting two clinical projects in phase 2 (IPED2015 and IP2018) for erectile dysfunction. This indication is common and affects millions of men globally. Well-known PDE5 inhibitors, such as Viagra from Pfizer, have been successful, but a large proportion (about 30%) of patients do not achieve the desired outcomes.

Big potential

IPED2015 is the company's most advanced project and has shown statistically significant efficacy in a placebo-controlled phase 2a trial. The next step is a phase 2b trial to be started in H2 2021, which will be funded by MAC Clinical Research. IPED2015 is a promising project with blockbuster potential in men who do not achieve good treatment outcomes with PDE5 inhibitors.

Attractively valued

Our SOTP valuation indicates a fair value of SEK 11–12 (WACC 16%), which rests on the company's two clinical projects. Clinical trial data are the greatest catalysts of the valuation. Results for IPED2015 are expected in H2 2022, and IP2018 phase 2a data towards the end of H1 2021. Positive outcomes in both studies could justify up to a tenfold increase of the share from today's level, but we want highlight the risk is high.

Estimate Changes (DKK)

	Now	Before	
EPS, adj 20e	-0.39	-0.39	0.0%
EPS, adj 21e	-0.37	-0.37	0.0%
EPS, adj 22e	-0.42	-0.42	0.0%

Calendar Events

Q4 2020	21 feb 2021

Key Figures (DKKm)

Number of Shares	25.6m
Market cap	107
Net Debt	(10)
EV	97
Free Float	100.00%
Avg. No. of Daily Traded Sh.	54.0(k)
Reuters/Bloomberg	Init.st/Init ss

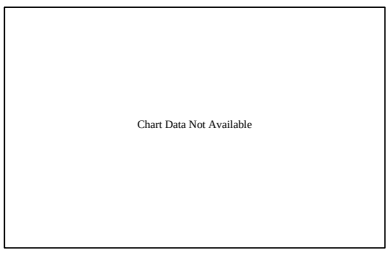
Estimates (DKK)

	19	20e	21e	22e
Sales,m	0	0	0	0
Sales Growth	NA%	NA%	NA%	NA%
EBITDA, m	(9.3)	(11.9)	(15.4)	(17.4)
EBIT, m	(9.3)	(12.0)	(15.4)	(17.4)
EPS, adj	(0.35)	(0.39)	(0.37)	(0.42)
EPS Growth	NA%	NA%	NA%	NA%
Equity/Share	0.4	0.2	1.3	0.7
Dividend	0.00	0.00	0.00	0.00
EBIT Marginal	-%	-%	NA%	NA%
ROE (%)	-%	-%	-%	-%
ROCE	-%	-%	-%	-%
EV/Sales	--x	--x	--x	--x
EV/EBITDA	(10.5)x	(8.2)x	(6.3)x	(5.6)x
EV/EBIT	(10.4)x	(8.1)x	(6.3)x	(5.6)x
P/E, adj	(12.0)x	(10.7)x	(11.5)x	(10.1)x
P/Equity	10.8x	18.5x	3.3x	6.0x
Dividend yield	0.0%	0.0%	0.0%	0.0%
FCF yield	(2.5)%	(6.9)%	(10.4)%	(11.3)%
Net Debt/EBITDA	0.8g	0.5g	2.0g	0.8g

Risk and Potential

Motivated value	11.00 - 12.00
Current price	SEK4.20
Risk level	High

One Year Performance Chart



Analysts

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This report was completed and disseminated 7 December 2020: 16:43 CET

Overview

On the rise

Investment Case

Initiator Pharma is a small company of Danish origin that has been under the radar of investors, and the success of the IPED2015 phase 2 project, in particular, has not received the plaudits it deserves. IPED2015 is a new treatment for erectile dysfunction, a mass market where there are still no effective treatment options for millions of men despite well-known drugs such as Viagra (a PDE5 inhibitor) from Pfizer. We see the great potential for IPED2015 in older men who do not achieve good treatment outcomes with PDE5 inhibitors, and we believe that it has blockbuster potential that would make it an attractive asset for large pharmaceutical companies. Erik Penser Bank initiates coverage of Initiator Pharma with a fair value of SEK 11 to 12, and we see multiple significant catalysts for the share over the next two years.

Phase 2b data is the most important expected event...

An exploratory phase 2a trial demonstrated statistically significant treatment outcomes and a good safety profile. This was admittedly a limited study (n=12), but given the unnatural in-clinic testing environment we believe it provides strong support for phase 2b. It should also be added that the men who participated had severe erectile dysfunction and usually respond poorly to drugs such as Viagra. We model a market uptake of 20 percent in men who do not achieve the desired treatment outcomes with med PDE5 inhibitors, which gives a sales potential of approximately USD 1.3bn. The phase 2b trial will start during H2 2021, and topline results are expected during H2 2022.

... with other important data as early as next year

The company's other project, IP2018, is being evaluated in a phase 2a trial, also in patients with erectile dysfunction. There are several similarities with the IPED2015 study in this trial design, but with a big difference that the individuals to be recruited are younger and also show mild to moderate depression. This group suffers partly from other causes for their erection problems, often stress, depression or anxiety. In addition to the potential for IP2018 to become a new treatment option in erectile dysfunction, it has shown promising results in animal studies for depression, making it suitable for this indication, called psychogenic erectile dysfunction. We are modelling a sales potential for IP2018 of USD 600m in psychogenic erectile dysfunction, but this could be significantly higher if the project is expanded as an antidepressant drug. The results of the ongoing phase 2a trial are expected towards the end of H1 2021.

Overview

On the rise

Valuation approach

To value Initiator, we have used a probability-weighted cash flow model in which we have individually valued each project and added it to a sum-of-the-parts (SOTP) model. The focus of this analysis is on clinical projects IPED2015 and IP2018, where we can see a clear plan to drive these forward. Our valuation factors in the company needing to bolster its finances by SEK 30-50m to cover costs until a licensing agreement that we assume could be signed in 2023.

Target Price

The above assumptions about financing lead us to a fair value for Initiator Pharma of SEK 11-12 per share.

News flow and its impact on valuation

Initiator upside and downside risks in our valuation					
Event	Timing	Uside	Per share SEK	Downside	Per share SEK
IP2018 Phase 2a data	End of H1 2021	Positive results	2	Negative outcome	-2
IPED2015 Phase 2b data	H2 2022	Positive results	19	Negative outcome	-9

Risks

Delays in the trials

The Covid-19 pandemic has had a significant impact on the ability to conduct clinical trials, and the company has already warned of delays in patient recruitment for the phase 2a trial on IP2018. Further delays due to the pandemic are a risk, but there are also other risks that could lead to a delayed start for the IPED2015 phase 2b trial and the recruitment of patients.

Negative outcome of trials

The most obvious risk is a negative outcome in ongoing and planned trials. We believe that the risk level in both projects remains high, and how this impacts the valuation is shown in the above scenario analysis.

Failure to sign partnerships

Initiator Pharma's projects focus on major primary care indications, and phase 3 programmes may need to include a couple of thousand patients. This can mean a need for extensive capital if the company fails to find a partner for the trials.

Funding may be needed

We estimate that the company's current cash reserves will cover its operating costs for around six months. This horizon could be extended by nine to twelve months if outstanding warrants are exercised. Regardless of the outcome of the warrants, we believe that the company has a capital requirement of SEK 30-50m to complete the trials and pursue active business development.

Company Profile

Initiator Pharma (Initiator) was founded in 2016 as a spin-off from Danish listed company Saniona, on the initiative of the people who are currently part of the management team (except the CFO). These individuals saw the potential to further develop three drug candidates with unique properties, known as monoamine reuptake inhibitors (MRIs). The development portfolio has since been expanded with another project, IP2018, which was acquired in early 2020, also from Saniona.

Initiator is a small company that focus on targets in the Central Nervous System (CNS) and assets that comes with significant de-risking packages consisting of preclinical and sometimes even clinical data. At present, it has prioritised IPED2015 and IP2018 for erectile dysfunction (ED). These two main assets have the potential to be first-in-class and are the two programs that we focus on in this analysis. IPED2015 has been successfully evaluated in a phase 2a trial, which showed positive results in individuals with severe ED. The next step, a phase 2b trial, is being prepared and favorable funding of the study was recently announced. A phase 2a trial has been initiated for IP2018.

Project portfolio

Product	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Next step	Timing
IPED2015	Erectil dysfunction (organic)					Fas 2b	H1 2021
IP2018	Erectil dysfunction (psychogenic)					Fas 2a	Q4 2020
IPDP2015	Depression					Fas 1	TBD
IPNP2015	Neuropatic pain					Fas 1	TBD

All the projects originate from Neurosearch (acquired by Saniona), which had a world-leading position in central nervous system (CNS) research and the development of small molecules for the treatment of CNS-related diseases. The reason why Saniona took over the assets was re-prioritisation at Neurosearch and the shuttering of all early research and development activities, which in turn was partly due to the company ending up in legal proceedings, including being convicted in a Danish court for share price manipulation.

Initiator Pharma's overall long-term business strategy is focused on, but not limited to, its current project portfolio of CNS-related assets. The portfolio could also be expanded further through the company's ability to select, acquire and reposition promising assets that address relevant unmet medical needs, that are significantly de-risked through clinical data and that have the potential to demonstrate clinical proof of concept within a limited time-space with a clear regulatory pathway towards market registration. More specifically, the de-risking and repositioning components in Initiator Pharma's business model build on taking assets that often come with clinical data from previous clinical studies. Studies that, for some reason, did not succeed because of mistakes: e.g., in study design, patient inclusion, dosing, or indication. We believe that the management has extensive competence and experience to be able to credibly back up such a strategy. An advantage of this approach is that Initiator Pharma significantly reduces the risk of adverse events compared to other new drugs in the same development stages.

We believe that a licensing partner will need to support or take over at the latest before phase 3 trials. Phase 3 regulatory trials for these indications will often require extensive resources, as such studies may involve over 1,000 patients. To date, none of the company's projects have been licensed to a partner, but we believe that the start of the Phase 2b study will accelerate interest of IPED2015 from pharma.

IPED2015 and IP2018 were initially focused on other indications when they were developed but based on research by founder Ulf Simonsen the unique potential of these two assets has been identified in ED. Ulf Simonsen has many years of experience in the field and has long been a member of the European Society of Sexual Medicine and a committee member of World Health Organisation's consultations on erectile dysfunction.

Since the introduction of Viagra (a PDE5 inhibitor, see below) and subsequent drugs with similar mechanisms for the treatment of ED, there has been interest from the pharmaceutical industry to identify new drugs with complementary mechanisms in areas such as CNS, but side effects and limited efficacy have put the brakes on. However, we would like to point out that the resources ploughed into this field have not been enormous, and this is likely explained by the great success of PDE5 inhibitors. Also, there was a period after the turn of the millennium when a number of pharmaceutical companies reduced their investments in CNS-related diseases as the field was considered too risky. Our view is that the trend was reversed a few years ago, and this may benefit Initiator.

Initiator has a virtual organisational structure, with CEO Claus Elsborg Olesen the only permanent employee and the remainder of the management team engaged as consultants. The company also outsources most of its research, development and clinical trials to contractors. Such arrangements can mean an increased risk that things will take longer and sometimes even wrong decisions will be made. However, we see no trace of such problems to date and, if anything, feel the management has delivered on its plan despite limited financing and the challenges resulting from the Covid-19 pandemic. An important factor in this may be that all members of the management team, in addition to extensive and relevant experience, have significant shareholdings (over 12 percent), which guarantees a strong commitment to the business.

Management

Position	Executives	Number of shares
CEO	Claus Elsborg Olesen	775,579
CFO	Torgeir Vaage	161,701
CTO	Dan Peters	1,036,711
CMO	Ulf Simonsen	585,2
CDO	Mikael Thomsen	618,191

The management team is focused and has knowledge that is relevant to the company within the indications, molecular development, preclinical and clinical trials. One area where we possibly see a need to strengthen the organisation is business development, to equip the company in negotiations with major pharmaceutical companies.

Initiator's shares have been listed on the Spotlight Stock Market since 2017. The shares are relatively well dispersed, despite the low market capitalisation, since Saniona initially received a 60% stake in the company that was then distributed to its shareholders prior to the spin-off and listing. What is missing from the list of shareholders is clear institutional ownership, and we believe the main explanations for this are the low market capitalisation and the fact that the shares are listed on Spotlight.

Shareholders		
Shareholder	**Shares**	**Capital**
Nordnet Pensionsförsäkring	1356617	5,75%
Avanza Pension	1317828	5,59%
Dan Peters	1036711	4,39%
Claus Olesen	779579	3,30%
Swedish Growth Fund	726804	3,08%
Lars Hendriksen	660070	2,80%
Mikael Thomsen	642201	2,51%
Simonsen og Mogensen Holding ApS	585200	2,48%
Thauser Holding Aps	295156	1,25%
Thomas Härlin	254520	1,08%
Coolmate Aps	249820	1,06%

Company history

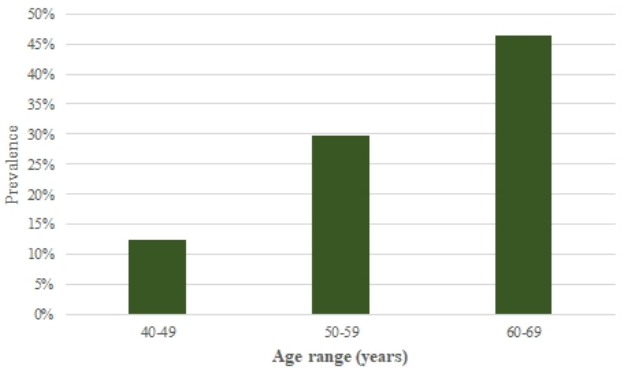
During its short time as a company, Initiator has succeeded in making significant progress in its pipeline, as summarised below.

Year	Event
2016	Initiator Pharma was founded with three substances acquired from Saniona, whose shareholders received a 60 percent stake.
2017	The company raised SEK 20.5m and the shares were listed on Aktietorget (now called Spotlight). Preclinical trials began on IPED2015
2018	The preclinical trials on IPED2015 were successfully completed. An application to initiate clinical trials was approved by the UK's Medicines & Healthcare products Regulatory Agency (MHRA) and a phase 1 trial on IPED2015 was begun in August. The company raised SEK 19.1m in a rights issue and an additional SEK 12.7m from the exercise of warrants. At the end of the year, an option was signed with Saniona for IP2018
2019	The phase 1 trial into IPED2015 was successfully completed and shortly thereafter a phase 2a test of concept was begun in patients with erectile dysfunction. Innovation Fund Denmark approved a grant of DKK 2m to develop IPED2015. Towards the end of the year, positive and statistically significant results were announced in the phase 2a trial into IPED2015
2020	The company exercised its option with Saniona and acquired IP2018. An application was submitted to begin a phase 2a trial in the UK, and this was later granted. A directed issue of approximately SEK 3m was made to Formue Nord and a preferential rights issue of SEK 7m. The company was awarded another grant by Innovation Fund Denmark, of DKK 3.8m, for the development of IP2018.

Overview of erectile dysfunction

Erectile dysfunction (ED) is the most common sexual medical condition for men, and global incidence is expected to rise to 300 million cases in 2025. It was a long time before ED (formerly called impotence) was given a clear definition, and it was previously regarded by doctors as a lifestyle problem. Today, however, it is described as the inability to achieve an erection or maintain an erection long enough to satisfactorily complete sexual activity. ED has shown a clear correlation with age in epidemiological studies.

Prevalence of erectile dysfunction in men (aged 40-69)



Source: Johannes C, et al. The Journal of Urology, 2000

ED is a medical condition and not a disease. However, its occurrence is usually driven by underlying diseases that may be a combination of vascular, neurological, hormonal and psychological. For a long time, ED was considered a psychologically induced condition in men, but that view has changed and today 80-90 percent of cases are estimated to be what is known as organic ED (see below) and the remainder are classified as psychogenic ED. That said, the demarcation between organic and psychogenic ED is not well defined and a significant proportion of patients with ED are classified in both categories (mixed ED).

The age correlation is most obvious in organic ED, and the condition often gradually deteriorates. It is mainly brought on by underlying issues such as cardiovascular disease, diabetes and obesity, as well as lifestyle choices such as high alcohol consumption and smoking.

The other category, psychogenic ED, does not have the same clear age link and usually arises earlier in life. It also progresses more rapidly. Psychogenic ED is considered to be triggered by issues such as stress, depression and anxiety, but has also been shown to be induced by medications such as those for depression and anxiety.
Regardless of the individual's classification of ED, the consequences are often the same and have a negative impact on self-esteem, can cause relationship problems and lead to low mood. So even though ED is not a disease per se, there is a clear logic in trying to treat affected men. Given the underlying diseases that are often linked to ED, men diagnosed with the condition usually also undergo an investigation of their overall health.

Demand for sex well into old age

There is no doubt that sex is important, not least in relationships to feel close to a partner. However, it is still common, seventy years after the sexual revolution, for sex to be associated primarily with younger people. Studies that have examined sexuality in older people clearly show that sex is of great importance well into advanced years (see the result of two such studies below).

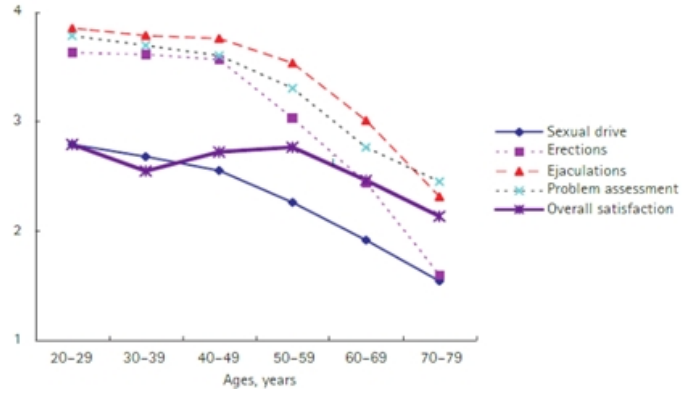
Sexual activity in men over 30

	German study	Japanese study
Age	Sexual activity	Sexual activity
30-39	96%	96%
40-49	92%	96%
50-59	89%	92-95%
60-69	84%	80-88%
70-79	71%	55-70%
>80	No data	44%

Source: International Journal of Impotence Research, 2000, Aging Male, Japan, 2000

As we have already mentioned, however, the ability to have sex deteriorates with age, and this is demonstrated by declining sexual drive, and increased difficulties getting an erection and reaching ejaculation.

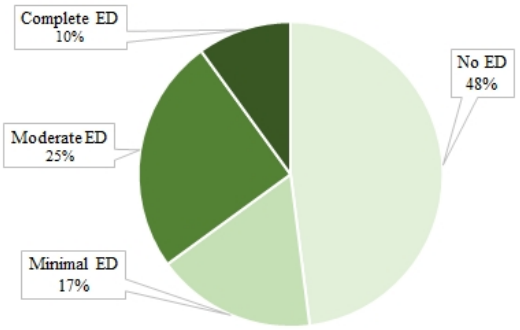
Average function score in different age groups, Norwegian study



Source: Mykletun A, et al, BJU International, 2006

One of the more comprehensive studies in the field to map the prevalence of ED is the Massachusetts Male Aging Study (MMAS), which included 1,709 healthy individuals between the ages of 40 and 70. The study monitored healthy individuals in their aging, and ED was one of several health parameters studied over time. The MMAS study showed that 52 percent of men had experienced problems to some extent with their erections. Of these, 10 percent of men reported severe ED and not being able to have intercourse.

Erectile dysfunction by severity



Source: Feldman HA, et al. The Journal of Urology, 1994

Another important study in this field is the European Male Aging Study (EMAS). This focused on men aged 40-79 and provides a wide range in prevalence of ED from 6 percent to 64 percent, with an average of 30 percent.

Both of these studies are aimed at men over 40, but there is also data that points to widespread problems of ED in younger men below 40. This lower age range accounts for about 25 percent of men seeking medical help for ED, and around half have severe ED (based on the IIEF scale).

The International Index of Erectile Function (IIEF) is a diagnostic patient-reporting form used to assess the severity of erectile dysfunction an individual is experiencing. The form is divided into fifteen questions about sexual function. A more concise version of the form is the IIEF 5, which has been developed to make it suitable for applications such as clinical trials but is still structured on the same issues. The questions are focused on erectile function, sexual desire, and the ability to achieve orgasm, sexual satisfaction and the patient's perceived satisfaction. Each question has five possible responses, and the scores are evaluated as follows:

1) Severe ED (1-7),
2) Moderate ED (8-11),
3) Mild to Moderate (12-16),
4) Mild ED (17-21)
5) No ED (22-25)

One focus of the epidemiological studies conducted in this field has its origins in the 1990s or early 2000s, in the wake of the major breakthroughs with PDE5 inhibitors (see more below) and initiatives that followed to map the patient base. We believe that these epidemiological studies provide a continued good indication of the incidence of ED, but that the incidence may be even higher today. The incidence of underlying diseases has continued to rise, the stigma surrounding ED is decreasing, and acceptance of the condition by the healthcare community is improving.

The little blue pill has revolutionised ED treatment

One of the most notable drug launches of all time followed the development by Pfizer in the 1990s of Viagra (sildenafil) and its approval in Europe and the US. Viagra was the first approved oral treatment for ED with a high level of efficacy and limited side effects. The launch was a success, and the product has since met competition from several successors aiming at the same target to inhibit the phosphodiesterase 5 (PDE5) enzyme. The introduction of PDE5 inhibitors has also brought with it increased

public awareness of ED as a problem that can be treated. Previous treatments for ED were relatively unattractive in their administration and effect and involved local administration of prostaglandin E1 (alprostadil) through injections or via the urethra. In addition, vacuum pumps have been used to induce erection. In more severe cases, it may be necessary to introduce a transplant.

The discovery of Viagra was made by chance during drug development that was initially targeted at a new treatment for angina pectoris (angina). In a small study during the early 1990s, it was noted that several patients who received UK-92,480 (the project name for Viagra) got an erection as a side effect. This fired the starting pistol for a realignment of the project towards ED. After undergoing an extensive development programme with Pfizer, Viagra was approved by the US Food and Drug Administration in March 1998, and the European Medicines Agency followed suit in September of that year.

The introduction of Viagra was followed by Levitra (vardenafil) from Bayer, and Cialis (tadalafil) from Eli Lilly, launched in 2003, both of which are PDE5 inhibitors. Subsequently, Stendra (avanafil) was developed by Mitsubishi Tanabe Pharma and received approval in Europe and the US. The main difference between the products is how quickly they have an effect and how long the effect lasts. In addition, Viagra and Levitra should be taken before a meal, which is not a requirement for the other two.

Characteristics of PDE5 inhibitors marketed in the EU and the US

Product	Viagra (sildenafil)	Cialis (tadalafil)	Levitra (vardenafil)	Stendra (avanafil)
Developer	Pfizer	Eli Lilly	Bayer	Mitsubishi Tanabe
FDA approval	1998	2003	2003	2012
Administered before sexual activity	~1 hour	~0.5 hour	~1 hour	~0.5 hour
Half-life	3-4 hours	17.5 hours	4-5 hours	1.5 hours
Affected by food	Yes	No	Yes	No
Peak sales, year	USD 2,051m, 2012	USD 2,472m, 2016	EUR 429m, 2010	NA

Source: Erik Penser Bank and various scientific articles

All approved PDE5 inhibitors are considered to work using the same mechanism, so the clinical outcomes do not differ significantly between the products. The proportion who achieves positive treatment outcomes in clinical trials amounts to approximately 60-70 percent of men with ED (organic and psychogenic) when they take up to the maximum dose.

In a systematic review and meta-analysis of randomized controlled trials (Tsertsvadze et al., Annals of Internal Medicine, 2009) the PDEs inhibitors showed similar efficacy in the treatment of ED. The Viagra analysis included 16 trials in men with various comorbidities, and the result displayed a mean percentage of successful sexual intercourse of 69.0% (ranging from 52.0%–85.0%) compared with 35.5% (ranging from 19.0%–68.0%) for placebo.

The review assessed a total of 15 trials with Cialis, including men with various comorbidities. Based on data collected, a mean success rate of 69.0% (ranging from

50.0%–85.0%) versus 33.0% for placebo (ranging from 23.0%–52.0%) was displayed. Data for Levitra was assessed from 13 trials and was very consistent with its competitors' results, showing a mean percentage of successful sexual intercourse attempts of 68.0% (ranging from 50.0%–88.0%) versus 35.0% for placebo (ranging from 20.0%–49.0%).

The differences are also relatively limited in terms of the side effect profiles.

Commonly reported side effects at maximum recommended dose

Adverse event	Viagra	Cialis	Levitra	Stendra
Headache	12.8%	14.5%	16,0%	9.3%
Redness	10.4%	4.1%	12,0%	3.7%
Dyspepsia	4.6%	12.3%	4,0%	
Blocked nose	1.1%	4.3%	10,0%	1.9%
Dizziness	1.2%	2.3%	2,0%	0.6%
Abnormal vision	1.9%		<2.0%	
Bakache		6.5%		<2.0%
Muscle ache		5.7%		<2.0%

Sourece: Hackett G. et al., The Journal of Sexual Medicine, 2018

Background - PDE5 inhibitors

During sexual arousal, nitric oxide (NO) is released from nerve cells in the penis. NO activates the enzyme guanylate cyclase, which leads to the formation of cyclic guanosine monophosphate (cGMP). An increase in cGMP in the muscle cells leads to relaxation of the smooth muscle in the corpus cavernosum (the swelling bodies in the penis), which enables increased blood flow to the penis and thus erection. However, it has been shown that cGMP is broken down by PDE5, which can thus be considered to counteract erection. The administration of PDE5 inhibitors can reduce the breakdown of cGMP and thereby restore the erection stimulating process.

Although PDE5 inhibitors have been shown to be effective treatments for ED, they have no direct effect on the sexual desire that triggers the process of releasing NO, and sufficient sexual stimulation is therefore necessary to achieve an erection.

Diabetics are a large and growing group of patients

Hundreds of clinical studies have been conducted to date with PDE5 inhibitors, and a clear pattern is that patients with certain underlying diseases achieve poorer results. One such group is diabetics, where the incidence of ED is significantly higher than in the rest of the population and is estimated to affect every other man and is more common among type 2 diabetics. Studies indicate that positive results with PDE5 inhibitors are achieved with 50-55 percent of patients within this group. The reason for the high frequency of ED among diabetics is probably related to both vascular and neurogenic factors. We believe that this patient group could be particularly interesting for Initiator's projects.

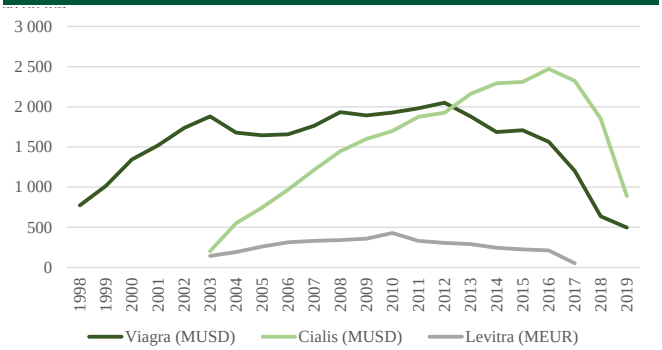
Diabetes is a disease that continues to increase, and the International Diabetes Federation estimates that its global prevalence will rise to about 700 million in 2045, from today's approximately 463 million.

PDE5 inhibitors have been a sales success

Although PDE5 inhibitors are not chronic treatments and are taken as needed, Viagra and Cialis have achieved great success and sales in excess of USD 2bn in their best years. Ten years after the launch of Viagra, Pfizer stated that over 37 million men had

taken the pill, and in 2016 it was estimated that 5.4 billion pills had been prescribed since its introduction.

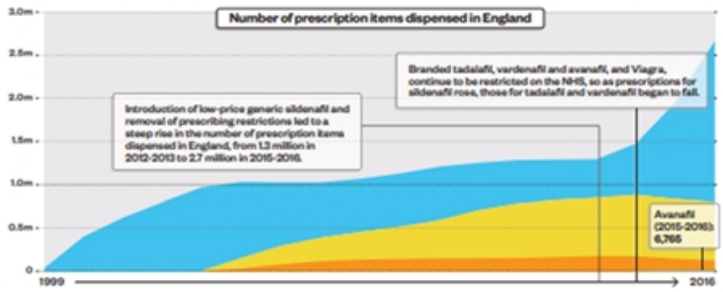
Sales history of PDE5 Inhibitors (USDm)



Source: Erik Penser Bank

In the 2010s, sales in this pharmaceutical class amounted to USD 4-5bn per year until important patents began to expire. The first to expire were the patents for Viagra, starting in 2013, and this explains the decline in sales in the graph above. The main patents for Cialis began to expire in 2017. After the patent expirations, cheap copies of the drugs were introduced at greatly reduced prices. This, combined with the fact that prescription requirements were relaxed in certain markets, led to volumes continuing to rise in recent years.

Prescriptions of PDE5 tablets in the UK (1999-2016)



Source: The Pharmaceutical Journal, 2017

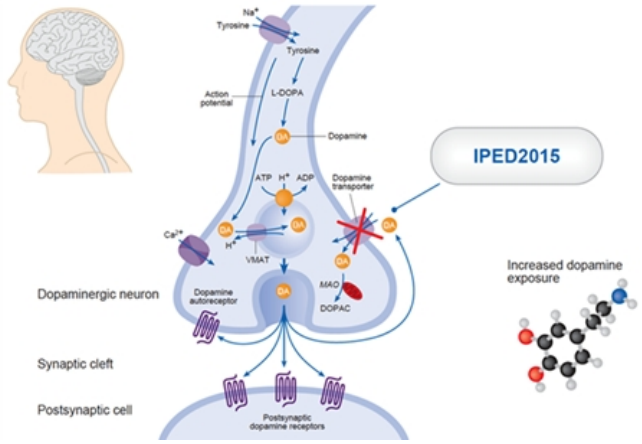
IPED2015 – Unique new approach

IPED2015 is being developed as a new oral treatment for erectile dysfunction, and more specifically is targeted at men with organic ED. Unlike established treatments, IPED2015 has a double-acting mechanism in both enhancing the desire to have sex and strengthening blood flow to the penis.

Professor Ulf Simonsen identified the potential of IPED2015 as a possible new treatment for ED during his research into the field. IPED2015 has undergone extensive analysis and has been selected from among 200 analogues based on the best properties to amplify natural erection signals that occur during sexual stimulus (such as touch of the penis, scents, memories or visual impressions).

IPED2015 belongs to a class of drugs called monoamine reuptake inhibitors, and acts on three neurotransmitters (dopamine, serotonin and noradrenaline) in the central nervous system. The molecule has the strongest binding to, and inhibition of, dopamine transporters (DATs), which act to reuptake released dopamine at the synaptic cleft. By inhibiting this process, dopamine levels can be kept higher and thus strengthen the erogenous and sexual signals in brain and nerve cells.

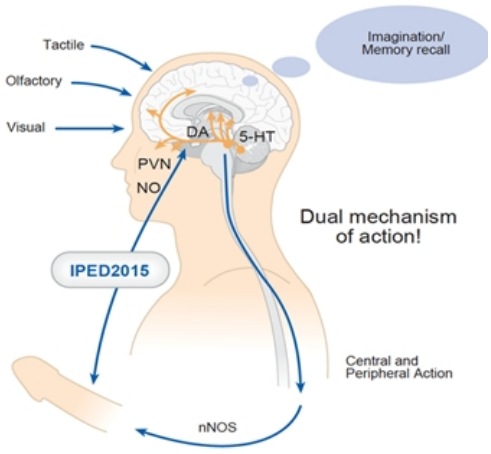
IPED2015 Mechanism



Source: Initiator Pharma

Sexual stimuli are processed in the brain and lead to increased release of dopamine, which in turn leads to arousal and a feeling of wellbeing and initiates a process of erection. Dopamine also signals via the spinal cord to nerves in the penis, where the enzyme nitric oxide synthase (NOS) is instructed to produce nitric oxide (NO). NO is the most important neurotransmitter in the penis and has a role in stimulating blood vessels for increased blood flow. This mechanism for IPED2015 is supported by preclinical trials, where it has been shown that IPED2015, in addition to increasing dopamine levels in the brain, enhances the release of NO in the penis and thus stimulates erection.

IPED2015 Mechanism



Source: Initiator Pharma

Dopamine has a central role in sexual drive and desire. Low levels of dopamine in the brain are considered to be an important reason why some men develop ED, and this is supported by research in, for example, Parkinson's disease (caused by dopamine deficiency). Studies have shown that patients with Parkinson's disease who are treated with drugs that raise dopamine levels have increased sex drive and increased erection frequency.

Raising dopamine levels also comes with risks since it is a very powerful neurotransmitter that gives individuals a feeling of wellbeing. At high levels in the brain, it can therefore lead to the development of drug addiction. A characteristic of both IPED2015 and IP2018i is that they have slow binding to DAT and markedly decrease the risk for addiction. Initiator has studied these risks in animal models, where it has been clearly shown that IPED2015 is not addictive at clinically relevant doses.

IPED2015 has a unique mechanism profile in ED with the potential to become first in class and a complement to standard treatments with PDE5 inhibitors for individuals who do not respond to the existing drugs. Results from animal studies also indicate that IPED2015 may have an additive effect together with PDE5 inhibitors in enhancing erection, giving it a potential in combination with these drugs.

Good signals from phase 2a trial

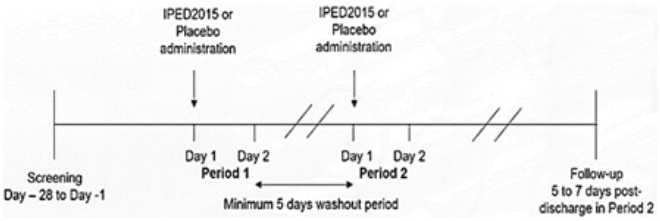
In August 2018, the clinical development of IPED2015 began and a phase 1 trial was initiated which was successfully completed and ended almost a year later. Immediately after the end of the phase 1 trial, phase 2a began with the aim of obtaining an initial indication of efficacy in men with severe ED.

The phase 2a trial was an exploratory proof of concept that included a total of twelve men with ED. One inclusion criterion was that participants had a score of less than twelve on the IIEF5 scale, meaning patients with moderate to severe ED. These are patients who usually respond poorly to treatment with PDE5 inhibitors.

This was a crossover trial, where the participants formed their own control group. Initially, half of the patients were administered IPED2015 and the rest received a placebo. The treatment was monitored for 24 hours at the clinic. At least five days

later, the groups were switched and those who initially received the placebo were given IPED2015 and vice versa. The end point was to measure stiffness in the penis.

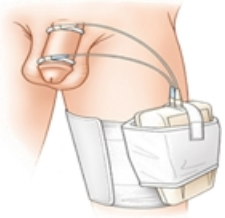
Design of phase 2a trial



Source: Initiator Pharma

Participants in the trial were each shown into a room where they were administered a dose and left to watch an erotic film. A RigiScan instrument was used to measure whether or not an erection was achieved, which is a well-established method to objectively measure stiffness in the penis and uses a strap stretched around the penis and connected to the system.

RigiScan rigidity measuring equipment



Source: Initiator Pharma

The results of the phase 2a trial showed statistically significant treatment efficacy for IPED2015 compared with a placebo ($p<0.05$), where 25 percent (three) of the patients achieved the endpoint. The trial also measured statistically significant efficacy for IPED2015 compared to a placebo in stiffness and swelling, measured with RigiScan and using Rigidity Activity Units (RAU) for stiffness and Tumescence Activity Units (TAU) for swelling.

Measured scores - RAU and TAU (cm)

	RAU		TAU	
	Tip	Base	Tip	Base
IPED2015 (n=12)	3.25	3.50	2.17	2.83
Placebo (n=12)	0.33	0.83	0.42	0.58
P-value		**p<0.05**	**p<0.05**	

Source: Initiator Pharma

Placebo effects are well known in this field, but we believe this risk is reduced given the severity of the medical condition of the individuals included in the study and the highly artificial environment during the trial. That three of twelve individuals achieved an erection is in our eyes very promising for the next step, when the trial will be

conducted in a more natural environment for patients. However, the risk may be that the placebo effect is amplified.

No unexpected side effects were observed for IPED2015 in the phase 2a trial compared to those found in phase 1. IPED2015 was well tolerated, and only less serious adverse reactions were reported. Two of the twelve participants who received IPED2015 experienced heart palpitations, but with a normal sinus rhythm and without changes in the ECG. In addition, mild dizziness was observed in two patients in measurements on the central nervous system. However, it was unclear whether this was related to IPED2015.

Good safety in phase 1

The phase 1 trial on IPED2015 was randomised, double-blind, and placebo-controlled, and included healthy volunteers who were studied for increasing single administrations of IPED2015. The results showed that IPED2015 was safe and well tolerated up to an expected clinically relevant dose.

At the beginning of the study, however, one cardiovascular incident was registered in an individual, but the patient did not show clinical symptoms and felt well throughout the evaluation period of the dosage. The incident led to a temporary dose adjustment and the evaluation of IPED2015 was restarted at a lower dose than that given at the time of the incident. After the lower dose went well, the escalation was able to continue and doses were tested that exceeded the level in the cardiovascular incident.
To date, IPED2015 has only been evaluated in single administrations. If we look at how PDE5 inhibitors are used – when required rather than daily– we believe this is quite sufficient to attract strong partner interest. However, we believe it will be necessary to trial multiple administrations in order to obtain regulatory approval for IPED2015.

The next step has begun

An agreement was recently signed MAC Clinical Research, an organisation that conducts research under contract, whereby MAC will fund up to SEK 23m of a planned phase 2b trial via a convertible credit agreement under the following key terms:

- Upon completion of the Phase 2b MAC can convert ca SEKM 23 at a share price of SEK 7.50 (approx. 70% premium to the current share price).
- If MAC chooses not to convert, the debt will carry an annual interest of 1% and be payable 3 years after the completion of the study.

The trial will recruit individuals with organic ED who do not respond to standard treatments with PDE5 inhibitors, and will be conducted at MAC's facilities around the UK.

The trial is scheduled to start in H2 2021 pending approval by the UK's Medicines and Healthcare products Regulatory Agency (MHRA). The final design has not been decided, but the clinical endpoint will be IIEF questionnaires. The number of patients to be included and the study design is currently being assessed to optimize the design of the later stage clinical trials and pathway towards market approval. We look forward to more details in the coming months. The schedule is to complete the trial and report the results during H2 2022.

The last step could begin in 2024

In order to create a picture of the timeframes for IPED2015 and when the product could achieve market approval, we have looked mainly at studies carried out with

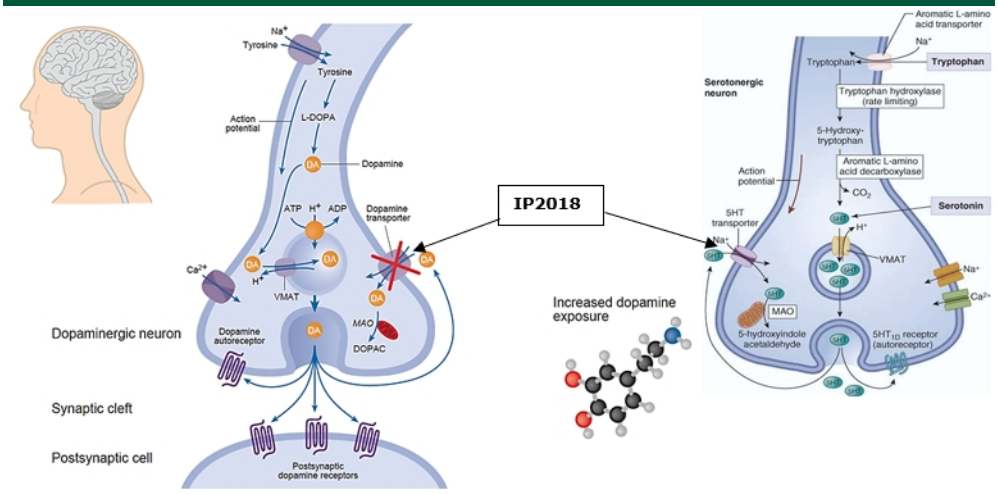
PDE5 inhibitors. We believe that two phase 3 trials will be needed, and will have to include 1,000-2,000 patients and a monitoring period of three to six months and then extension (open-label) up to 6 months. The time needed for these phase 3 trials largely depends on the partner conducting them, but we estimate that they will take at least two to three years to complete. With a regulatory evaluation of around one year, we estimate that IPED2015 could achieve market approval in 2027-28.

IP2018 – A focus on psychogenic ED

The latest project to be added to Initiator's pipeline is IP2018, which was acquired by Saniona in early 2020 and also has a history with Neurosearch, where it was designated NSD-788 (also NS9588). IP2018 was developed at Neurosearch as a new treatment for depression and anxiety, and two phase 1 trials were conducted for this indication. Following the acquisition, Saniona retains some ownership of the project and has rights to 20 percent of future revenues to Initiator and a single-digit royalty (we guess 2-3 percent) based on product sales.

Like IPED2015, IP2018 is a monoamine reuptake inhibitor. Its main focus is on the serotonin system, but it also inhibits dopamine reuptake. The project is different from IPED2015 and is being developed as a new treatment for individuals with mild to moderate depression with psychogenic ED.

IP2018 Mechanism

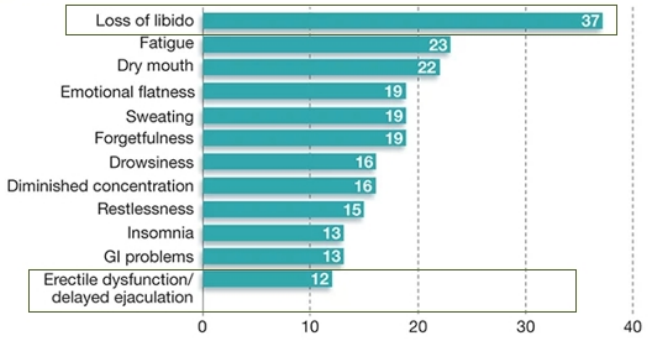


Source: Initiator Pharma

Initiator has conducted its own studies in animal models for depression which show that IP2018 has an antidepressant effect and a positive effect on erectile function. The results showed a dose-dependent efficacy and that the substance can have an antidepressant effect and strengthen erection within a single administration range. These trials compared IP2018 with drugs including Cipramil (citalopram hydrobromide) from Lundbeck, where it showed better or equivalent efficacy in mouse models for depression. Effects on ED have been shown at low dose levels.

Depression and anxiety can cause ED and, in addition, treatments for these conditions often have a negative effect on ED. Prescribing of antidepressant drugs is high and they constitute among the most prescribed drugs in Europe and the United States. A significant proportion of today's established treatments show a negative effect on sexual desire and/or sexual arousal.

Most common side effects of antidepressants reported in primary care in the US



Source: Psychiatric Times, 2014

We believe that a new drug with antidepressant potential that raises serotonin levels and has a positive effect on ED and sexual function could have significant potential not only in ED, but possibly also as a new differentiated drug for the treatment of mild to moderate depression in general.

Good fundamental work from Neurosearch

In addition to the preclinical results, IP2018 has been tested in a phase 1 trial and has also been examined in a positron emission tomography (PET) study in patients. The PET study was important and has helped to better understand the mechanism of the molecule, where it was confirmed that IP2018 binds to serotonin reuptake transporters and dopamine reuptake transporters.

The results of the phase 1 trial have not been published, but it has been completed. Old annual reports from Neurosearch mention IP2018, and the results of the phase 1 trial are described as promising. This was a placebo-controlled study in healthy subjects which a single administration of IP2018 was evaluated at increasing doses. IP2018 was well tolerated and showed a satisfactory pharmacokinetic profile. We believe that the trial included a number of doses that were probably higher than will be required in future studies in ED, so the side effect profile is likely to be further improved.

Recruitment has begun for phase 2a

Screening of patients began in early October 2020 for a phase 2a trial to be conducted in the UK at MAC. The trial will include 24 patients divided into three groups, two with different doses of IP2018 and one receiving a placebo. This will be a randomised, double-blind crossover study, the same as for IPED2015, where participants can also be regarded as their own control. The main purpose is to evaluate the efficacy, and we expect a similar procedure to the phase 2a trial with IPED2015. The main difference in this study is that the individuals to be recruited are younger and show mild to moderate depression. The age range extends between 18-55 years. The recruitment of patients has to date been affected by the Covid-19 pandemic, and there is therefore a risk of delays. However, the plan is still to be able to complete the trial end of H1 2021.

If the outcome is positive, the next step will be a phase 2b trial. We believe the main focus to be psychogenic ED, but a potential licensing partner may see the greater potential to also develop IP2018 as a new drug for the treatment of mild to moderate

depression with a unique sexual functional profile. However, this would require an extensive programme of trials and longer follow-ups.

Based on what we know today, we judge that IP2018 is just over a year behind IPED2015, and we thus estimate that a market launch will not be achieved before 2028.

No obvious challengers

As mentioned earlier in this report, 30-40 percent of ED patients state that they do not achieve satisfactory results with PDE5 inhibitors. For these individuals, there are limited documented effective treatment options (see also appendix).

Although large groups of people lack an effective and simple treatment, development activity is relatively low and there are only a few active clinical projects ongoing. In addition to the projects listed below, there are also some local development projects, including in Asia, and a number of academic initiatives, but our general impression is that these are in early development with unclear commercial plans.

Selected ED projects in development

Project	Company	Development Phase
MED-3000	Futura Medical	Phase 3
IPED2015	Initiator Pharma	Phase 2b
IP2018	Initiator Pharma	Phase 2a
BZ-371	Biozeus Pharmaceutical	Phase 1
Cellgram-ED	Pharmicell Co Ltd	Phase 1
Fadanafil	XuanZhu Pharma	Phase 1
ILG-F	ILGEN Inc	Preclinic
Libiguins	Dicot AB	Preclinic

Source: Erik Penser Bank

The most advanced is MED3000, a topically applied gel rubbed into the penis. The active ingredient is glyceryl trinitrate, a well-known vasodilator. The first results from a phase 3 trial (FM57) were presented in December 2019, demonstrating improved outcomes for patients compared with their baseline (metrics including the IIEF questionnaire) at all dosages. However, there was no statistically significant difference compared with a placebo. The regulatory authorities in Europe and the US seem well disposed and have indicated that the product could receive medical device authorisation, allowing the potential for it to be sold over the counter. We do not consider MED3000 to be a direct competitor to Initiator's project based on the OTC track, and it is also a product that will probably be aimed at patients with very mild symptoms.

BZ371A is a peptide drug that can enhance the production of NO in the penis and thus increase blood supply and stimulate erection. It is a topically applied gel, which reduces the risk of systemic side effects. A first phase 1 trial was performed with twelve healthy volunteers (six men and six women), with BZ371A applied to the genital area. The company says that good safety was noted and blood flow to the area was improved. Data is still sparse, but our view is that this can be viewed as a complementary treatment rather than a direct competitor to Initiator's drug candidates.

Cellgram-ED is a stem cell-based treatment that is injected into the erectile tissue of the penis. A phase 2 trial was recently begun, with 54 patients to be recruited, treated and monitored for twelve months. The expectation is that the treatment will lead to long-term improvements in nerve cells and strengthened blood vessels in the penis. One challenge we see with this kind of treatment is that the pricing could be high, making it most suited to patients who lack alternatives.

In general, competition from new treatments under development looks thin. The activity among pharmaceutical majors seems to have more or less disappeared, which we believe may mean that Initiator will need a solid data package that provides support for efficacy and safety in order to be able to reach a lucrative licensing agreement.

Drugs with similar properties to Initiator's candidates

The projects listed above are mainly focused on stimulating blood flow locally to the penis. However, the natural erection process involves both central and peripheral signalling pathways. We know that dopamine-related signalling pathways are linked to the erection process, both centrally and in the spinal cord, and probably also locally in the penis. There has previously been interest in dopamine substances, and apomorphine went all the way to approval in Europe in 2001. Apomorphine, developed by Abbott Laboratories, acts via dopamine D_2 receptors and has been used in the treatment of Parkinson's disease. To overcome side effects such as nausea and vomiting, the drug was formulated sublingually (Apomorphine SL). In a phase 3 trial in patients with moderate to severe ED, 74 percent of participants had an erection within 10-25 minutes of administration and 54 percent had an erection sufficient to perform intercourse, compared with 34 percent for a placebo. However, the FDA was concerned about the observed cases of low blood pressure and never approved the drug for this indication, although it is approved for Parkinson's disease. An aftermarket study that included over 11,000 patients showed a high frequency of treatment discontinuation due to poor efficacy. After ten years in Europe, Apomorphine SL was withdrawn from the market.

Other substances targeting dopamine receptors that have been under development include ABT-670 and ABT-724 from Abbott Laboratories. These bind mainly to dopamine D_4 receptors and are partial agonists, but their development was halted in phases 1 and 2 respectively. The action via dopamine D_4 receptors avoided the side effects that were an issue with apomorphine, but also reduced the efficacy.

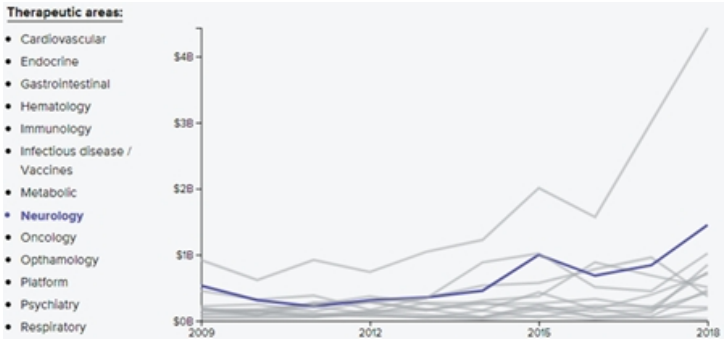
We believe that IPED2015 has obvious similarities to apomorphine, but shows a better side effect profile in animal models and in clinical trials in phases 1 and 2a.

Growing interest in the field

In our eyes, the mechanism involved gives both projects greater similarities with the development of drugs in CNS rather than in urology or cardiovascular disease. However, being branded as a company with a focus on CNS drug development may appear unattractive given the trend of the past decade, with many of the major pharmaceutical companies backing away from or entirely withdrawing from this field. That said, we would like to point out that the field is extensive and sales are predicted to exceed USD 100bn in 2022, according to Evaluatepharma. In addition, we are seeing some signals that the earlier negative trend has turned around.

According to the stakeholder group BIO, neurology was where most business was done after oncology in 2018, and the second-largest therapy area for venture capital investment (the trend has been rising for several years).

VC investments by therapeutic area (USDbn)



Source: Bio 2020, BioPharma Dive 2020, blue line represents neurology

Key industry leaders point to this field as the next big area for growth, including Roche Pharmaceuticals' CEO Bill Anderson, who during this year's investor meeting at JP Morgan pointed out neuroscience as a potential winner in the 2020s, similar to oncology in the 2010s. If this materialises, many of the major pharmaceutical and biotechnology companies will need to make large investments in assets through licensing agreements and build up internal knowledge.

A number of major licensing agreements have been signed in this field over the past year, and are listed below.

Selection of license deal 2019-2020 within the CNS field

Company / Licensor	Dev. Phase	Upfront (MUSD)	Total deal value (MUSD)	Date
Voyager Therapeutics / Neurocine Biosciences	Phase 2	165	1.865	Jan 2019
Alivio Therapeutics / Purdue Pharma	Preclinical	15	275	Jan 2019
SK Biopharmaceuticals / Arvelie Therapeutics	Phase 1	100	530	Feb 2020
StrideBio / Takeda	Preclinical	30	710	March 2019
Oncodesign / Les Laboratoires Servier	Preclinical	3	360	Mars 2019
Centrexion Therapeutics / Lilly	Phase 1	48	988	May 2019
Xenon Pharmaceuticals / Neurocrine Biosciences	Phase 1	30	1.730	Dec 2019
Pfizer / Biogen	Phase 1	75	710	Jan 2020
Sangamo Therapeutics / Biogen	Preclinical	350	2.720	Feb 2020
Vanderbilt University / Acadia Pharmaceuticals	Preclinical	10	515	May 2020
Sage Therapeutics / Biogen	Phase 3	875	1.525	Nov 2020

Source: Erik Penser Bank

Project estimates

Blockbuster potential for IPED2015

To assess the commercial potential for IPED2015 and IP2018, we start from a patient-based model. We include sales in Europe and the United States, which are the markets where we see the greatest potential for the projects. It is estimated that about 30 million men in the US have problems with ED and that the number in Europe amounts to just over 33 million. We expect the incidence of ED to increase over time, driven by an aging population and an increased number of cases of patients with underlying diseases.

A significant number of individuals with the diagnosis will not seek care or treat their ED, but we estimate that about 60 percent will to some extent be treated with PDE5 inhibitors (psychogenic ED 15% and organic ED about 85%). Of these, we have calculated that 30 percent do not achieve the desired results and are in need of effective new products such as those being developed by Initiator.

ED is an indication that is classified under urology. Based on the mechanisms of the projects, however, we believe that the development risks have more similarities with drugs that are developed in the field of neurology, and we use this as our reference when assessing the development risks. The table below shows results from two sources that we consider relevant, showing historical outcomes from clinical trials in the field during different development phases.

Clinical development risk - comparison of two studies

	Phase 1 to 2	LOA	Phase 2 to 3	LOA	Phase 3 to NDA	LOA	NDA to approval	LOA
Bio Industry Analysis, 2016	59,1%	8,4%	29,7%	14,2%	57,4%	47,8%	83,2%	83,2%
Hay et al, Nature Biotechnology, 2014	62,4%	9,4%	30,2%	15,0%	60,6%	49,8%	82,2%	82,2%

Based on the promising results reported for IPED2015 in the phase 2a trial, the project has a reduced risk compared to a general project included in phase 2, which is why we have set a 19 percent probability that the project will reach all the way to a market launch. For IP2018, we have chosen to be somewhat more conservative in our assumptions than the reference data above.

IPED2015 - projected timetable and risks per clinical phase

	Preclinical	Phase 1	Phase 2a/b		Phase 3	NDA	Launch
Timing				**2021**	**2024**	**2026**	**2027**
Probability per phase	100%	100%	100%	40%	57%	85%	19%

IP2018 - projected timetable and risks per clinical phase

	Preclinical	Phase 1	Phase 2a/b		Phase 3	NDA	Launch
Timing				**2022**	**2025**	**2027**	**2028**
Probability per phase	100%	100%	60%	40%	57%	85%	12%

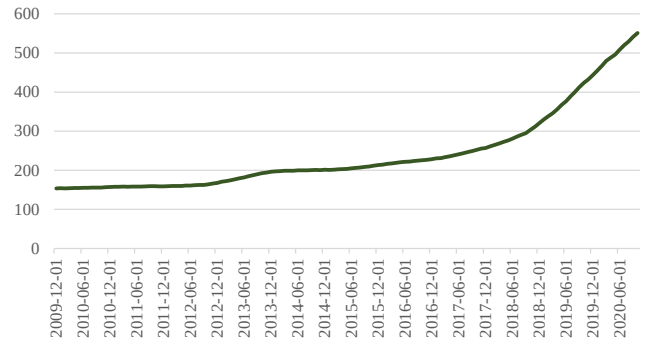
To assess the pricing, we have assumed that this will be at the same level for both projects and that the drugs will be used as required. If we look at how PDE5 inhibitors have been priced historically, Viagra was introduced at around USD 7 in the US but increased to just over USD 20 before a customary overhaul with the introduction of generics. We understand that the current prices per tablet for the Cialis and Viagra brands are around USD 10, according to Drugs.com, while generics can be purchased for around USD 1-2. In Europe, we estimate that the pricing will be about 30 percent below North America.

The main patient group that IPED2015 targets is men over 40. We have assumed, based on various articles, that for this group the average number of intercourses per year is 26, i.e. every other week.

Organic ED	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
North America											
ED patients (millions)	31,2	31,5	31,7	31,9	32,2	32,4	32,7	32,9	33,2	33,4	33,7
Groth y/y	*0,8%*	*0,7%*	*0,7%*	*0,8%*	*0,8%*	*0,8%*	*0,8%*	*0,8%*	*0,8%*	*0,8%*	*0,8%*
On PDE5 therapy (millions)	15,9	16,0	16,2	16,3	16,4	16,5	16,7	16,8	16,9	17,0	17,2
PDE5 failures (millions)	4,8	4,8	4,9	4,9	4,9	5,0	5,0	5,0	5,1	5,1	5,1
Price per tablett (USD)	27,6	28,2	28,7	29,3	29,9	30,5	31,1	31,7	32,3	33,0	33,6
Price increase per year	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Intercourse per patient per year	26	26	26	26	26	26	26	26	26	26	26
IPED2015 market share			1,8%	6,0%	11,9%	17,0%	20%	19%	18%	10,8%	2,2%
No. of patients on IPED2015			0,1	0,3	0,6	0,8	1,0	1,0	0,9	0,6	0,1
IPED2015 tablets sold (millions)			2,3	7,6	15,2	21,9	26,0	24,9	23,8	14,4	2,9
Net Sales			**64,6**	**221,4**	**455,1**	**668,1**	**807,8**	**788,6**	**769,9**	**474,7**	**97,6**

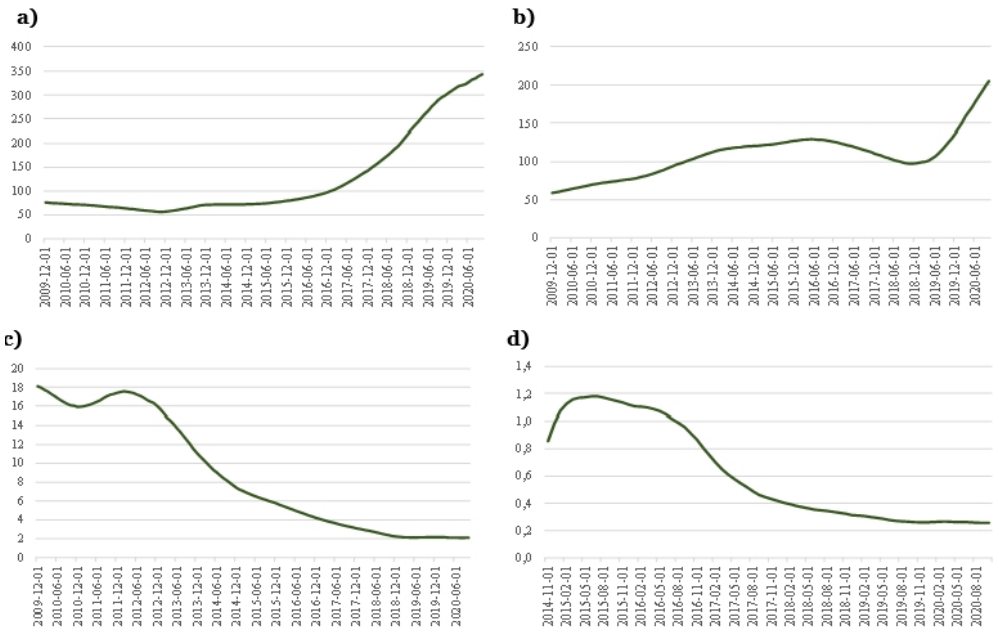
We estimate that IPED2015 could take a market share of 20 percent among those patients who do not achieve good results with PDE5. Using the above assumptions, IPED2015 is expected to reach sales of over USD 800m in the US and prescriptions of just over 26 million tablets per year. As a sanity check, we have compared this with prescription data from Symphony Health Solutions, see below.

Sales volume, PDE5 inhibitors, United States (millions)



Source: Symphony Health Solutions, 2020

Rolling twelve-month prescriptions in the United States of sildenafil (a), tadalafil (b), vardenafil (c) and avanafil (number of tablets, millions)



Source: Symphony Health Solutions, 2020

Prior to the patent expirations for Cialis, Levitra and Viagra, prescriptions were around 180 million tablets per year in the United States. IPED2015 being able to achieve less than 15 percent of these combined levels is, we believe, a reasonable assumption. For the European market, we expect sales to be able to achieve USD 500m, with similar volumes in the US.

Organic ED	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**	**2034**	**2035**
European countries											
ED patients (millions)	33,59	33,60	33,62	33,65	33,68	33,72	33,75	33,78	33,82	33,85	33,88
Groth y/y	0,02%	0,03%	0,05%	0,08%	0,10%	0,10%	0,10%	0,10%	0,10%	0,10%	0,10%
On PDE5 therapy (millions)	17,1	17,1	17,1	17,2	17,2	17,2	17,2	17,2	17,2	17,3	17,3
PDE5 failures (millions)	5,1	5,1	5,1	5,1	5,2	5,2	5,2	5,2	5,2	5,2	5,2
Price per tablett (USD)	18,2	18,2	18,2	18,2	18,2	18,2	18,2	18,2	18,2	18,2	18,2
Price increase per year	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Intercourse per patient per year	26	26	26	26	26	26	26	26	26	26	26
IPED2015 market share			1,8%	6,0%	11,9%	17,0%	20%	19%	18%	3,6%	0,4%
No. of patients on IPED2015			0,1	0,3	0,6	0,9	1,0	1,0	0,9	0,2	0,0
IPED2015 tablets sold (millions)			2,4	8,0	15,9	22,8	26,9	25,5	24,3	4,9	0,5
Net Sales			**43,3**	**144,5**	**289,4**	**413,8**	**487,3**	**463,4**	**440,7**	**88,2**	**8,8**

For IP2018, we expect that the drug will be ready for market launch in Europe and the US in 2028. Our calculations are based on IP2018 being launched as a treatment for psychogenic ED and used as required. The main differences compared to IPED2015 is that the patient group is smaller, making up about 15 percent of the ED population. However, we believe this age group is more motivated to seek treatment and have therefore assumed a higher market penetration of 25 percent. We also believe, based on various studies, that sexual activity is higher and we model one intercourse per week for this patient category.

Psychogenic ED	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
North America											
ED patients (millions)	31,2	31,5	31,7	31,9	32,2	32,4	32,7	32,9	33,2	33,4	33,7
Groth y/y	*0,8%*	*0,7%*	*0,7%*	*0,8%*	*0,8%*	*0,8%*	*0,8%*	*0,8%*	*0,8%*	*0,8%*	*0,8%*
On PDE5 therapy (millions)	2,8	2,8	2,9	2,9	2,9	2,9	2,9	3,0	3,0	3,0	3,0
PDE5 failures (millions)	0,8	0,8	0,9	0,9	0,9	0,9	0,9	0,9	0,9	0,9	0,9
Price per tablett (USD)	27,6	28,2	28,7	29,3	29,9	30,5	31,1	31,7	32,3	33,0	33,6
Price increase per year	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Intercourse per patient per year	52	52	52	52	52	52	52	52	52	52	52
IP2018 market share				2,2%	7,4%	14,9%	21,3%	25%	24%	23%	11,3%
No. of patients on IP2018				0,0	0,1	0,1	0,2	0,2	0,2	0,2	0,1
IP2018 tablets sold (millions)				1,0	3,3	6,7	9,7	11,5	11,0	10,5	5,3
Net Sales				**29,1**	**99,6**	**204,8**	**300,7**	**363,5**	**354,9**	**346,5**	**178,0**

Using our assumptions, we estimate the sales potential in North America at just under USD 400m and in Europe at just over USD 200m. If IP2018 is repositioned as an antidepressant, after promising results, the potential could be significantly greater and probably end up above USD 1bn.

Psychogenic ED	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
European countries											
ED patients (million)	33,6	33,6	33,6	33,6	33,7	33,7	33,7	33,8	33,8	33,9	33,9
Groth y/y	0,02%	0,03%	0,05%	0,08%	0,10%	0,10%	0,10%	0,10%	0,10%	0,10%	0,10%
On PDE5 therapy (millions)	3,0	3,0	3,0	3,0	3,0	3,0	3,0	3,0	3,0	3,0	3,0
PDE5 failures (millions)	0,9	0,9	0,9	0,9	0,9	0,9	0,9	0,9	0,9	0,9	0,9
Price per tablett (USD)	16,6	16,9	17,2	17,6	17,9	18,3	18,7	19,0	19,4	19,8	20,2
Price increase per year	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Intercourse per patient per year	52	52	52	52	52	52	52	52	52	52	52
IP2018 market share				2,2%	7,4%	14,9%	21,3%	25%	24%	23%	4,5%
No. of patients on IP2018				0,0	0,1	0,1	0,2	0,2	0,2	0,2	0,0
IP2018 tablets sold (millions)				1,1	3,5	7,0	10,1	11,8	11,3	10,7	2,1
Net Sales				**18,5**	**63,0**	**128,6**	**187,6**	**225,4**	**218,6**	**212,0**	**43,3**

Since both projects are aimed at large patient groups and the prescribing will mainly take place within primary care, we believe that Initiator Pharma will need a partner for the projects no later than following phase 2b. We model an agreement for IPED2015 in 2023, once phase 2b data is available. We assume a cash settlement of USD 30m and a total contract value of USD 400m, plus royalties of 10-12 percent.
We have made similar assumptions for IP2018, but that it will happen a year later and that the agreement package is slightly smaller, at USD 300m. Here too, we would like to point out that if future studies indicate potential for IP2018 as an antidepressant, there is potential for a more comprehensive agreement and our expectations may need to be adjusted upwards.

Overall financial forecasts for the company

For the first nine months of the year, Initiator reported an operating profit of DKK -8.5m (-6.8), and for the third quarter DKK -3.1m (-2.0). The company had no revenue during the first nine months. Cash flow from operating activities amounted to DKK -5.6m (-6.0) for the first three quarters of the year and to DKK -4.4m (-3.0) for the third quarter. At the end of September, cash and cash equivalents amounted to DKK 8.2m on a debt-free basis. We estimate that the current funding is sufficient to finance the business some way into H1 2021.

We envisage that the company's costs will gradually increase, even though the agreement with MAC Clinical Research significantly reduces the financial burden from the planned phase 2b trial. Our assessment is that the company has a financing need of SEK 30-50m until an agreement is signed for IPED2015 in 2023, as we have outlined. The ongoing warrant programmes may solve some of this financing, but at present this is uncertain since the share is trading significantly below the subscription price of SEK 4.9.

Valuation

To value Initiator, we have used a probability-weighted cash flow model in which we have individually valued each project and added it to a sum-of-the-parts (SOTP) model. We believe that this model is suitable for valuing companies in drug development when there are no ongoing revenues as it clarifies the potential and risks in the projects. The focus of this analysis is on clinical projects IPED2015 and IP2018, where we can see a clear plan to drive these forward.

Our NPV SOTP provides a value for Initiator of SEK 14.6 per share when we apply a required rate of return of 16 percent. The valuation has a large bias towards IPED2015, which represents about 80 percent of the value.

Sum-of-the-parts Valuation					
Project	**Indication**	**Likelihood of approval**	**Peak sales (USDm)**	**Launch**	**NPV***
IPED2015	Organic ED	19%	1 200	2027	345
IP2018	Psychogenic ED	12%	600	2028	84
Technology value					**429**
Net cash					11
General and admin costs					-24
NPV					417
Number of shares**					28,6
NPV per share					14,6
* MSEK, **including full conversion by MAC					

In our model assumptions for IPED2015, presented earlier in this report, we have judged that Initiator will sign a licensing agreement with a pharmaceutical company in 2023 that provides USD 30m in cash. However, we do not expect any revenue before then and estimate that the company will need to strengthen its finances by SEK 30-50m to finance the operation and development of the projects. There may be various ways to resolve this financing, as the company has clearly shown through its agreement with MAC. However, we choose to be cautious in our assumptions and assess that capital will need to be brought in from the stock market. We model that this takes place via a new issue of shares at a price of SEK 4. Including transaction costs, we estimate that this could lead to dilution of approximately 8.5-14.0 million shares, and this is in principle regardless of the outcome of the ongoing warrants. Using these assumptions about financing, we arrive at a fair value for Initiator Pharma of SEK 11-12 per share.

Sensitivity analysis

To make visible how the value of the projects per share is affected by changed basic assumptions, we have performed a sensitivity analysis. We use the current number of shares plus the average value of the number of shares we have in the dilution range we calculated above.

IPED2015 - LOA / WACC - Value per share					
	12%	14%	16%	18%	20%
29%	15,9	13,4	11,2	9,5	8,1
24%	14,1	11,8	10,0	8,5	7,2
19%	12,3	10,4	8,8	7,5	6,4
14%	10,3	8,7	7,4	6,4	5,5
9%	8,5	7,2	6,2	5,3	4,6

IPED2015 - LOA / Market share - Value per share					
	10%	15%	20%	25%	30%
29%	7,6	9,4	11,2	13,1	14,9
24%	6,9	8,4	10,0	11,5	13,0
19%	6,3	7,5	8,8	9,9	11,1
14%	5,6	6,5	7,4	8,3	9,2
9%	5,0	5,6	6,2	6,7	7,3

IP2018 - LOA / WACC - Value per share					
	12%	14%	16%	18%	20%
20%	4,1	3,4	2,8	2,3	1,9
16%	3,6	3,0	2,4	2,0	1,7
12%	3,1	2,6	2,1	1,7	1,4
8%	2,7	2,2	1,8	1,5	1,3
4%	2,2	1,8	1,5	1,3	1,0

IP2018 - LOA / Market share - Value per share					
	15%	20%	25%	30%	35%
20%	2,1	2,4	2,8	3,1	3,4
16%	1,9	2,2	2,4	2,7	2,9
12%	1,8	1,9	2,1	2,3	2,5
8%	1,6	1,7	1,8	1,9	2,1
4%	1,4	1,4	1,5	1,6	1,6

Valuation of comparable companies

As Initiator has not yet reached profitability in its operations, we believe that accepted key figures are not useful in a relative valuation. Instead, we use the technology value (EV) to give an idea of the valuation compared to similar companies listed in Sweden.

(MSEK)	Market cap	Net cash	Technology value(EV)	Dev. Phase
Listed peers within the CNS/ED field				
Asarina	119	65	54	Phase 2
Dicot	51	18	33	Preclinical
Gabather	75	33	42	Phase 1
Initiator Pharma	112	11	101	Phase 2
Irlab	2 110	170	1 940	Phase 2
Saniona	1 347	622	725	Phase 2
Mean	636		483	
Median	116		78	

There are large differences in valuation between the companies, where Irlab and Saniona stand out with a clearly higher valuation. A common denominator, in addition to both having a background from Neurosearch, is that they are platform companies. In addition, both companies are listed on Nasdaq Stockholm's main list and have succeeded in attracting institutional capital. Asarina is also listed on the main list, but the pricing is weighed down by the spring's negative outcome for the previous main project sepranolone in a phase 2b study. Prior to the results, the share was traded at near 8x today's price (SEK 48), which gives an indication of the potential for the Initiator share before phase 2b data at the end of 2022.

The lower valuation of Dicot and Gabather indicates that investors want to see efficacy data in patients before a re-valuation.

Scenario analysis

As we mentioned, several important milestones are expected in the next two years. By far the most important are the phase 2b results for IPED2015 during H2 2022, followed by IP2018 phase 2a results which are expected towards the end of H1 2021.

Initiator upside and downside risks in our valuation

Event	Timing	Uside	Per share SEK	Downside	Per share SEK
IP2018 Phase 2a data	End of H1 2021	Positive results	2	Negative outcome	-2
IPED2015 Phase 2b data	H2 2022	Positive results	19	Negative outcome	-9

Risks in our assumptions

Delays in the trials

The Covid-19 pandemic has had a significant impact on the ability to conduct clinical trials, and the company has already warned of delays in patient recruitment for the phase 2a trial on IP2018. Further delays due to the pandemic are a risk, but there are also other risks that could lead to a delayed start for the IPED2015 phase 2b trial and the recruitment of patients.

Negative outcome of trials

The most obvious risk is a negative outcome in ongoing and planned trials. We believe that the risk level in both projects remains high, and how this impacts the valuation is shown in the above scenario analysis.

Failure to create partnerships

Initiator Pharma's projects focus on major primary care indications, and phase 3 programmes may need to include a couple of thousand patients. This can mean a need for extensive capital if the company fails to find a partner for the trials.

Appendix: Other projects

The two early-stage assets IPNP2015 and IPDP2015 was included in the package that was spun-out of Saniona in 2016. However, the compounds have a longer history that goes back to Neurosearch, which was the inventor of the compounds. For the moment, we believe Initiator Pharma is focused on the two lead programs and expect that the company will initiate the development of the above assets - both supported by extensive preclinical data and target unmet need and commercially attractive indications - at an appropriate point of time.

IPNP2015 is being developed for the treatment of neuropathic pain, usually, a chronic condition related to progressive nerve disease affecting millions of patients worldwide. IPNP2015 monoamine reuptake inhibitor, inhibiting transporters of serotonin (SERT), noradrenaline (NAT), and dopamine (DAT) in rodent brains. This has been shown in human cell lines expressing these neurotransmitter transporter systems. It is believed that IPNP2015 may enhance the activity of the neurotransmitters serotonin, noradrenaline, and dopamine within central pain circuits leading to pain relief.

Neuropathic pain is a disease resulting from and treatment related of HIV infections, diabetes, chemotherapy, alcohol and herpes zoster infections. In patients with mild to moderate neuropathic pain, the treatment is focused on anticonvulsants drugs and antidepressants as well as local topical formulations of NSAIDs. A large part of the patients (millions with neuropathic pain worldwide) receiving these treatments do not get proper pain relief, why there is a significant unmet medical need and market for new effective treatments.

IPNP2015 worked well in rat models of persistent and neuropathic pain, and pre-clinical studies has shown signs of a good safety profile. When comparing IPNP2015 in animal models to already approved monoamine reuptake inhibitor duloxetine (SERT/NAT) it showed superior efficacy.

Duloxetine (brand name Cymbalta) was launched in 2004 by Eli Lilly for both the treatment of depression and diabetic neuropathic pain. Later, the drug reached a series of additional approvals followed for other indications. The patent expired in 2013, and during the year the product reached top sales of USD 5.1bn and was Eli Lilly's then-largest selling product.

IPDP2015 has unique properties for the treatment of depression. It preferentially inhibits DAT and does not seem to develop risks of abuse. In mouse models of depression, IPDP2015 has shown promising activity. As depression and pain share biological pathways and neurotransmitters, IPDP2015 might be effective for the treatment of both concurrently. In rat models of neuropathic pain, IPDP2015 displayed activity.

Appendix: Patent portfolio

Patents are the key to being able to capitalise on drug assets, and are especially important in the development of small-molecule drugs – like the candidates being developed by Initiator – as these are usually easy to copy. The company took over some patents when acquiring the assets, but has also continued to build on this with new patent applications.

IPED2015 has granted patent protection in the US that runs until 2031. We understand that the company has a plan to further strengthen its protection with new patent applications providing new solid IPR coverage based on inventions and results from company's clinical development of IPED2015.

IP2018 has granted patents that run until July 2026 in the US. In addition, there are granted patents in Germany, France, UK, Switzerland, Japan and Israel that run until September 2025.

There are also granted patents for IPNP2015 in the United States, Germany, France, the United Kingdom, and Switzerland.

IPDP2015 has granted patents in the United States, Germany, France and the United Kingdom.

The company has a stated active patent strategy to build on the protection of its assets, and we expect to hear of more patent applications next year.
In addition to IPR estate it is important worth to consider data exclusivity in United States provides 5 years of guaranteed exclusivity for small molecules that are new chemical entities, although in practice this exclusivity provides closer to 7 years of market protection for small molecules because the FDA cannot begin reviewing applications from generic competitors until the 5 year's have elapsed. In Europe the data exclusivity period is 8 year that can be extended with two year's of marketing exclusivity and a one year extension.

Appendix: Management

Dr. Claus Elsborg Olesen – CEO and Director

Claus Olesen (born 1974) earned his PhD in Physiology and Biophysics from Aarhus University in 2008 and has been engaged in both basic and applied research with an emphasis on structural biology and function of membrane proteins ever since. Furthermore, Olesen has been in involved in numerous drug development projects in both academic and industrial collaborations. Olesen has entrepreneurial experience from his participation in the founding of two biotech companies, Pcovery ApS and NMD Pharma. Olesen took up his position as CEO of Initiator Pharma in connection with the company's formation on May 2, 2016 and subsequently took up his board position at Initiator Pharma on September 19, 2016.

Claus Olesen owns 779,579 shares and 178,019 warrants in Initiator Pharma through his wholly-owned holding company Claus Olesen Holding ApS.

Dr. Torgeir Vaage - CFO
Torgeir Vaage (born 1964) holds an MSc from the Norwegian School of Economics and a PhD from UC Berkeley. Vaage has extensive experience from the financial industry in Norway, including through his role as a financial analyst with ABG Sundal Collier, Handelsbanken Markets and Norden Equity. Vaage has been involved in a number of early stage pharmaceutical and biotechnology start-ups.

Torgeir Vaage owns 161,701 shares and 151,967 warrants in Initiator Pharma through his wholly-owned company Caerus Capital AS.

Dr. Mikael Thomsen – CDO
Mikael Thomsen (born 1968) has a PhD in Pharmacology and Toxicology from the University of Copenhagen. Thomsen has worked in the pharmaceutical area for over 20 years, both within small companies and at Novartis and Novo Nordisk. Through a number of roles at these companies, Thomsen has extensive experience of drug development, in both preclinical and clinical phases. Thomsen's primary focus and expertise in drug development is rapid development in the early phases. In addition, Thomsen is also a member of a number of medical societies and has participated in the writing of over 50 scientific articles and a number of patents.

Mikael Thomsen owns 618,191 shares and 169,334 warrants in Initiator Pharma through his wholly-owned holding company Mikael Søndergaard Thomsen ApS.

Ulf Simonsen (PhD, Professor) – CMO/CSO
Ulf Simonsen (born 1963) is trained as a medical doctor from Aarhus University and earned his PhD in Physiology from Complutense University, Madrid. Simonsen became Professor of Pharmacology at Aarhus University in 2005 and was head of the university's Department of Pharmacology from 2006-2011. Simonsen is a world-leading researcher in ED and is also an active member of the European Society of Sexual Medicine. Simonsen has contributed to the writing of over 155 scientific articles, a number of textbook chapters and a number of patents.

Ulf Simonsen owns 585,200 shares and 104,208 warrants in Initiator Pharma through holding company Simonsen og Mogensen Holding ApS, which is 50 percent owned by Simonsen and 50 percent owned by related parties.

Dan Peters (PhD) – CTO
Dan Peters (born 1961) holds a PhD in Organic Chemistry from the University of Lund. Peters started working with medicinal chemistry at NeuroSearch A/S in 1991, and served as project manager for the monoamine reuptake programme from 1999, the technology on which Initiator Pharma's drug candidates are based. Within these projects, Peters developed a drugs platform for indications such as depression, pain and obesity. Peters has authored over 70 scientific articles, registered over 100 patent families and is the founder of DanPET AB.

Dan Peters owns 1,036,711 shares and 78,162 warrants in Initiator Pharma through his wholly-owned holding company DanPET AB.

Appendix: Board of Directors

Magnus Persson – Chairman
Magnus Persson (born 1960) is a medical doctor and associate professor of physiology at the Karolinska Institute in Stockholm. Persson has extensive experience in the financing of medicine, life science and biotech. He has led development teams in phase II and III programmes in the pharmaceutical industry and has founded and led both private and public biotech and medical technology companies as well as being a chairman and director in Europe and the United States. In addition, Persson has been involved in about ten IPOs. He took up his position on the board of Initiator Pharma on September 19, 2016.

Magnus Persson owns 120,036 shares and 147,627 warrants in Initiator Pharma through his wholly-owned company P O Persson i Lidingö AB.

Peter Holm – Director
Peter Holm (born 1974) has a PhD in Biochemistry from the Karolinska Institute in Stockholm, and a Master's degree in Chemistry from the University of Linköping. Holm is European Patent Attorney, Partner and Country Manager for Sweden at the Patent Law Firm HØIBERG . Through this position, Holm has extensive experience in strategic global intellectual property law and counselling on commercialisation strategies for companies and organisations in the lifescience sector. Holm took up his position on the board of Initiator Pharma on September 19, 2016.

Peter Holm holds no capital or votes in Initiator Pharma.

Henrik Moltke – Director
Henrik Moltke (born 1958) holds a Master's degree in International Economics and Strategic Management from Copenhagen Business School. Moltke has more than 25 years of experience as CFO and Senior Vice President within life sciences and health care. The primary focus in his career has been in venture financing, IPOs, follow on capital increases in the public market, investor relations and business development with companies like Scandinavian Micro Biodevices ApS, Astion Pharma A/S, NeuroSearch A/S, Novo A/S , Ferrosan A/S and Zoetis Denmark. Moltke also has extensive experience as a director of several listed and unlisted companies. CFO at FluoGuide listed at Spotlight Stockmarket. Moltke is a director of charity foundation Werner Richter og Hustrus Legat. Moltke is also a director of Hartmanns A/S. He took up his position on the board of Initiator Pharma on September 19, 2016.

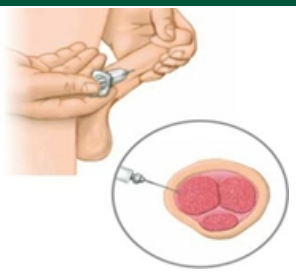
Henrik Moltke owns 59,248 shares and 39,077 warrants in Initiator Pharma.

Appendix: Other ED treatments

PDE5 inhibitors are today recommended as the first-line treatment for ED in major markets. Patients who do not respond well to these drugs have a number of options available, but we regard these other products as unattractive for the broad patient population. We believe that an effective treatment that can be given as a tablet will be preferred to the existing options described below.

The most frequent second-line treatment is intracavernous injection (ICIT) with prostaglandin E1 (PGE1, also called alprostadil). Injection of PGE1 into the erectile tissue is marketed by Pfizer under the Caverject brand and by UCB Pharma under the Viridal brand. ICIT has a relatively rapid effect that lasts for 30-50 minutes. Clinical results with PGE1 have been good, with 70-80 percent of patients feeling that they can have intercourse.

Injection of PGE1



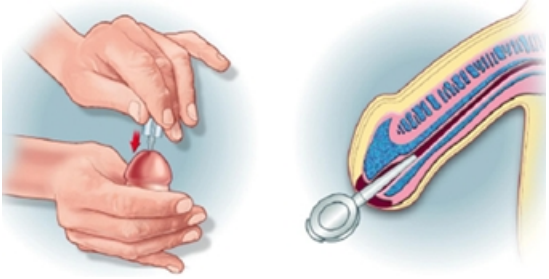
Source: Boston Scientific

The main inhibitor for the use of injections is that they can cause pain afterwards and require training. Most ED drugs are prescribed by general practitioners who often lack the knowledge to teach the administration. In addition, there are challenges in the convenience of this form of administration and it has been shown that relatively few maintain it long-term. After 2-3 months, more than half of patients usually stop the treatment. We believe that it is mainly specialised urologists who prescribe this treatment and this limits its use.

Another injection product is Invicorp, sold by Evolan Pharma in Europe, where it is approved. This is a combination treatment with aviptadil and phentolamine injected into the erectile tissue. Clinical studies have shown efficacy in ED that is on a par with ICIT.

PGE1 can also be administered directly into the urethra, known as transurethral administration. However, the procedure has been shown to be difficult to master and many patients experience side effects such as pain in the urethra or even bleeding.

Administration of PGE1 in the urethra



Source: Porst et al., Journal of Sexual Medication, 2013

In clinical trials, however, the medicated urethral system for erection (MUSE) has not shown the same good results as ICIT, which is why we believe that its use is limited. Ferring markets Vitaros under this concept.

Comparison of MUSE and ICIT

Author	No. of patients	MUSE®	i.c. alprostadil
Ghazi, 1998 [124]	125	48% (61)	79% (98)
Werthman, 1997 [125]	100	37%	89%
Porst, 1997 [126]	103	43% (44)	70% (72)
Shabsigh, 1998 [127]	106	27%	66% (buckling test)
Shabsigh, 2000 [128]	68	53%	83% (at home use)
Flynn, 1998 [129]	Literature review	45%	>70%

MUSE = Medicated Urethral System for Erection

Source: Porst et al., Journal of Sexual Medication, 2013

PGE1 can also be administered topically as a cream, rubbed into the penis before intercourse. This method of administration is attractive but the efficacy in clinical studies has been modest. In addition, there have been side effects such as a burning sensation in the patient, as well as sometimes for the partner.

In addition to topical drug administration, there are vacuum pumps that work regardless of the underlying cause of ED. This is an old and well-proven method for achieving an erection, but studies indicate it has a low degree of acceptance. We judge that vacuum pumps are a niche treatment.

For patients with severe ED who do not respond to injection therapy or other alternatives, penile implants can be offered. This means that an operation is required, and because ED has a low priority in healthcare, the waiting times can be long.

Once the implant is in place, it can be inflated when an erection is desired. The clinical results are very good and a high proportion can complete intercourse. The implants have also shown good longevity, with 93 percent still working after five years. We believe that very few patients receive implants.

There is also a plethora of over-the-counter products for the treatment of ED, but most lack clinical documentation. These products are probably used as a first option for any men with ED problems before seeking treatment.

Appendix: Penis anatomy

The penis is made up of:

- Two chambers called the corpora cavernosa, which run the length of the organ and contain a maze of blood vessels shaped like cavernous spaces (like a sponge)
- The urethra, or channel for urine and sperm, which runs along the underside of the corpora cavernosa
- Erectile tissue, which surrounds the urethra, two main arteries and several veins and nerves
- The shaft, the longest part of the penis, where the head (glans) is at the end of the shaft, where urine and semen are discharged

How does an erection occur?

When the blood vessels of the corpora cavernosa relax and open up, blood rushes in through the cavernosa arteries to fill them. The blood then gets trapped under high pressure, creating an erection.

An erection begins with sensory and mental stimulation. During sexual arousal, nerve messages begin to stimulate the penis. Impulses from the brain and local nerves cause the muscles of the corpora cavernosa to relax, allowing blood to flow in and fill the open spaces. The blood creates pressure in the corpora cavernosa, making the penis expand and creating an erection.
The tunica albuginea (the membrane surrounding the corpora cavernosa), helps to trap the blood in the corpora cavernosa, sustaining the erection. Erection is reversed when muscles in the penis contract, stopping the inflow of blood and opening outflow channels.

Consolidated statement of comprehensive income (MDKK)

	2015	2016	2017A	2018A	2019A	2020E	2021E	2022E
Net sales			0,0	0,0	0,0	0,0	0,0	0,0
Other income			0,0	0,0	0,0	0,0	0,0	0,0
Costs of goods sold			0,0	0,0	0,0	0,0	0,0	0,0
Gross profit			**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**
Capitalized work for own account			0,0	0,0	0,0	0,0	0,0	0,0
Personell expenses			-1,3	-1,1	-0,9	-1,6	-1,9	-2,4
Other external expenses			-8,2	-11,4	-8,4	-10,3	-13,5	-15,0
Extra ordinary costs			0,0	0,0	0,0	0,0	0,0	0,0
Operating earnings before depreciation (EBITDA)			**-9,5**	**-12,5**	**-9,3**	**-11,9**	**-15,4**	**-17,4**
Depreciations			-0,1	-0,1	-0,1	0,0	0,0	0,0
Goodwill write-down			0,0	0,0	0,0	0,0	0,0	0,0
Operating earnings (EBIT)			**-9,6**	**-12,6**	**-9,3**	**-12,0**	**-15,4**	**-17,4**
Extra ordinary post			0,0	0,0	0,0	0,0	0,0	0,0
Adjusted earnings (EBIT)			**-9,6**	**-12,6**	**-9,3**	**-12,0**	**-15,4**	**-17,4**
Financal income			0,0	0,0	0,0	0,0	0,0	0,0
Financal expenses			-0,8	-0,1	-0,6	-0,1	-0,2	-0,4
Earnings before tax			-10,4	-12,7	-10,0	-12,0	-15,6	-17,8
Tax			1,8	2,4	1,7	2,0	2,6	3,0
Minority			0,0	0,0	0,0	0,0	0,0	0,0
Net profit			-8,6	-10,3	-8,3	-10,0	-13,0	-14,8

Cash flow statement (MDKK)

	2015	2016	2017A	2018A	2019A	2020E	2021E	2022E
Net profit			-7,0	-15,2	-10,3	-7,3	-13,6	-15,2
Changes in working capital			-0,8	1,6	1,8	-0,1	-2,0	-1,7
Cash flow from operating activities			**-7,8**	**-13,6**	**-8,6**	**-7,4**	**-15,6**	**-16,9**
Investments			-0,1	0,0	0,0	0,0	0,0	0,0
Divestments			0,0	0,0	0,0	0,0	0,0	0,0
Free cash flow			**-7,9**	**-13,6**	**-8,6**	**-7,4**	**-15,6**	**-16,9**
Dividends			0,0	0,0	0,0	0,0	0,0	0,0
Cash from financing activities			**14,9**	**20,9**	**1,6**	**6,2**	**40,0**	**0,0**
Acquisition			0,0	0,0	0,0	0,0	0,0	0,0
Loans			0,0	0,0	0,0	0,0	0,0	0,0
Cash flow			**7,0**	**7,3**	**-6,9**	**-1,2**	**24,4**	**-16,9**

Balance sheet (MDKK)

	2015	2016	2017A	2018A	2019A	2020E	2021E	2022E
Assets								
Goodwill			0,1	0,1	0,0	0,0	1,0	1,0
Other intangible assets			0,0	0,0	0,0	0,0	0,0	0,0
Tangible assets			0,1	0,1	0,0	0,0	0,0	0,0
Interest bearing assets			0,0	0,0	0,0	0,0	0,0	0,0
Assets in other companies			0,0	0,0	0,0	0,0	0,0	0,0
Other tangible assets			0,0	0,0	0,0	0,0	0,0	0,0
Total fixed assets			**0,2**	**0,1**	**0,0**	**0,0**	**1,0**	**1,0**
Inventories			0,0	0,0	0,0	0,0	0,0	0,0
Accounts receivable and other receivables			1,9	2,7	3,8	0,3	4,0	5,0
Cash and cash equivalents			7,2	14,5	7,6	6,4	30,8	13,9
Total current assets			**9,1**	**17,2**	**11,4**	**6,7**	**34,8**	**18,9**
Total assets			**9,3**	**17,3**	**11,4**	**6,7**	**35,8**	**19,9**
Shareholders equity and liabilities								
Shareholders equity			6,0	16,6	9,9	5,8	32,8	18,0
Minority			0,0	0,0	0,0	0,0	0,0	0,0
Total shareholders' equity			**6,0**	**16,6**	**9,9**	**5,8**	**32,8**	**18,0**
Long-term liabilities, interest bearing			0,0	0,0	0,0	0,0	0,0	0,0
Pension liabilities			0,0	0,0	0,0	0,0	0,0	0,0
Total long-term liabilities			**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**
Accounts payable			0,0	0,0	0,0	0,0	0,0	0,0
Current tax liabilities			0,0	0,0	0,0	0,0	0,0	0,0
Other short-term non-interest-bearing liabilities			3,3	0,7	1,5	0,9	3,0	1,9
Total short-term liabilities			**3,3**	**0,7**	**1,5**	**0,9**	**3,0**	**1,9**
Total shareholders' equity and liabilities			**9,3**	**17,3**	**11,4**	**6,7**	**35,8**	**19,9**

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