Initiator Pharma

Sector: Biotech

Q2 2024 – Silent advancements

Redeye provides a research update following the Q2 report published by Initiator Pharma earlier today. The report did not include any significant surprises as the company continues to operate at a low cash burn, showing promise for the financial runway ahead. Following the recent patent application for pudafensine, we restate that the full priority for H2 2024 will be to find a licensing partner for the candidate. We reiterate our fair value range with a base case valuation of SEK24.

Summary of the Q2 report

In the second quarter of 2024, Initiator Pharma reported an operating profit (loss) of DKK-5.0m (-8.8), while Free cash flow for the period amounted to DKK-4.3m (-7.8). The company continues to operate at a low cash burn, currently prioritizing business development efforts in front of further clinical development. Accordingly, the company reported a cash position at the quarter-end of DKK14.5m (25.9).

Strengthening the IP protection

In July, Initiator Pharma announced the publication of its international patent application for a new dosage regime of pudafensine to treat erectile dysfunction (ED). This patent, being a part of the company's broader strategy to protect its drug pipeline, adds multiple layers of protection for pudafensine until 2044, with the possibility of a further extension. The publication of this patent application marks a milestone for Initiator Pharma and paves the way for future clinical trials and potential commercialization of pudafensine.

Valuation – Base case of SEK24 per share

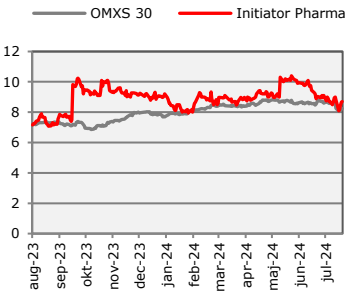
We value Initiator Pharma using a sum-of-the-parts (SOTP) valuation analysis based on discounted cash flow (DCF) models of the clinical pipeline candidates. We reiterate our fair value range of SEK7-40 per share with a base case of SEK24, bull case: SEK40; bear case: SEK7. Accordingly, our base case suggests a substantial upside potential from current share price levels as we continue to have a strong outlook on the case.

Key Financials (DKKm)	2022	2023	2024e	2025e	2026e
Revenues	0	0	138	0	52
Revenue growth	N/A	N/A	N/A	-1	N/A
EBITDA	-41,7	-26,9	120,2	-26,0	12,2
EBIT	-41,7	-26,9	120,2	-26,0	12,2
EBIT Margin (%)	N/A	N/A	N/A	N/A	N/A
Net Income	-38	-29	89	-26	12

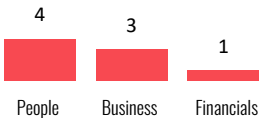
FAIR VALUE RANGE

BEAR	BASE	BULL
7	**24**	40

INIT VS OMXS30(LTM)



REDEYE RATING



KEY STATS

Ticker	INIT
Market	First North
Share Price (SEK)	7.8
Market Cap (MSEK)	420
Free Float	75%
Avg.daily volume ('000)	455

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Important information: All information regarding limitation of liability and potential conflicts of interest can be found at the end of the report

Investment Case

Case: Generating de-risked shareholder value

We argue that Initiator Pharma is evolving beyond the status of an ordinary research and development-stage biotech company. The company employs a dynamic approach that involves identifying lucrative and underpriced clinical-stage assets in areas with significant unmet medical needs and propelling them through critical value inflection points in a cost-effective manner. We maintain our view that the management team has consistently demonstrated its adeptness at identifying de-risked prospects that can generate long-term value for shareholders.

With three candidates in clinical development, and numerous value inflection points on the horizon, we see compelling short- and long-term potential.

Evidence: Well-positioned to lead paradigm shift

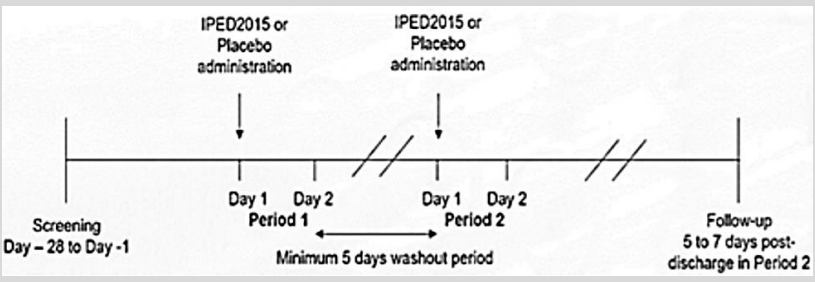
We believe that Initiator Pharma's most advanced program, pudafensine (IPED2015), is well-positioned to fundamentally change the treatment paradigm for erectile dysfunction (ED). Its active pharmaceutical ingredient (API), IP2015, has a unique dual-action mechanism – strengthening both the sexual drive of patients and increasing penile blood flow – which distinguishes it from its competitors and provides it with a broader reach.

The study results from the company's phase IIb trial were announced in Q4 2023, and pudafensine demonstrated statistically significant efficacy on the primary and exploratory endpoints. Furthermore, no safety concerns were reported. Being the first study in a natural setting, and with a larger study size (n=120), this represented a true milestone and inflection point for the company.

Supportive analysis: Pudafensine clinical evidence

The Phase IIa PoC study was designed as an exploratory trial and included 12 patients who had severe ED, meaning that they do not respond to currently available treatment. Patients were enrolled after a thorough selection and screening process and obtained a single dose of either pudafensine or placebo in a cross-over study design.

Pudafensine – Phase IIa dosing schedule



Source: Initiator Pharma

Pudafensine demonstrated a solid safety profile and statistically and clinically significant efficacy data on ED:

- The effect of pudafensine (n=12) was significant vs. placebo (n=12) on penis stiffness measured as 80-100% rigidity (P<0.05).
- The observed positive effects on erectile function were closely related to the plasma concentrations and were seen in a total of 25% of the patients.
- Pudafensine was well tolerated with no reported unexpected adverse events.

Challenge I: Patent expirations

Patent expiry and sensitivity to delays in the development process are risks that all biotech companies face and can jeopardize future sales exclusivity. The composition of matter patents for pudafensine is set to expire in 2031. Patent extensions are possible, though, subject to market authorization prior to patent expiry. However, we expect Initiator Pharma to pursue an active patent strategy to protect its assets further in the long term. This is evident from the granted patent extending the protection of IP2018 in Europe until 2040 (previously 2026).

Challenge II: Extensive capital required

Initiator Pharma is a pre-revenue company in the clinical stage that will likely remain dependent on the capital markets and partnerships for the coming years to come. Given its anticipated broad scope of clinical activities from here on out, substantial capital will be required. However, with the past capital raises, the company has strengthened its cash position and secured financing into 2025e, we argue.

Valuation: Enticing upside potential with near-term inflection points

Our Base Case fair value estimate for Initiator Pharma is SEK24 per share, suggesting significant upside potential from today's share price levels. Our Bull and Bear cases are SEK40 and SEK7 per share, respectively. Overall, we argue that the share trades at a substantial discount to its fundamental value and offers an attractive risk/reward proposition.

We see a rich news flow for Initiator Pharma in the near future. Specifically, we judge that a potential licensing deal for pudafensine will constitute the main catalysts coming up.

Counter Points

- **Possible Delays in Development**
  As we have seen in the IP2018 phase IIa study, which was significantly prolonged due to slower patient recruitment than expected (due to the covid-19 pandemic), there are risks of possible delays in clinical development.

- **Difficulties in Clinical Assessment**
  High placebo response rates and the lack of an objective efficacy measure are two common challenges in ED clinical trials. The ongoing phase IIb intercourse study in pudafensine will be based on subjective scoring methods (the IIEF score that was the pivotal endpoint in the approval of e.g., Viagra and Cialis), and if the placebo arm shows significant improvements, this could taint the image of treatment's true efficacy.

- **Partnership Dependency**
  Given the significant resources and large number of patients needed for a potential upcoming pivotal phase III trial in pudafensine (and IP2018), we believe that Initiator Pharma is largely dependent on finding and co-operating with a licensing partner to conduct late-stage development of its candidates.

Key Catalysts

- **PUDAFENSINE – licensing deal**

  Pudafensine continues to attract interest from Big Pharma, and we believe a partnership deal for the phase III trial and onwards is likely.

  Timeframe: 0-6 months

  Impact: Major

- **IP2018 –phase IIb trial initiation**

  Following encouraging data in the phase IIa study with the company's second ED treatment program, IP2018, we expect a subsequent phase IIb trial to be initiated in 2025. The trial should study the efficacy and safety of IP2018 in natural settings in young, depressed patients with ED.

  Timeframe: 6-12 months

  Impact: Minor

- **IPTN2021 – Phase I MAD study**

  The initiation, and the subsequent results, from the upcoming IPTN2021 phase I multiple ascending dose (MAD) trial are inflection points in the near future that could act as positive triggers for the stock price.

  Time frame: 6-9 months

  Impact: Moderate

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Q2 2024 – Review

Financials Q2 2024

- **Net Sales** for Q2 were DKK0m (0m).
- **OPEX** came in at DKK-5.0m (-8.8m) for the quarter. While being slightly higher in absolute terms than our estimate of DKK-3.8m, the company continues to operate at a low cash burn.

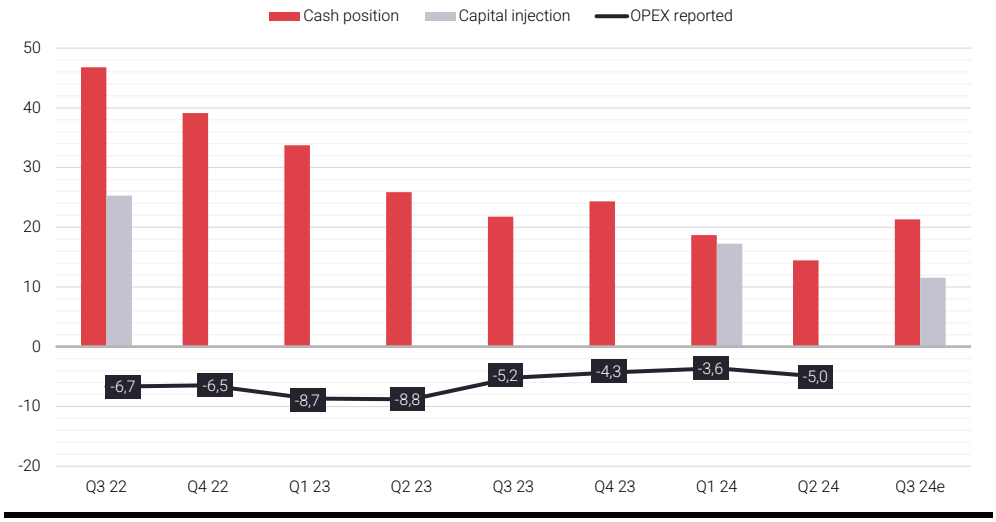
Initiator Pharma: Q2 Financial estimates (DKKm)

Initiator Pharma: Actual vs. Estimates (DKKm)				
DKKm	Q2 23	Q2 24a	Q2 24e	Diff (%)
Net sales	0,0	0,0	0,0	0%
Sales growth Y/Y	N/A	N/A	N/A	N/A
OPEX	8,8	5,0	3,8	-32%
EBITDA	-8,8	-5,0	-3,8	-32%
EBITDA margin (%)	N/A	N/A	N/A	N/A
EBIT	-8,8	-5,0	-3,8	-32%
EBIT margin (%)	N/A	N/A	N/A	N/A
Free cash flow	-7,8	-4,3	-3,9	-9%
Cash & Equivalents	25,9	14,5	14,8	-2%

Source: Company data, Redeye Research

- **Free cash flow** was DKK-4.3m (-7.8m), slightly below our estimation of DKK-3.9m.
- **Cash position** at the end of Q2 was DKK14.5m (25.9m), accordingly.

Cash position and reported OPEX Q3 2022 – Q3 2024e (DKKm)



Source: Redeye Research, Initiator Pharma

We argue that the current cash position of the company remains robust, standing at DKK14.5m, even though it is slightly below our initial projection of DKK14.8m. Based on this, we remain confident that the current resources will be sufficient to finance the company's operations into

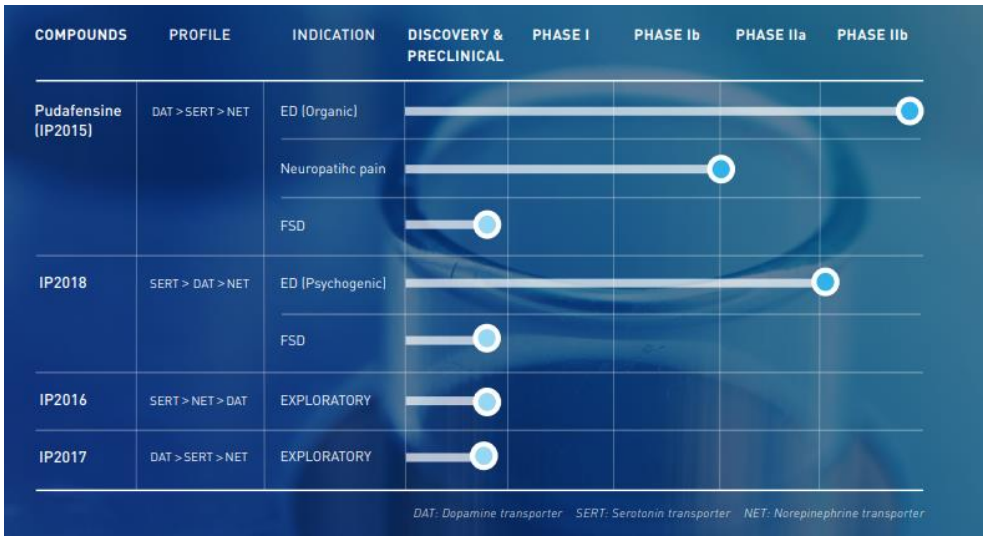
2025. While OPEX increased somewhat from the previous quarter, we are likely to see a continued low cash burn from the company for 2024 as the main priority will be to intensify discussions and negotiations with potential partners.

However, as previously explained, we believe that Initiator Pharma could seek to bolster its financial position further by raising capital sometime during the year. This measure would serve to pre-empt any potential financial challenges, ensure the company's continued stability, and strengthen the company's negotiating position in potential partner discussions.

In our comprehensive valuation model, we include a SEK20-25m capital raise as we believe that the company could look to perform a capital raise to extend its financial runway. However, should Initiator Pharma successfully manage to enter into a license agreement with a partner during H2 2024, it would likely receive some form of upfront payment. Accordingly, this would then eradicate the company's need to perform any capital raise.

Clinical progress and key events

Clinical development plan



Source: Redeye Research, Initiator Pharma

Pudafensine – Promising phase IIb data

In October 2023, Initiator Pharma announced positive initial findings from the phase IIb study. Pudafensine demonstrated statistically significant efficacy on the primary endpoint compared to placebo [p=0.034] and baseline [p=0.046]. At the same time, several other intercourse activity-related clinical endpoints obtained from the IIEF also demonstrated significant efficacy compared to baseline. This result was consistent throughout the treatment period and clinical assessments of the patients. Furthermore, no safety concerns were reported as any adverse events (AEs) observed were of a mild to moderate nature and comparable to those observed in the placebo group.

Following these initial results, we chose to raise our probability of success (PoS) for the phase II development of pudafensine to 80% (38%), and the overall likelihood of approval (LoA) to 39% (18%). We argue that the risk related to the pudafensine program has been greatly reduced and that the data warrants further clinical advancement of the asset.

International patent application

In July, Initiator Pharma announced the publication of its international (PCT) patent application no. PCT/EP2024/050061 directed to a dosage regime of pudafensine for treatment of erectile dysfunction (ED). The patent, published under number WO2024/146892, extends the pudafensine patent portfolio to include a composition of matter patent and three medical use patent families. These patents cover the treatment of erectile dysfunction, female sexual dysfunction, and pain, offering extensive protection for pudafensine until 2044, with the potential for an additional five-year extension. This strategic patent filing is part of Initiator Pharma's broader effort to protect its drug development pipeline and maintain market exclusivity.

Pudafensine has demonstrated promising results in clinical trials, showing significant improvement in patients with severe to moderate ED, particularly those who do not respond well to existing treatments like phosphodiesterase type 5 (PDE5) inhibitors. With clinical data suggesting that pudafensine could serve as both a standalone therapy and as an add-on to existing treatments due to its unique mechanism of action (MoA) and favorable safety profile, having a multi-layered patent portfolio protecting the candidate is vital. The publication of this patent application marks a milestone for Initiator Pharma and paves the way for future clinical trials and potential commercialization of pudafensine.

Valuation

Valuation Summary

We estimate the sales potential in each program in the company's clinical pipeline, along with an associated likelihood of reaching market approval. We then incorporated this into a sum-of-the-parts (SOTP) valuation model based on a risk-adjusted discounted cash flow (DCF) model, which provides us with our fair value Base Case.

Initiator Pharma – Valuation

Valuation summary (SEKm) - Base case						
Program	Indication	Stage	Launch	Peak sales ($m)	Probability (LoA)	Value, r-adj (SEKm)
IPED2015	ED (Organic)	Phase IIb	2028	1037	39%	1276
IP2018	ED (Psychogenic)	Phase IIa	2029	743	18%	357
IPTN2021	Trigeminal Neuralgia	Phase Ib	2029	315	13%	268
				Tech Value (SEKm)		1901
				Est. net cash		25,9
				Shared costs		-501,4
				Equity Value		1426
				Shares outstanding		57,3
				Est. Increase of shares		2,6
				Est. Increase of cash (SEKm)		18,0
WACC: 14,5%				Base case		24

Source: Redeye Research
* Our estimate of the company's net cash position, post rights issue.
** Numbers may not add up due to rounding.

Summary of changes in valuation

- We update the SEK/USD exchange rate to 10.5 according to Redeye policy.
- We make slight modifications to our OPEX estimates.

Bear Case: SEK 7

- We factor in failure in finding a licensing partner for pudafensine and see limited prospects in the indication.

Base Case: SEK 24

- The SOTP model above represents our Base Case scenario.

Bull Case: SEK 40

- We factor in a satisfactory licensing deal with a Big Pharma company for pudafensine ahead of phase III development.
- IPTN2021 receives ODD and fast track designation from regulatory authorities.

Sensitivity Analysis

Our valuation of Initiator Pharma is highly affected by the WACC we attribute to the company. WACC plays an essential part in calculating the discounted cash flow and reflects the uncertainties related to the company and the market. We illustrate the impact of applying changes to WACC on our fair value range (Base Case, Bull Case, and Bear Case) valuation in a sensitivity analysis below.

Initiator Pharma: Sensitivity analysis

Sensitivity analysis: WACC						
		12,5%	13,5%	14,5%	15,5%	16,5%
Value (SEK/share)	Bull	49,5	44,5	40	36,1	32,6
	Base	29,7	26,7	24	21,7	19,6
	Bear	8,7	7,8	7	6,3	5,7

Source: Redeye Research

Peer Valuation

To provide additional insight into the current valuation of similar biotech companies, we include an updated peer group analysis. The valuation of listed biotech companies in clinical development varies considerably, depending on project validation, potential, financial position, risk, etc. However, we base our relative valuation on the enterprise value (EV) (market cap minus net cash) of what we consider to be comparable drug development companies. Below we present a sample of Nordic peers.

Initiator Pharma: Peer valuation

Peer analysis						
(SEKm)		Market Cap	Cash*	EV	No. Projects	Dev. Stage
Company						
IRLAB Therapeutics		748	98	650	2	Phase II
AlzeCure Pharma		182	19	163	3	Phase II
Egetis Therapeutics		1744	252	1492	2	Phase III
Cereno Scientific		1673	49	1624	3	Phase II
Herantis Pharma		387	74	312	2	Phase I
Saniona		467	71	396	3	Phase II
Alzinova		299	26	273	2	Phase I/II
Dicot		271	80	191	1	Phase II
	Mean	**721**	**84**	**638**	**2**	Phase I/II
	Median	**427**	**73**	**354**	**2**	Phase II
Initiator Pharma		**411**	**19**	**391**	**3**	**Phase II/III**

* Based on the latest interim report and Redeye estimates
Source: Holdings, Company interim reports, Redeye Research

Our peer valuation has no impact on our fair value range. It is instead a snapshot of comparable companies. Initiator Pharma's valuation is currently valued in line with its peers, trading between the median and the mean valuation of the peers listed in the table. The company's market cap (SEK411m) is significantly below the mean value of its peers' market cap (SEK721m) and slightly below the median market cap (SEK427m). Similarly, the company's EV (SEK391m) is slightly above the mean of its peers (SEK354m) while being significantly below the mean (SEK638m). However, we argue that a **premium** over its peers is justified for Initiator Pharma due to the company having showcased PoC with encouraging data from multiple phase II studies. In contrast, its peers are in phase I/II development on average.

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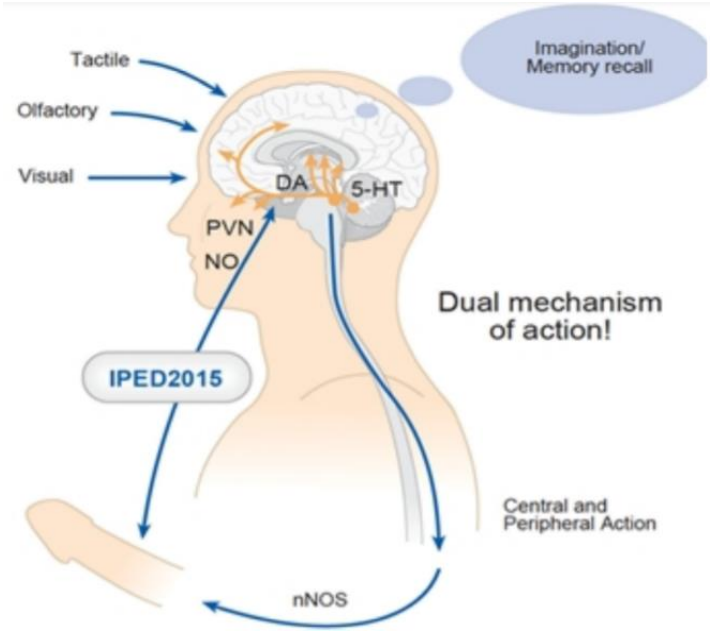
General summary

Pudafensine – The Most Advanced Program

Pudafensine (IPED2015) is Initiator Pharma's furthest developed treatment program and is based on the company's active pharmaceutical ingredient (API) IP2015. This novel drug is being developed as a new oral treatment for erectile dysfunction (ED), primarily intended for patients suffering from organic ED. It represents a new innovative development in the field of ED treatment owing to its dual-action mechanism – both improving the sexual drive of patients through a central effect initiating arousal and increasing penile blood flow potentiating erection via a peripheral smooth muscle relaxing effect. It is the Company's aim to create a new First-Line treatment for the large group of patients not responding to the currently established treatment options.

The most common currently established treatments for ED are the PDE5i class drugs (phosphodiesterase-5 inhibitors), such as Viagra (sildenafil), Cialis (tadalafil), and Stendra (avanafil). They are orally administered drugs that work by blocking the inhibitory actions of phosphodiesterase type 5 on cyclic guanosine monophosphate (cGMP) in the smooth muscle cells covering the blood vessels. However, the PDE5i class drugs only increase blood flow to the penis and do not influence the patients' sexual desire, and they will only work if the patient can become sexually aroused naturally. IP2015's unique mechanism of action (MOA) is what makes it an exciting alternative, coupled with the minimal competition to primarily treat PDE5i non-responders.

Pudafensine – Mechanism of action



Source: Initiator Pharma

The drug is a monoamine reuptake inhibitor (MRI). It is a molecule that alters the synaptic concentration of the three central monoamine neurotransmitters – dopamine, serotonin, and noradrenaline – by blocking their respective transporters. Monoamine modulation is a validated therapy approach with a long history of use as a treatment for depression and pain.

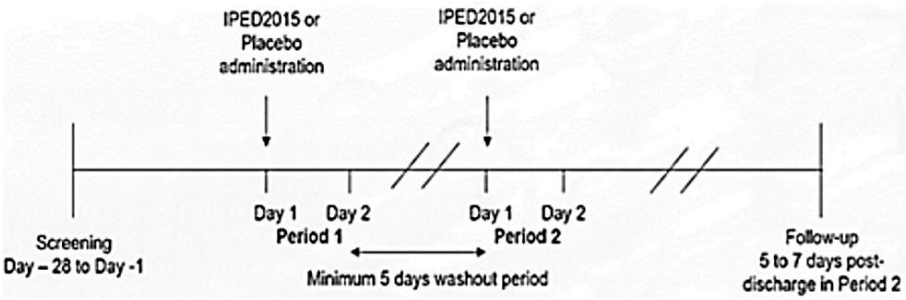
IP2015 mainly binds to and acts on the dopamine transporter (DAT), preventing dopamine overflow from the synaptic cleft back to the cytoplasm of the pre-synaptic neuron. This increases the concentration of dopamine levels in the synapses, strengthening the natural erectile response by affecting sexual activation in the paraventricular nucleus of the hypothalamus (PVN).

Clinical Evidence

Phase IIa study

Following a well-demonstrated safety profile in an initial phase I clinical study, Initiator Pharma commenced its phase II proof-of-concept study in pudafensine. The study included 12 patients suffering from severe ED. The selection of patients was via a thorough screening process where only males with a measured value of less than 12 on the International Index of Erectile Function (IIEF-5) scale qualified as test subjects. These are typically patients who do not respond well to current PDE5i treatment. The patients were enrolled in the MAC Phase I unit in Manchester, UK, during the dosing and observation period of the study.

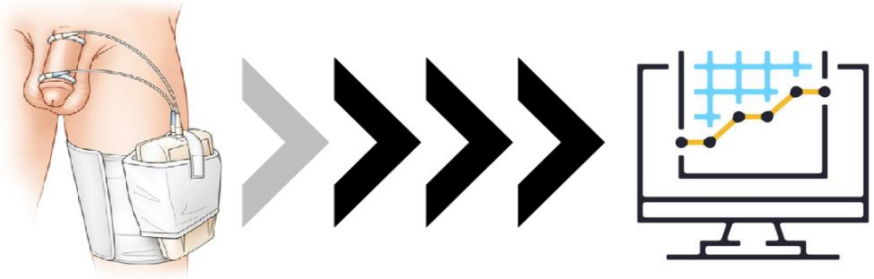
Pudafensine – Phase IIa dosing schedule



Source: Initiator Pharma

The dosing followed a crossover design with two dosing occasions when half of the patients were given a dose of IP2015 on the first occasion and a placebo on the second occasion, while the other half of the patients received the reverse. Each of the two dosing occasions was followed up by an observation period of 24 hours, with a five-day washout period between dosing to ensure the absence of residual effects. The efficacy assessment of the drug was conducted with a RigiScan device measuring penile rigidity and tumescence. RigiScan is a well-renowned instrument for measuring penile stiffness and swelling in Rigidity Activity Units (RAU) and Tumescence Activity Units (TAU), respectively.

RigiScan device



Source: Gesiva Medical, Redeye Research

The results of the Phase IIa study demonstrated statistically significant treatment effects with IP2015, with a response rate of 25% among the patients. There were also no reports of any critical safety observations or side effects from the study, which is in line with the results of the previously performed phase I study on healthy subjects.

Current status

Phase IIb study

Patient recruitment was initiated in July 2021 after the company received CTA approval from the MHRA (Medicines and Healthcare products Regulatory Agency) and Ethics Committee. Later that year, in September, Initiator Pharma announced that it had completed the dosing of the first patient in the study.

This study is a crucial point in the development of IP2015 as it is the first intercourse study where the candidate's efficacy is tested under more natural circumstances. The study includes 120 recruited patients suffering from severe organic ED who do not respond to regular PDE5i treatment. It is a randomized, double-blind, parallel group, repeat single oral dose study where the patients are divided into three parallel arms receiving a higher and a lower dose of IP2015 and placebo, respectively. The treatment consists of four dosings over four weeks with frequent assessments of erectile function (IIEF questionaries), as well as safety and pharmacokinetics.

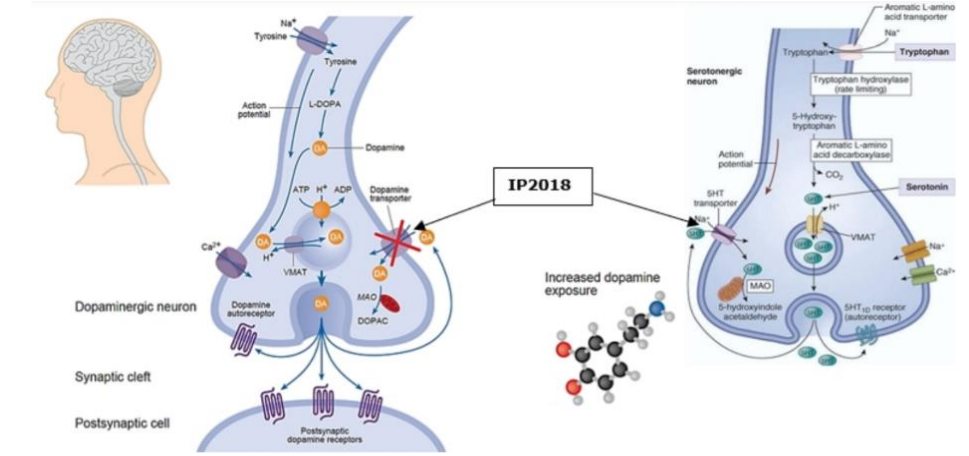
In other words, the study relies on subjective scoring methods in the erectile function treatment effect assessment. This is a relatively common practice within ED trials based in natural settings. However, it is essential to acknowledge that this could somewhat bias the results and make the study prone to high placebo effects.

In October 2023, Initiator Pharma announced positive initial findings from the phase IIb study. Pudafensine demonstrated statistically significant efficacy on the primary endpoint compared to placebo [p=0.034] and baseline [p=0.046], while several other intercourse activity-related clinical endpoints obtained from the IIEF also demonstrated significant efficacy compared to baseline. This result was consistent throughout the treatment period and clinical assessments of the patients. Furthermore, no safety concerns were reported as any adverse events (AEs) observed were of a mild to moderate nature and comparable to those observed in the placebo group.

IP2018 – Psychogenic ED

IP2018 targets patients suffering from psychogenic ED and has been proven to have both an anti-depressive and an erectile function enhancing effect in animal studies. It is being developed as a potential new treatment for individuals with mild to moderate depression and ED. IP2018 is also an MRI, but unlike Initiator Pharma's frontrunner IP2015, it mainly targets the inhibition of serotonin, but also affects dopamine reuptake.

IP2018 – Synaptic functioning



Source: Initiator Pharma

IP2018 has previously been tested in a phase I placebo-controlled study in healthy subjects who received increasing single doses of IP2018. In addition to the pre-clinical and phase I studies, Initiator Pharma also conducted a proof-of-mechanism positron emission tomography (PET) study. The results from these studies were robust in their findings, demonstrating an excellent safety profile and confirming the MOA of the drug, with successful binding to serotonin and dopamine reuptake transporters.

Clinical evidence

Phase IIa study

Following regulatory approvals, Initiator Pharma began the screening of patients in October 2020 for a phase IIa proof-of-concept (PoC) trial for IP2018 using the criteria of young subjects (18-55 years) suffering from depression and ED. The first patient was dosed in December that year.

The study is a randomized, double-blind, placebo-controlled, three-way crossover trial conducted in 24 patients at the MAC unit in Manchester, UK. It is designed such that the patients are divided into three groups, two of which receive different doses of IP2018 while the last group receives the placebo. The main aim of the study is to evaluate the effects of IP2018 on penile rigidity and tumescence when patients are exposed to visual sexual stimulation.

The recruitment rate for the study was initially slower than expected due to the impact of the COVID-19 pandemic. In July 2021, however, Initiator Pharma received approval from MHRA and the Ethics Committee to optimize the patient recruitment of the study by modifying certain inclusion criteria. As a result, the study was fully recruited and completed in H1 2023.

The results of the study revealed promising and clinically significant efficacy data for the treatment of ED, providing support for a new therapeutic approach for this particular patient population. The high dose of IP2018, administered orally as a single dose, exhibited a statistically significant increase in penile tumescence (p=0.04) and duration of rigidity (p=0.025), sufficient for successful intercourse. Thus, the positive effect of IP2018 on erectile function was evident and dependent on the dosage. It is worth noting that dose-dependent efficacy is commonly observed in early- to mid-stage clinical trials, as the optimal dosing regimen for a candidate is not yet fully understood. This aspect will be considered and adjusted in future clinical studies, which we believe may involve testing multiple higher dosages to determine the optimal level. Additionally, no safety concerns were reported, indicating that the higher dose of IP2018 should be tolerable without any issues.

These results mark a significant milestone for Initiator Pharma and lay the groundwork for further development of IP2018. The positive outcomes serve as a proof-of-concept (PoC), reducing the risks associated with the asset and justifying the continued exploration of IP2018 as a treatment for psychogenic ED. Therefore, the next logical step for the candidate would likely be a phase IIb study conducted in natural settings, similar to the ongoing phase IIb trial involving pudafensine.

IPTN2021 – Trigeminal Neuralgia

In April last year, Initiator Pharma announced the expansion of its clinical product portfolio by initiating the IPTN2021 program. The treatment targets patients with severe neuropathic pain, specifically those suffering from the chronic disease trigeminal neuralgia (TN). Similar to the pudafensine program, IPTN2021 is also based on the API IP2015. Thus, it has previously already proven safety, tolerability, and efficacy in clinical trials. In addition, the pre-clinical testing of IP2015 demonstrated significant effects in inhibiting neuralgic pain in animal pain models. As previously mentioned, the drug asset is an MRI. Monoamines play an essential role in regulating the endogenous pain system, particularly in neuropathic pain, and are considered a validated drug target. We believe this provides a rationale for clinical expansion into the field.

Today's treatment regimen for TN includes medications and, in many cases, invasive procedures. Current clinical guidelines recommend carbamazepine, which is the only FDA-approved drug for TN, and oxcarbazepine as first-line therapies for TN. However, these are often found ineffective and entail serious side effects. Accordingly, there is a significant need for new therapies, which Initiator Pharma intends to address with the development of IPTN2021.

Clinical Evidence

Positive Phase I Proof-of-Principle (PoP) study topline results

In 2022, the company initiated and completed the dosing of all subjects in the IPTN2021 phase I Proof-of-Principle (PoP) study. The study is a randomized, double-blind, placebo-controlled study in 24 healthy male subjects, investigating the effects of two single oral dose levels of IP2015 (the active substance in IPTN2021) on different pain measures: hyperalgesia (increased pain response), allodynia (decreased pain threshold), and subjective pain rating. The subjects were induced pain by being exposed to a sensory nerve stimulant capsaicin injected intradermally, and first-line neuropathic pain treatment pregabalin (Lyrica) was used as an active control (alongside placebo control).

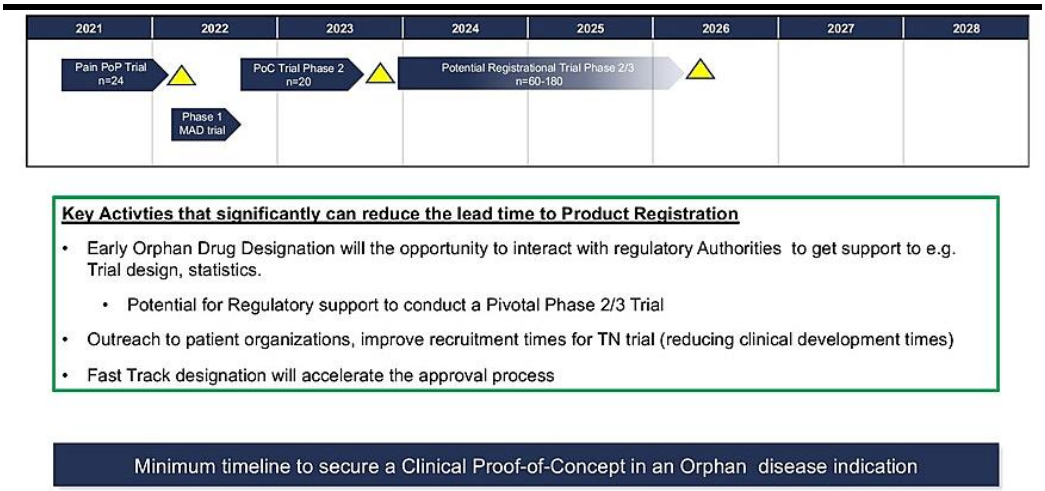
Following the completion of the study, an analysis of the final data read-out was obtained. The analysis and evaluations suggest a statistically significant effect of IP2015 on allodynia ($p=0.049$) and a dose-dependent effect on the measured pain parameters. The candidate also seemed to reduce hyperalgesia ($p=0.051$), as did pregabalin ($p=0.083$), although the effects were not statistically significant compared to placebo controls. Furthermore, there were no observed adverse events related to treatment with IP2015, reinstating the compound's promising safety profile.

We truly believe that the first results of the study are encouraging for the continued development of IPTN2021. The main aim of the study is to investigate the safety and tolerability of the candidate – in an indication where the current standard of care is associated with severe adverse effects, IP2015 only demonstrated mild side effects. We have previously explained that we see a rationale for IP2015 to treat neuropathic pain, and we believe that these data further bolster that view.

Current Status

The next step in the IPTN2021 development plan is a multiple ascending dose (MAD) study, expected to be initiated later this year. This will be followed by a PoC phase II trial, studying the candidate's efficacy in patients suffering from TN. The exact designs of the studies are yet to be disclosed, although Initiator Pharma has stated that communication with the regulatory authorities will help to provide guidance for the study designs.

Potential IPTN2021 development timeline



Source: Initiator Pharma

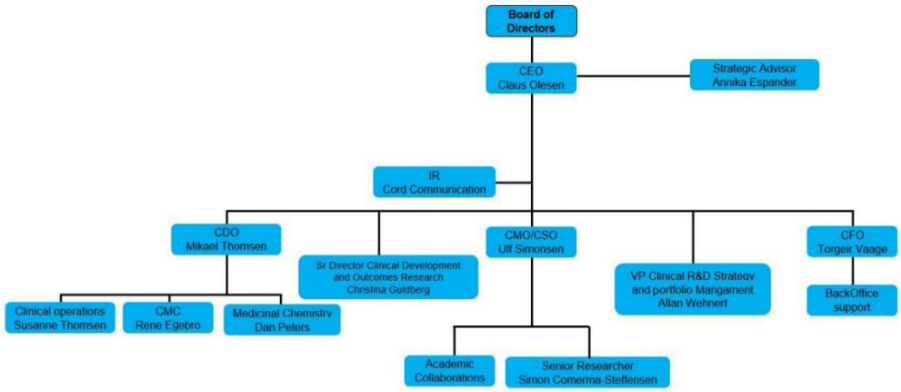
The company's development plan for IPTN2021 aims to obtain orphan drug designation (ODD) for trigeminal neuralgia, with a future ambition to seek a fast-track designation from the FDA and EMA to obtain regulatory support from the authorities. This would ultimately reduce the lead time to product registration significantly.

Commercialization and Marketing

Business strategy

Initiator Pharma aims to become a widely recognized biotech company through the development of innovative and paradigm-shifting drugs. Its ambition is to provide pharmaceutical alternatives that satisfy unmet medical needs for the central and peripheral nervous systems. By identifying risk-reduced potential projects based on previous clinical or pre-clinical data that can complement a product's research and development, it aspires to limit the liability of its candidates.

Initiator Pharma – Company Structure



Source: Initiator Pharma

The primary business model revolves around commercializing the research prospects through:

- Collaboration with investment companies and pharmaceutical companies who fund the research and development process, as we have seen with the MAC clinical research partnership for the pudafensine phase IIb trials

- Developing the early stages of a drug before out-licensing it to more established pharmaceutical companies for continuation with the clinical development of the product.

In both cases, Initiator Pharma receives revenue through different installments such as upfront payments, milestone payments, and royalty payments based on product sales.

Screening Agreement with the National Institute on Drug Abuse (NIDA)

In September 2021, Initiator Pharma signed a screening agreement with the National Institute on Drug Abuse (NIDA) to evaluate the pharmacology of preclinical assets IPDP2015 and IPNP2015. It was decided that Nida's addiction Treatment Discovery Program would study the candidates' potential as treatments for stimulant addiction, specifically their effects on cocaine- and methamphetamine-related behavior.

Although still early in the development process of these assets, we see this as something that reaffirms the broad capabilities of the underlying compound. A venture into a completely new indication, substance use disorder, shows the wide scope of Initiator Pharma's pipeline potential. Also, the fact that NIDA performs the studies at no cost to the company, while Initiator Pharma maintains all rights to the assets, is noteworthy and, basically, indicates a zero-risk opportunity to generate value.

Sales Models

Sales potential – Pudafensine

The key assumptions in our pudafensine sales model are:

- Market launch in 2027
- Peak market penetration of 20% in the US and Europe
- Annual pricing of USD1,050 and USD750 per patient in the US and Europe, respectively.
- Royalty rate of 12% in both markets
- Deal size of USD300m
- On-demand treatment frequency
- 39% likelihood of reaching the market

Based on these assumptions, we arrive at annual global peak sales of more than USD1,000m for pudafensine.

Pudafensine (millions) – US

		2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037
US												
ED prevalence		31.9	32.2	32.5	32.8	33.2	33.5	33.8	34.2	34.5	34.9	35.2
% Organic ED	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%
% on ED treatment	45%	45%	45%	45%	45%	45%	45%	45%	45%	45%	45%	45%
% of PDE5i-therapy non-responders	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%
Addressable population		4.3	4.3	4.4	4.4	4.4	4.5	4.5	4.6	4.6	4.7	4.7
Launch curve		0.10	0.25	0.50	0.70	0.90	1.00	0.90	0.80	0.80	0.70	0.20
Market share	20%	2%	5%	10%	14%	18%	20%	18%	16%	16%	14%	4%
Treated patients		0.1	0.2	0.4	0.6	0.8	0.9	0.8	0.7	0.7	0.7	0.2
Compliance rate	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
Treatment occasions per patient	30	30	30	30	30	30	30	30	30	30	30	30
List price (per pill)	35	35	35	35	35	35	35	35	35	35	35	35
Gross to net %	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Net price	28	28	28	28	28	28	28	28	28	28	28	28
Revenue ($m)		**57**	**145**	**293**	**414**	**537**	**603**	**548**	**492**	**497**	**439**	**127**
growth			153%	102%	41%	30%	12%	-9%	-10%	1%	-12%	-71%

Source: Redeye Research

Pudafensine (millions) – Europe

		2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037
Europe												
ED prevalence		34.3	34.6	35.0	35.3	35.7	36.0	36.4	36.7	37.1	37.5	37.9
% Organic ED	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%
% on treatment	45%	45%	45%	45%	45%	45%	45%	45%	45%	45%	45%	45%
% of PDE5i-therapy non-responders	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%
Addressable population		4.6	4.6	4.7	4.7	4.8	4.8	4.9	4.9	5.0	5.0	5.1
Launch curve		0.10	0.25	0.50	0.70	0.90	1.00	0.90	0.80	0.80	0.70	0.20
Market share	20%	2%	5%	10%	14%	18%	20%	18%	16%	16%	14%	4%
Treated patients		0.1	0.2	0.5	0.7	0.9	1.0	0.9	0.8	0.8	0.7	0.2
Compliance rate	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
Treatment occasions per patient	30	30	30	30	30	30	30	30	30	30	30	30
List price (per pill)	25	25	25	25	25	25	25	25	25	25	25	25
Gross to net %	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Net price	20	20	20	20	20	20	20	20	20	20	20	20
Revenue ($m)		**44**	**111**	**225**	**318**	**412**	**463**	**421**	**378**	**382**	**337**	**97**
growth			153%	102%	41%	30%	12%	-9%	-10%	1%	-12%	-71%

Source: Redeye Research

Sales potential – IP2018

The key assumptions in our IP2018 sales model are:

- Market launch in 2029
- Peak market penetration of 20% in the US and Europe
- Annual pricing of USD5,475 and USD3,650 per patient in the US and Europe, respectively.
- Royalty rate of 12% in both markets
- Deal size of USD 250m
- Daily treatment frequency
- 18% likelihood of reaching the market
- 20% of earnings paid to Saniona as part of the option agreement

Based on these assumptions, we arrive at annual global peak sales of USD~750m for IP2018.

IP2018 (millions) – US

		2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038
US												
ED prevalence		32.2	32.5	32.8	33.2	33.5	33.8	34.2	34.5	34.9	35.2	35.6
% Psychogenic ED	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
% on ED treatment	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%
% of PDE5i-therapy non-responders	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%
Addressable population		0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.7
Launch curve		0.00	0.10	0.25	0.50	0.70	0.90	1.00	0.90	0.80	0.80	0.70
Market share	20%	0%	2%	5%	10%	14%	18%	20%	18%	16%	16%	14%
Treated patients		0.00	0.01	0.03	0.06	0.09	0.11	0.13	0.11	0.10	0.10	0.09
Compliance rate	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
Treatment occasions per patient	365	365	365	365	365	365	365	365	365	365	365	365
List price (per pill)	15	15	15	15	15	15	15	15	15	15	15	15
Gross to net %	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Net price	12	12	12	12	12	12	12	12	12	12	12	12
Revenue ($m)		**0**	**42**	**106**	**214**	**302**	**392**	**440**	**400**	**359**	**363**	**321**
growth				153%	102%	41%	30%	12%	-9%	-10%	1%	-12%

Source: Redeye Research

IP2018 (millions) – Europe

		2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038
Europe												
ED prevalence		34.6	35.0	35.3	35.7	36.0	36.4	36.7	37.1	37.5	37.9	38.2
% Psychogenic ED	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
% on treatment	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%
% of PDE5i-therapy non-responders	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%
Addressable population		0.6	0.6	0.6	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7
Launch curve		0.00	0.10	0.25	0.50	0.70	0.90	1.00	0.90	0.80	0.80	0.70
Market share	20%	0%	2%	5%	10%	14%	18%	20%	18%	16%	16%	14%
Treated patients		0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Compliance rate	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
Treatment occasions per patient	365	365	365	365	365	365	365	365	365	365	365	365
List price (per pill)	10	10	10	10	10	10	10	10	10	10	10	10
Gross to net %	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Net price	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0
Revenue ($m)		**0**	**30**	**76**	**153**	**216**	**281**	**315**	**287**	**257**	**260**	**230**
growth				153%	102%	41%	30%	12%	-9%	-10%	1%	-12%

Source: Redeye Research

Sales potential – IPTN2021

The key assumptions in our IPTN2021 sales model are:

- Market launch in 2029
- Peak market penetration of 20% in the US and Europe
- Annual pricing of USD18,250 and USD14,600 per patient in the US and Europe, respectively.
- Daily treatment frequency
- Complete in-house development
- 13% likelihood of reaching the market

Based on these assumptions, we arrive at annual global peak sales of more than USD300m for IPTN2021.

IPTN2021 – US

		2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039
US												
TN prevalence		71 469	72 183	72 905	73 634	74 370	75 114	75 865	76 624	77 390	78 164	78 946
% on TN treatment	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
Addressable population		57 175	57 747	58 324	58 907	59 496	60 091	60 692	61 299	61 912	62 531	63 157
Launch curve		0,10	0,20	0,50	0,60	0,90	1,00	0,90	0,70	0,50	0,40	0,20
Market share	20%	2%	4%	10%	12%	18%	20%	18%	14%	10%	8%	4%
Treated patients		1 143	2 310	5 832	7 069	10 709	12 018	10 925	8 582	6 191	5 003	2 526
Compliance rate	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	
Treatment occasions per patient	365	365	365	365	365	365	365	365	365	365	365	365
List price (per pill)	50	50	50	50	50	50	50	50	50	50	50	50
Gross to net %	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Net price	40	40	40	40	40	40	40	40	40	40	40	40
Revenue ($m)		**13**	**27**	**68**	**83**	**125**	**140**	**128**	**100**	**72**	**58**	**37**
growth			102%	153%	21%	52%	12%	-9%	-21%	-28%	-19%	-37%

Source: Redeye Research

IPTN2021 – Europe

		2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039
Europe												
TN prevalence		111 209	112 321	113 445	114 579	115 725	116 882	118 051	119 232	120 424	121 628	122 844
% on TN treatment	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
Addressable population		88 968	89 857	90 756	91 663	92 580	93 506	94 441	95 385	96 339	97 302	98 275
Launch curve		0,10	0,20	0,50	0,60	0,90	1,00	0,90	0,70	0,50	0,40	0,20
Market share	20%	2%	4%	10%	12%	18%	20%	18%	14%	10%	8%	4%
Treated patients		1 779	3 594	9 076	11 000	16 664	18 701	16 999	13 354	9 634	7 784	3 931
Compliance rate	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	
Treatment occasions per patient	365	365	365	365	365	365	365	365	365	365	365	365
List price (per pill)	40	40	40	40	40	40	40	40	40	40	40	40
Gross to net %	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Net price	32	32	32	32	32	32	32	32	32	32	32	32
Revenue ($m)		**17**	**34**	**85**	**103**	**156**	**175**	**159**	**125**	**90**	**73**	**46**
growth			102%	153%	21%	52%	12%	-9%	-21%	-28%	-19%	-37%

Source: Redeye Research

(DKKm)	2023	2024e	2025e	2026e
INCOME STATEMENT				
Revenues	0	138	0	52
Cost of Revenues	0	0	0	0
Gross Profit	0	138	0	52
Operating Expenses	27	18	26	40
EBITDA	-27	120	-26	12
Depreciation & Amortization	0	0	0	0
EBIT	-27	120	-26	12
Net Financial Items	-2	0	0	0
EBT	-29	120	-26	12
Income Tax Expenses	0	31	0	0
Non-Controlling Interest	0	0	0	0
Net Income	-29	89	-26	12
BALANCE SHEET				
Assets				
Current assets				
Cash & Equivalents	24	111	84	96
Inventories	0	0	0	0
Accounts Receivable	6	6	7	8
Other Current Assets	0	0	0	0
Total Current Assets	30	117	91	104
Non-current assets				
Property, Plant & Equipment,	0	0	0	0
Goodwill	0	0	0	0
Intangible Assets	0	0	0	0
Right-of-Use Assets	0	0	0	0
Shares in Associates	0	0	0	0
Other Long-Term Assets	0	0	0	0
Total Non-Current Assets	0	0	0	0
Total Assets	30	117	91	104
Liabilities				
Current liabilities				
Short-Term Debt	0	0	0	0
Short-Term Lease Liabilities	0	0	0	0
Accounts Payable	0	0	0	1
Other Current Liabilities	3	1	1	1
Total Current Liabilities	3	1	2	2
Non-current liabilities				
Long-Term Debt	0	0	0	0
Long-Term Lease Liabilities	0	0	0	0
Other Long-Term Liabilities	15	0	0	0
Total Non-current Liabilities	15	0	0	0
Non-Controlling Interest	0	0	0	0
Shareholder's Equity	4	116	90	102
Total Liabilities & Equity	23	117	91	104
CASH FLOW				
NOPAT	-27	89	-26	12
Change in Working Capital	5	-2	0	0
Operating Cash Flow	-18	87	-27	12
Capital Expenditures	0	0	0	0
Investment in Intangible Asse	0	0	0	0
Investing Cash Flow	0	0	0	0
Financing Cash Flow	3	0	0	0
Free Cash Flow	-15	87	-27	12

DCF Valuation Metrics	**Sum FCF (SEKm)**
Initial Period	212,9
Momentum Period	922,5
Stable Period	283,8
Firm Value	1419,2
Net Debt (last quarter)	46,8
Cash and Equivalents	19,3
Equity Value	1392
Fair Value per Share	24,00

	2023	2024e	2025e	2026e
CAPITAL STRUCTURE				
Equity Ratio	0,1	1,0	1,0	1,0
Debt to equity	0,0	0,0	0,0	0,0
Net Debt	-24	-111	-84	-96
Capital Employed	27	116	90	102
Working Capital Turnover	0,0	0,0	0,0	0,0
GROWTH				
Revenue Growth	n/a	n/a	-100%	n/a
Basic EPS Growth	-24%	-434%	-129%	-147%
Adjusted Basic EPS Growth	-24%	-434%	-129%	-147%
PROFITABILITY				
ROE	-152%	148%	-25%	13%
ROCE	-100%	104%	-29%	12%
ROIC	-526%	2263%	-487%	211%
EBITDA Margin (%)	neg	neg	neg	neg
EBIT Margin (%)	neg	neg	neg	neg
Net Income Margin (%)	neg	neg	neg	neg
VALUATION				
Basic EPS	neg	1,7	-0,5	0,2
Adjusted Basic EPS	neg	1,7	-0,5	0,2
P/E	neg	6,8	neg	60,1
EV/Revenue	n/a	357%	n/a	1220%
EV/EBITDA	neg	4,1	neg	52,3
EV/EBIT	neg	4,1	neg	52,3
P/B	13891%	520%	741%	721%

SHAREHOLDER STRUCTURE	**CAPITAL**	**VOTES**
Linc AB	18,0%	18,0%
Adrigo Asset Management	7,6%	7,6%
Avanza Pension	5,8%	5,8%
MAC	5,5%	5,5%
Claus Elsborg Olesen	2,4%	2,4%

SHARE INFORMATION	
Reuters code	INIT
List	First North
Share price	7,75
Total shares, million	57,3

MANAGEMENT & BOARD	
CEO	Claus Olesen
CFO	Torgeir Vaage
Chairman	Magnus Persson

ANALYSTS Redeye AB
Kevin Sule Mäster Samuelsgatan 42, 10tr
Fredrik Thor 111 57 Stockholm

Summary Redeye Rating

The rating consists of three valuation keys, each constituting an overall assessment of several factors that are rated on a scale of 0 to 1 point. The maximum score for a valuation key is 5 points.

Rating changes in the report

People: 4

CEO Claus Elsborg Olesen (co-founder) has extensive experience in the pharma industry and is a merited serial entrepreneur having co-founded and operated multiple life science companies (Pcovery ApS, Stipe Therapeutics, and NMD Pharma). Each member (except for the CFO) of the management team is also a co-founder of the company, suggesting they know the business in and out.

Business: 3

At present, Initiator Pharma is a biotech company without any history of profitability. However, the sales potential for its treatments is huge. Should they demonstrate significant clinical efficacy in upcoming trials, there is no denying their great value. In our sales model, we estimate peak annual sales potential of USD +1bn for pudafensine, at this early stage.

Financials: 1

With the latest capital raise, Initiator Pharma has strengthened its short-term cash position and secured financing into 2025e, we argue. However, as previously explained, the company is in a pre-revenue stage and will likely remain dependent on the capital markets or licensing partners for some years to come before recording any recurrent revenue.

Redeye Rating and Background Definitions

Company Quality

Company Quality is based on a set of quality checks across three categories: PEOPLE, BUSINESS, FINANCE. These are the building blocks that enable a company to deliver sustained operational outperformance and attractive long-term earnings growth.

Each category is grouped into multiple sub-categories assessed by five checks. These are based on widely accepted and tested investment criteria and used by demonstrably successful investors and investment firms. Each sub-category may also include a complementary check that provides additional information to assist with investment decision-making.

If a check is successful, it is assigned a score of one point; the total successful checks are added to give a score for each sub-category. The overall score for a category is the average of all sub-category scores, based on a scale that ranges from 0 to 5 rounded up to the nearest whole number. The overall score for each category is then used to generate the size of the bar in the Company Quality graphic.

People

At the end of the day, people drive profits. Not numbers. Understanding the motivations of the people behind a business is a significant part of understanding the long-term drivers of the company. It all comes down to doing business with people you trust or at least avoiding dealing with people of questionable character.

The People rating is based on quantitative scores in seven categories:

- Passion, Execution, Capital Allocation, Communication, Compensation, Ownership, and Board.

Business

If you don't understand the competitive environment and don't have a clear sense of how the business will engage customers, create value and consistently deliver that value at a profit, you won't succeed as an investor. Knowing the business model inside out will provide you some level of certainty and reduce the risk when you buy a stock.

The Business rating is based on quantitative scores grouped into five sub-categories:

- Business Scalability, Market Structure, Value Proposition, Economic Moat, and Operational Risks.

Financials

Investing is part art, part science. Financial ratios make up most of the science. Ratios are used to evaluate the financial soundness of a business. Also, these ratios are key factors that will impact a company's financial performance and valuation. However, you only need a few to determine whether a company is financially strong or weak.

The Financial rating is based on quantitative scores that are grouped into five separate categories:

- Earnings Power, Profit Margin, Growth Rate, Financial Health, and Earnings Quality.

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Disclaimer

Important information
Redeye AB ("Redeye" or "the Company") is a specialist financial advisory boutique that focuses on small and mid-cap growth companies in the Nordic region. We focus on the technology and life science sectors. We provide services within Corporate Broking, Corporate Finance, equity research, and investor relations. Our strengths are our award-winning research department, experienced advisers, a unique investor network, and the powerful distribution channel redeye.se. Redeye was founded in 1999 and since 2007 has been subject to the supervision of the Swedish Financial Supervisory Authority.
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Redeye Rating (2024-08-23)

Rating	People	Business	Financials
5p	7	6	2
3p - 4p	163	155	38
0p - 2p	26	35	156
Company N	196	196	196

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CONFLICT OF INTERESTS

Kevin Sule owns shares in the company: Yes
Fredrik Thor owns shares in the company: No
Redeye performs/has performed services for the Company and receives/has received compensation from the Company in connection with this.