Pila Pharma

Sector: Biotech

A Spicy Approach

Redeye initiates coverage of Pila Pharma, a phase II company developing a novel approach to type 2 diabetes treatment with XEN-D0501, a TRPV1 antagonist with a solid safety profile. We see little of this potential priced into the share and believe the current share price levels represent an opportunity ahead of the catalyst of the phase IIb readout.

Novel approach towards massive market

Pila's XEN-D0501 is a TRPV1 antagonist taking a new approach to treating type 2 diabetes (T2D). Using conservative assumptions, we estimate non-risk-adjusted peak royalties of USD 127m. The candidate has shown a solid safety profile and a statistically significant effect on insulin secretion, placing it in an encouraging position as it approaches the phase IIb trial, expected to commence in 2023.

High-conviction management and founder

Pila's approach to T2D builds on CEO and founder Dorte X. Gram's thesis that inflammation plays a significant role in T2D. She has devoted her career to her findings and intends Pila Pharma to develop and commercialize the TRPV1 antagonist as an efficient, safe, and affordable T2D treatment. Her 31 percent holding in Pila further demonstrates her conviction.

Phase II Prospects At a Discount

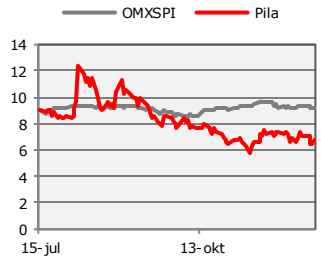
Trading at an EV of some SEK 80m, the share fails to reflect Pila's prospects as a phase II company with a new approach to T2D. A lack of short-term catalysts has likely contributed to the share price decline, but we identify a true inflection point in the phase IIb readout. We expect investor sentiment to improve with this trial. We initiate coverage with a Base Case of SEK 12, suggesting ~75 percent upside. Our respective Bull and Bear cases are SEK 2 and SEK 30.

Key Financials (SEKm)	2019	2020	2021E	2022E	2023E
Net Sales	**0**	**0**	**0**	**0**	**0**
Sales Growth	N/A	N/A	N/A	N/A	N/A
EBIT	**-5**	**-3**	**-9**	**-32**	**-93**
EBIT Margin (%)	N/A	N/A	N/A	N/A	N/A
Net Income	**-9**	**-7**	**-9**	**-32**	**-93**
EV/Sales	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
EV/EBIT	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**

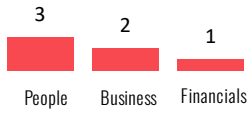
FAIR VALUE RANGE

BEAR	BASE	BULL
2	12	30

PILA VERSUS OMXS30



REDEYE RATING



KEY STATS

Ticker	PILA
Market	First North
Share Price (SEK)	6.8
Market Cap (SEKm)	116
Net Debt (SEKm)	30
Free Float (%)	48%
Avg. daily volume ('000)	110

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Investment Case

Redeye considers investment in Pila as an opportunity for investors to position in a phase II company targeting a commercially attractive indication with its "First-in-Class" oral small molecule drug, while trading at a notable discount compared to Swedish peer phase II biotech's. Likely, the discount can be derived from the lack of near-term catalysts.

New approach to USD ~240bn market
On the verge of an inflection point backed by a body of clinical data
High-conviction founder leads the way

New approach to USD 50bn market

Type 2 diabetes (T2D) has reached pandemic proportions and, according to the American Diabetes Association, represented direct medical expenses of USD ~237bn in 2017. Moreover, our research supports a TAM for XEN-D0501 of some 21 million patients in the US and EU5, suggesting an addressable market of USD ~50bn. Pila is a founder-led company, and its management has relevant experience from the life science sector and in-depth knowledge of the TRPV1 compound's potential as a new treatment for T2D. However, there are typically several obstacles on the path to take a drug to market, and not just development-related hurdles. Thus, we see a risk in Pila's management not having a proven track record of taking a drug through development and launching on their own. This risk is partly offset by the company's ambition to out-license the project, though, provided that competitive data are reported in the phase IIb trial. XEN-D0501 has demonstrated a solid safety profile, which slightly de-risks the case ahead of the phase IIb study. The compound has gathered a body of data from previous clinical studies representing a solid safety profile as well as a statistically significant insulin secretion increase in T2D patients.

On the verge of an inflection point

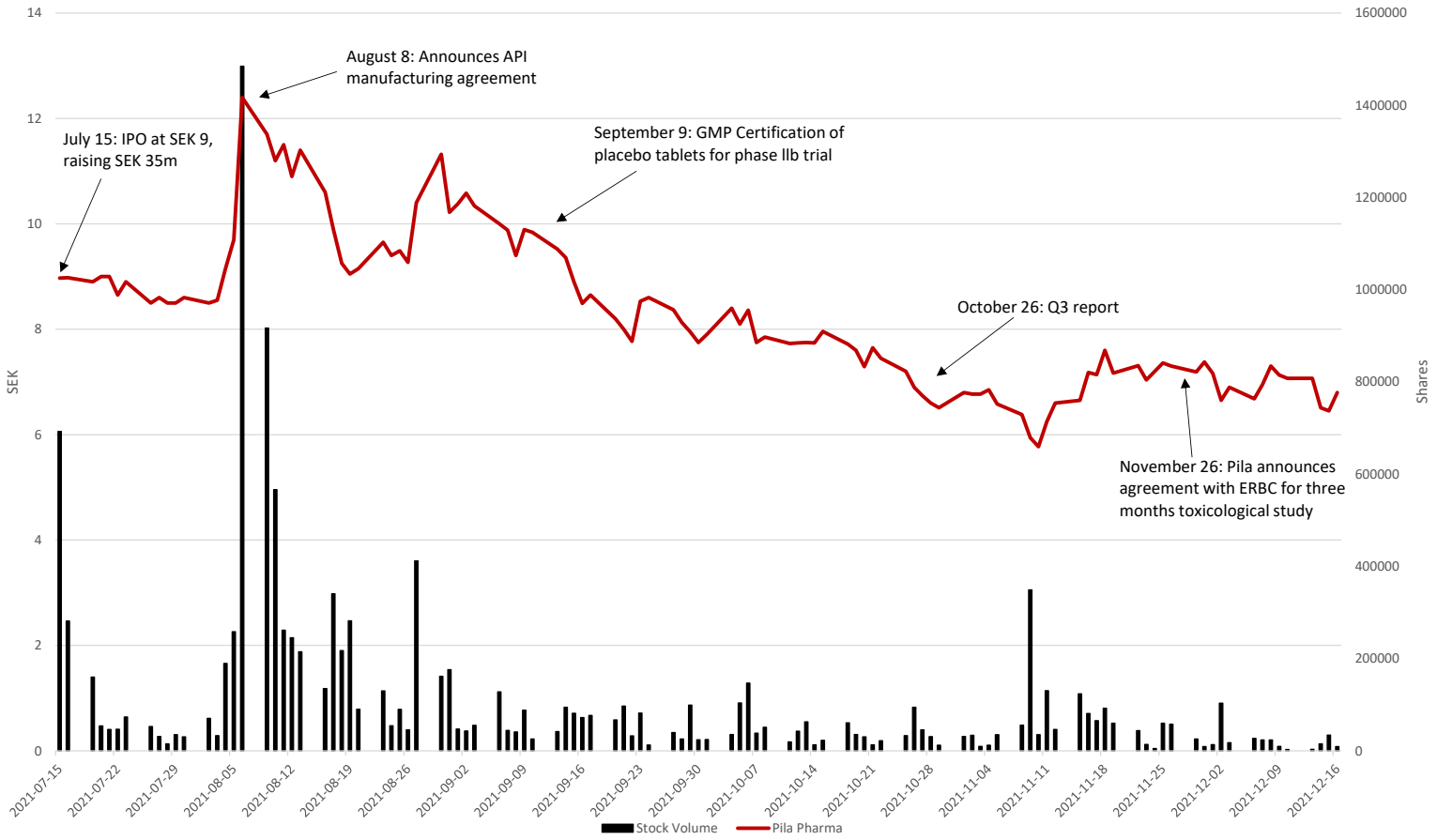
Redeye views the phase IIb study as a possible value inflection point for Pila Pharma, provided the company maintains a solid safety profile and concludes a competitive efficacy for XEN-D0501 in T2D patients. Pila will be positioned to out-license XEN-D0501 to a partner (the company has in-house deal experience) to take the project through the subsequent phase III study and navigate the highly competitive field of T2D therapeutics. We assume that Pila could sign a deal worth USD ~300m with low double-digit royalties (~12 percent). The company's compelling IP position further strengthens its deal prospects. It holds the global rights for treatment of obesity and related diseases with TRPV 1 antagonists, plus it has filed a global substance patent for XEN-D0501 in T2D, which is expected to be approved in 2022. In our view, the phase IIb readout expected in the second half of 2023 is make or break for Pila.

High-conviction management leads the way

Redeye views current share price levels as an attractive entry point into a founder-led company with high insider ownership that is approaching an inflection point with its phase IIb trial. The binary risk of the phase IIb trial readout is hard to offset for a biotech company. However, we want to emphasize that the CEO has researched TRPV1 for more than 20 years, and as a majority owner (controlling ~31 percent of Pila shares), she has significant skin in the game and aligned interests with shareholders. Our Base Case amounts to SEK 12, representing upside potential of ~75 percent. However, the valuation upgrade could take some time to materialize due to the lack of near-term triggers.

Share Price Development

Share price development since the IPO



Source: Redeye Research, Millistream

Since the IPO in July this year, Pila's share price has declined and is currently trading at SEK 6.8, some ~20 percent down from its listing price. The sentiment surrounding the share has cooled off, and the share trades in limited volumes, with the lack of substantial near-term catalysts likely contributing to the decline.

In view of the approaching potential inflection point thanks to Pila's phase IIb study, we anticipate an improvement in investor sentiment in the coming 12 months, and we believe the discount to our Base Case will narrow as progress is made. We expect the trial, which could represent a significant value inflection point, to commence in the first half of 2023.

Catalysts

Phase IIb start – The fundamental value of a biotech company is closely tied to its project advancement. Pila's phase IIb study for XEN-D0501 is expected to commence at the first half of 2023.

Anticipated impact: Moderate

Time horizon: 12 months

Further patents granted – To protect XEN-D0501's commercial attractiveness and generic competition, Pila is expected to broaden its intellectual property for the compound. A substance patent for use in T2D worldwide was filed in October 2021. Further secondary patents and new geographies are likely to follow.

Anticipated impact: Moderate

Time horizon: Three to 24 months

Warrant funding – Pila has outstanding warrants from its TO1 program, for which the exercise period is in May/June 2022. A successful outcome would strengthen the company's financial position and reduce the financing risk for Pila ahead of the phase IIb study.

Anticipated impact: Moderate

Time horizon: Six months

Phase IIb readout - The phase IIb readout will be the most substantial catalyst for Pila, as a positive outcome with XEN-D0501 will be a significant value inflection point.

Anticipated impact: Major

Time Horizon: 12-24 Months

Partnership – Given a positive outcome in Pila's phase IIb study, the company will likely sign a partnership deal for the commercialization and late-stage development of XEN-D0501. Robust data, together with the vast market opportunity of T2D, would allow Pila to negotiate from a strong position for an advantageous deal.

Anticipated impact: Major

Time horizon: 24-30 months

Key Risks

Financial risk – Pila is still several years away from profitability, and with SEK ~30m in cash there is no immediate capital need. But further dilution is expected to finance the necessary trials with XEN-D0501.

Development risk – XEN-D0501 is in mid-stage development for T2D and is Pila's only candidate in clinical development. The company is yet to conclude competitive efficacy data in a phase IIb study to complement the findings in its phase IIa studies. The future share price trajectory will thus be closely tied to the outcome of the planned phase IIb study.

Partnership risk – In addition to a positive outcome in the phase IIb study, the ongoing development and future commercialization of XEN-D0501 is contingent upon Pila signing a partnership deal before starting a phase III study so as to finance and navigate this highly competitive commercial landscape.

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Company Overview

Background

Based in Malmö, Sweden, Pila Pharma is a biotech company with the primary goal of developing an oral anti-diabetic agent that effectively controls hyperglycemia and body weight gain in type 2 diabetes (T2D) without increasing the risk of cardiovascular disease. The company was founded in 2014 and employs five full-time employees, along with several consultants.

Pila Pharma's trajectory started in 2000 based on the research conducted by the CEO and largest owner Dorte X. Gram for her University of Copenhagen PhD thesis while working at Novo Nordisk. The company is currently pursuing one drug development program: XEN-D0501, a TRPV-1 antagonist that reported encouraging outcomes from its phase IIa study in 2020.

The company conducted a pre-IPO, raising SEK 15m in March, and then went public in July 2021 on Nasdaq First North Growth Market, raising some SEK 35m at SEK 9 per share. Since the IPO, Pila has reported further progress, facilitating its way towards the phase IIb trial.

Company history

Year	Milestone
1999	Dorte X. Gram discovers that TRPV1 can regulate blood sugar in diabetic rats
1999-2005	The Gram-hypothesis is formulated and preclinical studies support the hypothesis
2005	Dorte X. Gram files use patents on the treatment of diabetes and obesity with TRPV1 antagonists for Novo Nordisk
2008	XENIA PHARMA acquires the patent rights for treatment of diabetes and obesity with TRPV1 antagonists from Novo Nordisk
2011	Use patent in the US issued to XENIA PHARMA for treatment of obesity with TRPV1 antagonists
2013	Use patent in the US and Europe issued to XENIA PHARMA for treatment of T1D and T2D with TRPV1 antagonists
2014	Pila Pharma founded as a fully owned subsidiary to XENIA PHARMA and use patent was transfered to Pila upon establishment
2016	TRPV1 antagonist assets including XEN-D0501 inlicensed from Arioa Pharma (indirectly Bayer)
2017	Permission to try single ascending dose for T2D patients with XEN-D0501 (clinical study PP-CT01)
2018	PP-CT01 shows that XEN-D0501 concludes a good safety profile
2019	Pila's second clinical study PP-CT02 is conducted
2020	Licensing agreement regarding royalties for XEN-D0501 to Ario Pharma ceases
2020	PP-CT02 shows a good safety profile in T2D and statistically significant effect on insulin secretion following 28 days of treatment in T2D patients with XEN-D0501
2021	IPO in July, raising SEK 35m

Source: Pila Pharma, Redeye Research

Summary of Significant Events Ahead (Our estimates)

	2022		2023		2024	
	H1	H2	H1	H2	H1	H2
XEN-D0501	API Manufacturing	Tox studies	Phase IIb start	Phase IIb readout / Partner		Phase III start
Other	Warrant exercise		Rights issue SEK ~50m			

Source: Redeye Research , Pila Pharma

The most relevant near-term events for the company relate to it completing a tox study with XEN-D0501 to confirm the safety profile needed for it to submit for regulatory approval to start a phase IIb study. To conduct the tox study, Pila has hired the contract research organization (CRO) European Research Biology Center (ERBC), and this is expected to be finished by the second half of 2022; shortly thereafter, the phase IIb study is scheduled to commence, likely late in the first half of 2023, we believe.

What's next?

Moreover, the company is working on manufacturing API starting materials and settling on the final phase IIb trial synopsis. Pila has already acquired GMP certification for the 4mg tablets to be used in the phase IIb trial.

The company has been transparent about its activities for 2022, and at Redeye's Investor Forum in December 2021, Pila listed the following planned activities for next year:

Q1

- Sign agreement for pharmacokinetic (PK) Measurements from tox studies with central laboratory
- Establish method to measure rodent and non-rodent PK
- Hire new internal staff and consultants
- Write statistical analysis plan (SAP), data management plan (DMP) and medical monitoring plan (MMP)
- Update investigators' brochure with PP-CT02 results and the Investigational Medicinal Product Dossier with new tablets, information, and write protocol with patient information and label design

Q2

- Settle on final phase IIb trial synopsis
- Select and sign agreement with clinical trial CRO to select clinical trial sites and investigators
- Manufacture 17.5 kg non-GMP API
- Transfer non-GMP to tox CRO
- Tox CRO to conduct 13 week tox studies in rodent and non-rodent
- Site qualification visits by clinical trial CRO (50-100 sites)

Q3

- Rodent and non-rodent tox PK analyses
- Tox CRO to report 13-week tox studies in rodent and non-rodent models
- Update investigators' brochure with tox results
- Sign agreement / book slot for filing and labelling of investigational medicinal product (IMP)

Q4

- Create and submit the clinical trial application via EudraCT to CA and EC in X countries
- Clinical trial application approved
- Sign agreements with 50-100 clinical trial institutions, clinical trial investigators, sub-investigators, and project nurses
- Create online database
- Fill tablets to appropriate clinical trial packaging (IMP)
- Clinical trial CRO to prepare for trial site invitation visits
- Clinical trial application approved

Ownership & People

As an early to a mid-stage development company, Pila Pharma has a management team that we regard as being of significant weight to navigate both the development and financial challenges ahead. CEO and founder **Dorte X. Gram** has spent her career working on a thesis that is the basis of what Pila now develops. She spent more than ten years researching diabetes at Novo Nordisk, where she worked in several areas, including small molecules and peptides. She has also authored several scientific publications focusing on TRPV1 in diabetes and patents on the same subject, as well as on long-acting insulins. As the CEO and founder, she currently controls about one-third of the shares in Pila, and bolstered her ownership in November, which signals shareholder value alignment regarding management decisions.

Lars Bukhave Rasmussen has been the COO of Pila since May 2021 and was previously CFO (from September 2020). He has previous experience at global biopharma companies with operations in Denmark and the US. He has held several senior positions in life science companies with global operations, focusing on business development and partnering agreements. Moreover, he also brings additional insight and understanding to the TRPV1 target. His DVM master thesis, supervised by Dorte X. Gram, focused on the role of the receptor in preclinical diabetes.

Elna Lembrér Åström took on the role of CFO in Pila Pharma during the first half of 2021. She has more than 30 years of experience in financial management and accounting and was previously the auditor of Pila Pharma.

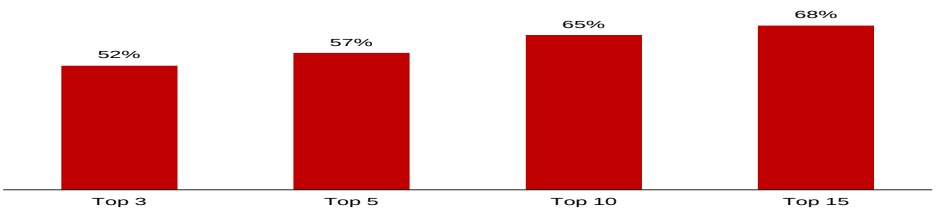
Pila Pharma's stock remains undiscovered by institutional capital and its shareholder base mainly consists of private investors. The insider holdings of 31.7 percent are almost solely held by CEO Dorte X. Gram (31.3 percent of Pila shares). We view the CEO's significant ownership positively as it signals alignment with shareholder value during management decision-making, positively reflected in our Redeye Rating Model where skin in the game is an essential parameter. Beyond the CEO's holdings, we would be encouraged to see a more widespread shareholding among management and the board. According to the prospectus, ALMI, the CEO (Xenia Pharma), and the board of directors have committed to a lock-up agreement for 12 months following the IPO.

Ownership structure

Pila Pharma - Ownership Structure				Pila Pharma - Insider Ownership			
Owner	**% of shares**	**Shares**	**Verified**	**Owner**	**% of shares**	**Shares**	**Verified**
Dorte X. Gram	31,3%	5 031 580	2021-09-30	Dorte X. Gram	31,3%	5 031 580	2021-09-30
Vimpu Intressenter AB	10,6%	1 710 044	2021-09-30	Lene Andersen	0,2%	26 000	2021-09-30
ALMI	9,9%	1 586 640	2021-09-30	Fredrik Buch	0,1%	21 330	2021-09-30
Nordnet Pensionsförsäkring	3,2%	507 270	2021-09-30	Tyge Korsgaard	0,1%	17 500	2021-09-30
Avanza Pension	2,2%	354 332	2021-09-30				
Johan Stein	2,0%	321 046	2021-09-30				
Sebastian Clausin	1,7%	280 570	2021-09-30				
Lld Nybohov Invest AB	1,4%	222 200	2021-09-30				
Göran Ofsén	1,2%	200 000	2021-09-30				
Anmi Förvaltning AB	1,1%	176 300	2021-09-30				
Total holdings	**64,5%**	**10 389 982**	**2021-09-30**	**Insider holdings**	**31,7%**	**5 096 410**	**2021-09-30**
Other shareholders	**35,5%**	**5 710 356**	**2021-09-30**	**Other shareholders**	**68,3%**	**11 003 928**	**2021-09-30**
Total	**100,0%**	**16 100 338**	**2021-09-30**	**Total**	**100,0%**	**16 100 338**	**2021-09-30**

Source: Holdings

Ownership concentration



XEN-D0501: TRPV-1 Antagonist for Type 2 Diabetes

XEN-D0501 is a first-in-class oral Transient Receptor Potential Vanilloid 1 (TRPV1) antagonist that takes a new approach to treating type 2 diabetes mellitus. The small molecule drug targets the "chili receptor," which has been proven to demonstrate applications across pain and inflammatory diseases and could potentially be a new mechanism of action in T2D. By regulating neurogenic inflammation, it has been shown in clinical studies that XEN-D0501 can improve insulin response in T2D patients. Its solid safety profile and cheap production cost strengthen the commercial case, which could possibly be extended for additional indications in the future.

XEN-D0501's background

Initially, XEN-D0501 was a Bayer asset in development for patients with an overactive bladder. For strategic reasons, Bayer sold its urogenital projects and patents in 2011, and the asset was transferred to Xention/Ario Pharma for development of overactive bladder disease and then refractory cough. XEN-D0501 demonstrated a solid safety profile but did not meet efficacy expectations in these indications. In 2016, Pila in-licensed XEN-D0501 from Ario Pharma for development in T2D.

Novel approach towards T2D

Pila Pharma's trajectory started in 1999 when Dorte X. Gram began testing her hypothesis that type 2 diabetes is an inflammatory disorder and should be treated as such. This hypothesis is based on the discovery that sensory nerves play a role in glucose regulation beyond targeting signal substances that control pain and inflammation. In 2003, she presented this theory in her PhD thesis. One year later, she wrote a use patent application for a method of selectively inhibiting the activity of the capsaicin receptor in obesity or obesity-related diseases or disorders, and this was filed by her employer Novo Nordisk. In 2008, when Novo Nordisk A/S decided to focus on injectable peptide-based drugs, it closed or spun off all patents and projects in the oral anti-diabetic category, and Dorte X. Gram was able to purchase the 2004 patent application via her own company, Xenia Pharma.

In 2014, Pila Pharma was established as a fully owned subsidiary of Xenia Pharma. The granted use patents were transferred to Pila with the aim of combining them with a clinically ready TRPV1 clinical development candidate.

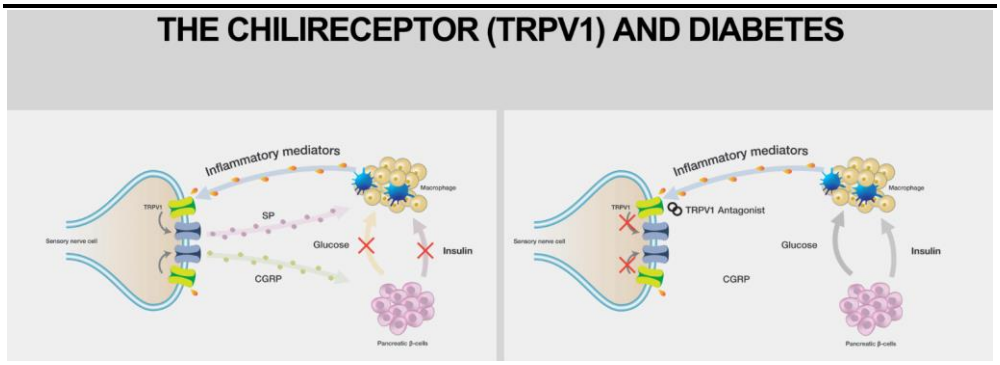
Pila's approach is that T2D could be an inflammatory disease, and so it intends to improve the insulin response in patients by regulating neurogenic inflammation. Members of the transient receptor potential (TRP) superfamily have been shown to have several biological functions and have become a potential drug candidate in numerous pathophysiological conditions. Findings also support that some of the TRP channels are involved in regulating whole-body metabolism, further asserting the therapeutic value. However, TRPV1 is an ion channel present on sensory neurons activated by heat, protons, capsaicin, and a variety of endogenous lipids termed endovanilloids. The activation of TRPV1 has in previous studies been linked to chronic inflammatory pain conditions and peripheral neuropathy, as observed in diabetes[1]. The link between diabetes and inhibiting TRPV1 is proposed at multiple levels, such as controlling appetite and weight, regulating pancreatic function, and the secretion of GLP-1, another important therapeutic agent for T2D.

TRPV1's role in obesity and weight regulation has a more extensive set of data than in T2D. However, the two indications are often related, suggesting potential extension indications for Pila.

1 Brito R, Sheth S, Mukherjea D, Rybak LP, Ramkumar V. TRPV1: A Potential Drug Target for Treating Various Diseases. Cells. 2014;3(2):517-545. Published 2014 May 23. doi:10.3390/cells3020517

The theory of TRPV1 in diabetes is primarily associated with the findings that inflammation inhibits insulin secretion. Thus, TRPV1 antagonists blocking the receptor will regulate the neurogenic inflammation and restore insulin secretion, as shown below:

TRPV1 and diabetes



Source: Dorte X. Gram, Jens J. Holst, Arpad Szallasi, 2017, 'A potential Therapeutic Target in Type 2 Diabetes and Comorbidities', Trends in Molecular Medicine, Vol. 23, No. 11

TRPV1 in the spotlight

The 2021 Nobel Prize in Physiology or Medicine was awarded to Professor David Julius and Professor Ardem Patapoutian for their thermal and mechanical transducers discoveries. Until this discovery, the identity of the molecular transducers responsible for detecting and converting heat, cold, and touch into nerve impulses in the sensory nervous system was unknown. Their findings expanded on the previous knowledge that temperature and pressure activate different types of nerves in the skin. Professor David Julius wished to identify the cellular target of capsaicin, as he believed this could provide fundamental insights into the mechanisms of pain. The work by the two Nobel Prize winners explained the molecular basis for sensing heat, cold and mechanical force. This plays a fundamental role in humans' ability to feel, interpret, and interact with both our internal and external environments.

Our underlying view on this significant scientific discovery is that it could likely spark further interest for the medical application of TRPV1 antagonists, and a more extensive scientific validation surrounding TRPV1 could probably, in the long run, facilitate the development and medical adoption of TRPV1 projects. This can be interpreted as positive for Pila's approach towards T2D. However, we refrain from asserting any value from this in our assessment of Pila. In our view, its effect on the company's operations and development is hard to pinpoint, and there is no clear connection to the use of TRPV1 in T2D treatment.

Clinical evidence supporting XEN-D0501

As a mid-stage asset, XEN-D0501 has gathered clinical evidence, and it has undergone several phase I and II studies in three indications, performed by Ario/Xention, Bayer, and Pila. We do prescribe value to the previous studies' safety data, as they further strengthen the case for XEN-D0501 in T2D. However, the publicly available information on the phase II studies conducted by Pila is limited. We summarize our findings below:

XEN-D0501- previous clinical studies

Study ID	Phase	Indication	Company	Patients
NCT03278158	IIa	T2D	Pila Pharma	26
N/A	IIa	T2D	Pila Pharma	52 (60)
NCT02233686	IIa	Cough	Xention/Ario Pharma	27
NCT02233699	IIa	Cough	Xention/Ario Pharma	18
N/A	IIa	Overactive bladder	Xention/Ario Pharma	50
N/A	Ia	Healthy Volunteers	Bayer Healthcare	10
N/A	Ia	Healthy Volunteers	Xention/Ario Pharma	11
N/A	Ia	Healthy Volunteers	Xention/Ario Pharma	18

Source: Redeye Research, Clinicaltrials.gov

According to our walkthrough of these studies, XEN-D0501 has been shown to be generally well tolerated from a safety point of view. However, XEN-D0501 had trouble demonstrating compelling efficacy data in the studies, and so these projects have been abandoned. Moreover, the most common adverse events (AEs) found were headaches, feeling cold/hot, dizziness, mouth pain, and a loss of taste. The studies tested doses ranging between 1mg and 5mg.

Pila-sponsored T2D studies

The publicly available information on Pila's phase IIa studies is relatively scarce. We have looked through what is available and found that XEN-D0501 has seemingly reiterated the previous studies' safety profile, which slightly de-risks the case and the approaching phase IIb study. We acknowledge that Pila is targeting a new indication and that the success of XEN-D0501 is contingent upon it demonstrating competitive efficacy in T2D patients.

Pila has conducted two phase IIa studies for XEN-D0501. These outcomes have strengthened the rationale for initiating the phase IIb study. XEN-D0501 confirmed its solid safety profile and, in line with the previously conducted clinical studies, reported transient AEs related to:

- Headache
- Body temperature change (feeling cold/hot)
- Oral pain and loss of taste

No serious adverse events were recorded in either of the two diabetes trials.

Moreover, in PP-CT02, the larger of the two studies, XEN-D0501 managed to show a statistically significant increase in insulin secretion for the patients in the active arm, which in turn affected the positive effect, lowering the relevant biomarker HbA1c – i.e., it reduced the glucose level for patients.

PP-CT01

In 2017, Pila performed its first clinical phase IIa study with XEN-D0501. The study's primary endpoint was to evaluate the safety and tolerability of the compound with a single dose of either 1mg, 2mg, 4mg, or 8mg compared to placebo on T2D patients. The 8mg dose was added as an amendment to the protocol thanks to the solid safety profile.

A total of 26 participants were enrolled in the study, and the outcome supported further investigation of XEN-D0501 in T2D. No serious AEs were reported, and only a few mild to moderate AEs were noted, which was largely in line with previous studies.

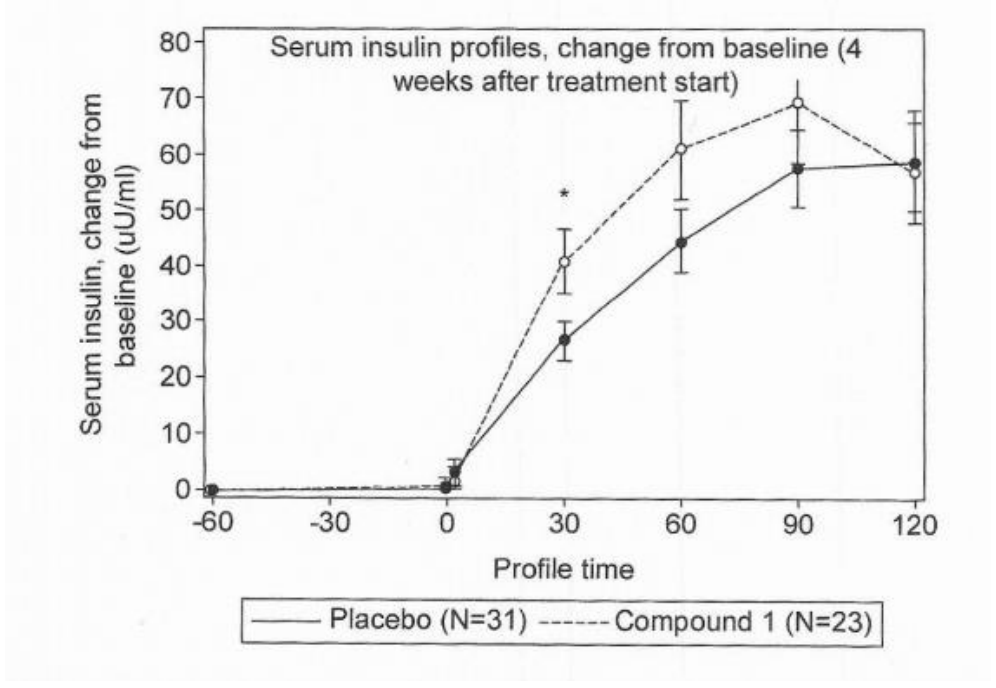
PP-CT02

As a follow-up to the results of the PP-CT01 study, Pila initiated a second phase IIa study on 60 patients, of whom 52 performed the efficacy tests at the appropriate time. The study was randomized, double-blind, and placebo controlled. Its primary endpoint was to investigate the

effects of four weeks of bi-daily dosing of XEN-D0501 (4mg BID) as an add-on to metformin on fasting blood glucose in patients with T2D. Several secondary endpoints were also listed, of which "To investigate the effects of bi-daily doses of XEN-D0501 (4mg) on insulin secretion during a two-hour oral glucose tolerance test (OGTT) in patients with T2D" was the endpoint presented in the prospectus at the time of Pila Pharma's IPO.

The OGTT simply means that the patient consumes sugar (often orally as water-dissolved sugar) to measure the effectiveness of the drug through the body's ability to regulate the glucose in the body compared to placebo. In the study, XEN-D0501 showed a statistically significant and clinically relevant effect on the patient's insulin secretion compared to placebo. Moreover, the company claims that it also proved statistically significant reductions in HbA1c levels in the patients in the trial. However, the complete data set is not publicly disclosed yet. We expect that Pila will provide more insight into this before announcing the financing for its phase IIb trial.

XEN-D0501's effect on insulin secretion in phase IIa study



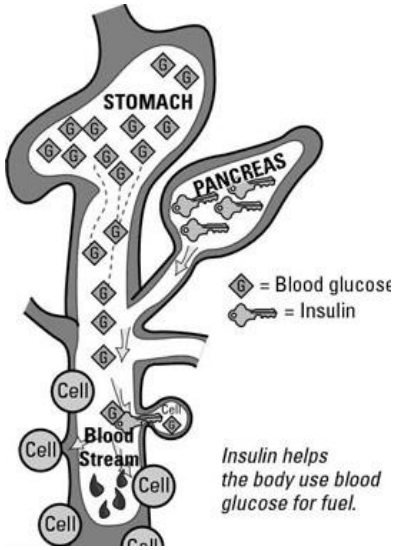
Source: Pila Pharma

Diabetes mellitus (T2D)

Background

Etiology and disease background

During digestion, the human body breaks down carbohydrates from foods such as bread, rice, and pasta into various sugar molecules. One of these molecules is glucose, the body's primary energy source. Glucose is absorbed directly into the bloodstream after eating. Through the help of the hormone insulin, glucose can enter the cells of the body's tissues. A simplification is that insulin acts as a key opening the door (cells) to allow the blood glucose to enter, as shown to the right.



Diabetes mellitus refers to a group of metabolic disorders characterized by hyperglycemia (elevated blood glucose levels) owing to insufficient insulin secretion or insulin sensitivity of the cells. The two main types of diabetes mellitus are type 1 and type 2 diabetes, with type 2 being by far the most common, estimated at 87-91 percent of all diabetes cases in high-income countries.

Type 1 diabetes is thought to be caused by autoimmune destruction of insulin-secreting beta cells in the pancreas, usually associated with auto-antibodies. The pathophysiology of type 2 diabetes is less clear. What is known is that the profile of insulin secretion in response to glucose is altered. Even before they develop type 2 diabetes, patients typically have insulin resistance due to obesity, physical inactivity, and signs of beta-cell dysfunction. As insulin resistance worsens, the pre-diabetic pancreas increases total insulin production to compensate, but diabetes develops when it is no longer able to do so, and insulin secretion falters. It is unclear to what extent the enhanced beta cell activity itself may contribute to the dysfunction and eventual destruction of beta cells. It is also unclear to what extent genetic versus environmental factors play a role in type 2 diabetes.

However, the traditional paradigms of type 2 diabetes occurring only in adults and type 1 diabetes only in children are no longer accurate, as both occur in both age groups. Other forms of diabetes include gestational diabetes, monogenic diabetes syndromes (e.g., neonatal diabetes and maturity-onset diabetes of the young (MODY)), latent autoimmune diabetes of adults (LADA; also referred to as type 1.5), diseases of the exocrine pancreas (e.g., cystic fibrosis and pancreatitis), and drug- or chemical-induced diabetes (e.g., due to glucocorticoid use, in the treatment of HIV/AIDS, or after organ transplantation).

In conclusion, the most significant difference between T1D and T2D is that with T1D, the pancreatic islets do not produce any insulin, leading to high blood glucose levels, while for T2D, not enough insulin is released from the pancreas and/or the cells become increasingly resistant to the insulin produced. Consequently, T2D therapeutics such as XEN-D0501 usually seek to increase insulin secretion and/or reduce the patient's resistance to the insulin produced.

Controlling HbA1c

Controlling the patient's glucose levels is essential in reducing long-term complications for the body's organs, eyes, blood vessels, feet, and more. Generally, if the patient has inadequate control of their blood glucose levels. If a patient often have hyperglycemia, the risk of mentioned long-term complications severely increases.

Physicians monitor the patient's HbA1c, a biomarker that provides information about the patient's average blood glucose over the last two to three months. HbA1c refers to glycated hemoglobin, which develops when hemoglobin, a protein within red blood cells that carries oxygen through the body joins with glucose in the blood, becomes "glycated". The more glucose in the blood, the more hemoglobin will bind glucose. The turnover of red blood cells is up to three months, which is why a phase IIb trial should be at least three months long. HbA1c is measured from a drop of blood from the patient. Preferably, T2D patients should have HbA1c-levels of 48mmol/mol (6.5 percent) or less to minimize the risk of long-term complications.

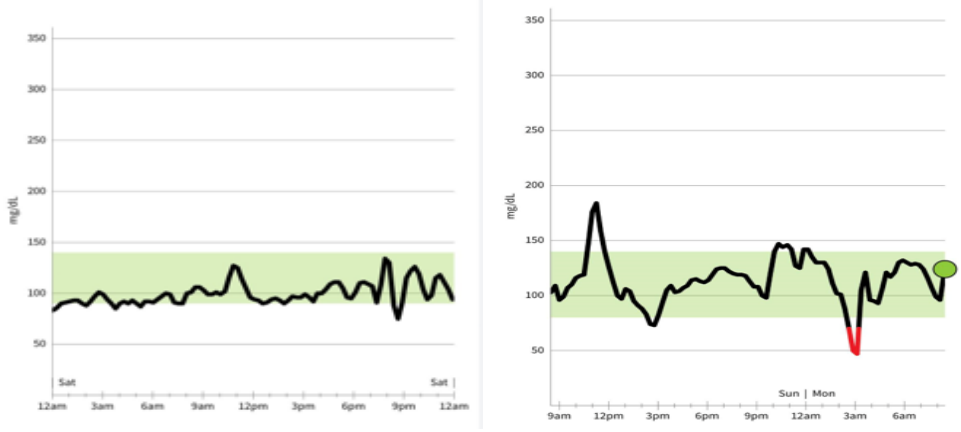
Blood glucose levels shift depending on oral medication intake, insulin injections, food intake, exercise, stress, tiredness, and other factors. Patients must monitor their blood glucose levels daily to reach optimal HbA1c-levels, so as to reduce the risk of long-term complications. Patients usually monitor this themselves daily using point-of-care testing with a continuous glucose monitor (CGM) or a traditional glucose meter (as illustrated below).

Point-of-care glucose monitoring (CGM left, glucose meter right)

Source: Abbott Laboratories

Below we illustrate real-world examples of continuous glucose monitoring of a non-diabetic person compared with a T2D patient. The green highlights represent the individual optimal blood glucose range.

CGM curve example (non-diabetic to the left and T2D example to the right)



Source: Abbott Laboratories

Hyperglycemia

Hyperglycemia refers to elevated blood glucose levels, usually occurring after meals owing to the body not producing enough insulin or not using the insulin properly. Illness and stress are also proven to trigger hyperglycemia because the hormones produced to combat these conditions can also cause blood glucose levels to rise. While individual differences occur, blood glucose levels greater than 7.0 mmol/L or 126mg/dl when fasting, or blood glucose levels greater than 11.0 mmol/L or 200mg/dl two hours after meals are frequently used as the definition of hyperglycemia.

During hyperglycemia, patients often experience frequent urination and increased thirst as the kidneys are being forced to work overtime to filter and absorb the excess glucose in the blood. When the kidneys cannot keep up, the excess glucose is excreted into the urine, dragging with it fluids from the body's tissues, making the patient dehydrated and often leaving them feeling thirsty. These are usually the symptoms patients experience before receiving a T1D/T2D diagnosis.

Momentarily or even prolonged slightly elevated glucose levels are not necessarily a danger to the patient in the short or long term. However, if blood sugar rises high enough or for a prolonged period of time, it could lead to two severe conditions even in the shorter term.

Diabetic ketoacidosis develops when the body does not have enough insulin, and the glucose cannot enter the cells for energy. Blood sugar levels rise, and the body begins to break down fat for energy, producing toxic acids known as ketones. Excess ketones accumulate in the blood and eventually spill over into the urine. Left untreated, diabetic ketoacidosis can lead to diabetic coma and can be life-threatening.

Hyperglycemic hyperosmolar state occurs when the body produces insulin, but it does not work properly. It may cause significantly elevated blood glucose levels, and the body is not able to use either glucose or fat for energy. Glucose then spills over into the urine, causing increased urination. If left untreated, diabetic hyperglycemic hyperosmolar state can lead to life-threatening dehydration and coma.

Hypoglycemia

Hypoglycemia is the opposite of hyperglycemia. It is a condition in which the blood glucose level is lower than normal, occurring mainly as an effect of subcutaneous insulin injections, leading to excess insulin in the blood, commonly due to the patient taking a too high dose of insulin. It could also be related to stress, or if the patients eat less than normal. However, it could also be an effect of increased insulin sensitivity, such as from oral medication or lifestyle change(s). For many patients, fasting blood glucose levels below 70 mg/dL or 3.9 mmol/L should serve as an alert for hypoglycemia. However, individual differences do occur.

Common symptoms of hypoglycemia include anxiety, fatigue, pale skin, shakiness, tingling or numbness, irregular or fast heartbeat, sweat, hunger, and irritability. Should the hypoglycemia worsen and levels become alarmingly low, the patient will experience more severe symptoms, such as confusion, visual disturbance, blurred vision, seizures, loss of consciousness, and, if very severe, even death. These symptoms occur as the cells are starved of energy. At first, patients might notice only minor symptoms such as hunger or headaches, but as the hypoglycemia becomes prolonged, more severe symptoms and complications are apparent.

Long-term complications of T2D

As previously mentioned, inadequate blood glucose control affects many major organs, including the heart, blood vessels, nerves, eyes, and kidneys. Moreover, factors that increase the risk of T2D are risk factors for other serious chronic diseases, including:

- Heart and blood vessel disease – such as stroke, high blood pressure, and a narrowing of the blood vessels
- Nerve damage (neuropathy) in limbs – elevated blood glucose levels over time commonly damage or destroy nerves. This can result in numbness, tingling, burning, pain, or eventual loss of feeling in parts of the body such as hands and feet, usually starting at the tips of the toes or fingers and gradually spreading upwards
- Eye damage – T2D significantly increases the risk of severe eye diseases, such as cataracts and glaucoma. It may also damage the retina's blood vessels, potentially leading to blindness.
- Slow healing – people with diabetes tend to have slower healing of wounds, cuts, and blisters. If left untreated, this could lead to severe infections that could then lead to amputations.
- Sleep apnea – obstructive sleep apnea is common in T2D patients, and obesity may contribute to both conditions.
- Elevated risk for dementia – T2D seems to increase the risk of Alzheimer's disease and other disorders that cause dementia. Poor blood sugar levels are associated with a more rapid decline in memory and other cognitive skills.

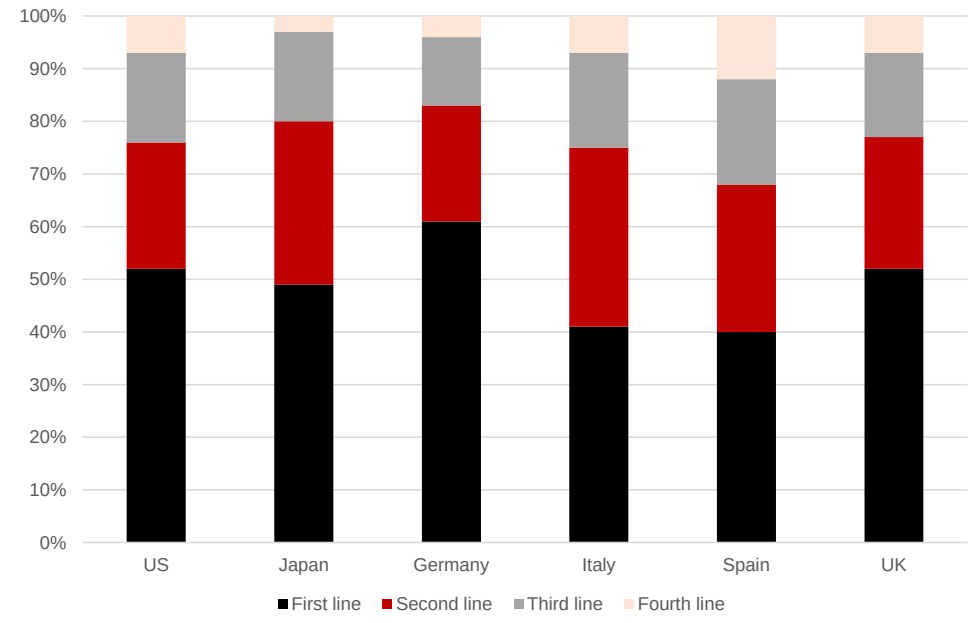
Patient Classification

Guidelines from the American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD) recommend segmenting patients by specific co-morbidities and patient factors, including cost, to better direct treatment. In the US, the CDC estimates the following therapeutic distribution:

- 19 percent not on any medication
- 52 percent on pills only
- 15 percent on insulin
- 14 percent on pills and insulin

Patients are also often segmented by the line of therapy since diabetes drugs are typically added step-by-step as patients lose glycemic control. The chart below provides a breakdown of the line of therapy for primary care in major markets.

Line of therapy for primary care of T2D

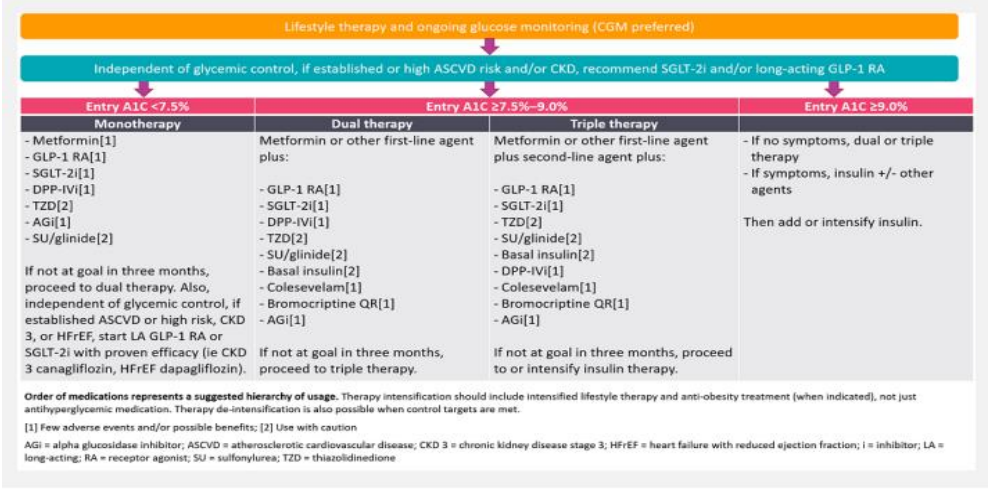


Source: Datamonitor Healthcare

Note that the majority of patients receive first-line treatment, which mainly consists of generic small molecule drugs, such as metformin. We assume that XEN-D0501 would be positioned as an early-stage therapy, likely after or as an add-on to metformin, provided it can demonstrate competitive efficacy in a more extensive study. It could possibly be positioned at a later stage, however.

We show the American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) treatment algorithm below. It offers some insight into how T2D patients are prescribed medications, and on the whole, the line of therapeutics is contingent upon how well the patient can manage their HbA1c levels.

AACE treatment algorithm



Source: AACE/ACE, 2020

The 2018 American Diabetes Association and European Association for the Study of Diabetes (ADA/EASD) consensus report from 2018 pointed out that patients with a sufficient life expectancy (around ten years) will see microvascular benefits with an HbA1c target of seven percent. However, these targets are individualized based on the risk of AEs and patient characteristics, as well as personal preferences.

Aiming at a lower HbA1c might be reasonable, provided it is achieved without increasing the risk for significant hypoglycemia. In general, physicians consider cardiovascular risk/benefits when assessing T2D patients, as these patients carry considerable risk. Patients could thus be recommended to move further down the treatment algorithm despite sufficient HbA1c levels, often for cardiovascular benefits. As a consequence, therapeutics providing clinically relevant cardiovascular or weight-loss-related benefits for the patient would bolster the drug from a marketing perspective.

Thankfully, the data regarding a TAM for XEN-D0501 are significant. We found plenty of support for the assumption that around 50 percent of T2D patients represent the total addressable market for XEN-D0501 as a small molecule first-line treatment.

Marketed Drugs

Below, we list and discuss what we consider to be the most relevant currently marketed peer drugs for XEN-D0501.

Small molecules

Metformin – generic

Recommended and typically used as first-line treatment in the US and Europe, metformin is the most common option for T2D patients. Its predominant mechanism is to suppress excess hepatic glucose production, both in the fasting and postprandial states. Additional mechanisms may allegedly play minor roles as well. Metformin is a widely used drug with proven efficacy and a solid safety profile. Around 25 percent of patients do, however, experience gastrointestinal side effects such as diarrhea. This risk can partly be offset by administering a lower dose, offering some effectiveness. Real-world data suggests that discontinuation of the drug over a year for various reasons could range from 21 to 40 percent. There are also tentative data from the UKPDS study that metformin could reduce the risk of

cardiovascular events and death. The FDA has raised concerns regarding the use of metformin in patients with renal impairment. Metformin does not increase weight and may contribute to weight loss.

Sulfonylureas (SUs) – generic

The use of sulfonylureas has declined due to the advent of newer drugs. However, they are still frequently used thanks to their affordability, depending on geographical location. As a percentage of metformin use, their use has been in the range of roughly 35-50 percent in the US and 20-50 percent in EU5 (Germany, France, Italy, Spain, and the UK). Seemingly, in the US, more regard is taken to cardiovascular benefits when choosing a drug, reducing sulfonylureas' market penetration. Sulfonylureas have high efficacy, but since they primarily regulate T2D through increased insulin secretion, they also bring a higher risk of hypoglycemia than metformin. A dose concomitant with mild to moderate weight gain is also observed in patients. Guidelines note uncertain cardiovascular safety and a lack of durable effect on glucose lowering.

Thiazolidinediones (TZDs) – generic

TZDs have limited usage despite high efficacy, a unique mechanism of increasing insulin sensitivity, and the best evidence for a long-lasting effect on glucose-lowering. This is due to concerns about the class regarding fluid retention and concomitant heart failure (HF), weight gain, fractures, and possibly bladder cancer. Their usage substantially declined following a meta-analysis of rosiglitazone, which suggested an increased risk of cardiovascular issues, subsequently included in a black box label warning in the US. However, later large studies did not confirm this risk with rosiglitazone, leading to the removal of the black box warning, but the findings did not help the drug recover. Another TZD, pioglitazone, was shown to reduce cardiovascular issues and steatohepatitis, but the results were not considered conclusive.

Alpha-glucosidase inhibitors – generic

While being relatively infrequently used in western countries such as the US and in Europe, alpha-glucosidase inhibitors are more widely used in Japan. They slow the digestion of carbohydrates, improving postprandial glucose excursions, which means a low risk of hypoglycemia. Still, they have modest efficacy, must be taken at the start of meals, and have frequent gastrointestinal side effects.

Meglitinides – generic

Like SUs and XEN-D0501, meglitinides stimulate increased insulin secretion. Still, while they have a more rapid onset of action, their duration is also shorter, reducing the efficacy in patients, albeit with a lower risk of hypoglycemia. Moreover, the treatment window for use before each meal and concerns about increased weight gain and uncertain cardiovascular safety listed in guidelines have led to their limited usage.

Bile acid sequestrants – generic

These drugs are approved for diabetes and dyslipidemia, as they reduce low-density lipoprotein cholesterol, although their mechanism for improving glycemic control is not well understood. No link with hypoglycemia has been found, but their usage is limited due to their modest efficacy, gastrointestinal side effects, pill burden, drug interactions, and potential for increasing triglycerides.

Others

GLP-1 receptor agonists – branded

Compared to other non-insulin drugs, GLP-1 receptor agonists have shown to be more effective at glycemic control. They have also been shown to be associated with reduced weight and blood pressure. However, a relatively high rate of nausea and vomiting has been

linked to the use of GLP-1 receptor agonists. While most GLP-1 receptor agonists are injected, the first oral formulation was approved in 2019 (Rybelsus). They tend to be used after patients have failed oral medications. The mechanism increases insulin secretion in the glucose-dependent, which means there is a lower risk of hypoglycemia. Warnings of hypoglycemia are still labeled when used with an insulin secretagogue such as SU or with insulin. There is also a black box warning for the class about the risk of thyroid C-cell tumors preclinically in the US. However, human relevance has not yet been determined. Their sales have been highly successful, primarily in the US, surpassing DPP-IV inhibitors.

Widely used class names include **Byetta**, which was the first approved drug in the class back in 2005, while **Victoza** has proven to have a moderately better glycemic efficacy during its approval several years later. **Bydreon** is an improvement of Byetta with twice-daily dosing, **Adlyxin** has a daily formulation but a limited duration of action, while **Trulicity** was approved in 2014 with a favorable profile compared to previously mentioned weekly drugs. **Ozempic** appears to be the most efficacious non-insulin drug approved and **Rybelsus** is an oral formulation of Ozempic approved in the US in 2019 and Europe and Japan in 2020. Notably, the GLP-1s only reach a limited group of patients due to their high costs (only around five percent).

DPP-IV inhibitors – branded

The DPP-IV inhibitors have been the most commonly used branded diabetes drugs still on patent thanks to their good safety and tolerability. Sales have been declining in the US owing to GLP-1 receptor agonists, and SGLT-2 inhibitors have overtaken them in usage. Outside the US, however, sales have been increasing modestly. No particular cardiovascular benefits have been linked to the use of DPP-IV inhibitors. Their effect is associated with blocking the DPP-IV enzyme. The inhibitor reduces the metabolism of GLP-1, a hormone that increases first-phase insulin secretion in a glucose-dependent manner and also suppresses the secretion of glucagon. Given the indirect mechanism, they have a more intermediate efficacy than GLP-1 receptor agonists, and thus no weight loss. The use of DPP-IV inhibitors is also more widespread in Japan. Branded drug examples include **Januvia**, which has taken the commercial lead among the DPP-IV inhibitors but will lose exclusivity in 2022 in the US and Europe. Other commonly used drugs are **Onglyza** and **Tradjenta**.

SGLT-2 inhibitors – branded

The use of SGLT-2 inhibitors is associated with the advantages of weight loss, blood pressure reduction, and efficacy in all stages of diabetes, seemingly with more robust glycemic control than DPP-IV inhibitors. However, they have a more disadvantageous side effect profile related to their mode of action. They increase glucose excretion by the kidneys, and so their glycemic efficacy depends on renal function. Side effects include conditions such as genitourinary infections, more frequent urination, and dizziness. The class can also cause diabetic ketoacidosis in patients concomitantly treated with insulin, possibly related to reduced insulin doses. The SGLT-2 inhibitors have been shown to be especially attractive in patients with cardiovascular diseases and as a primary prevention for patients at high risk. Commonly prescribed names in this class are **Invokana**, **Farxiga**, **Jardiance**, and **Steglatro**.

Summary of Side-effect profiles

Substance	Possible side-effects
Metformin	Gastrointestinal side effects (diarrhea, nausea, vitamin B12-deficiency)
SGLT-2 inhibitor	Increased risk of skeletal fractures, abdominal infections, hypotension raised LDL cholesterol, Fournier's gangrene
GLP-1	Gastrointestinal side effects, injection reactions acute pancreatitis, and C-Cell tumors of the tyroid gland
DPP-IV inhibitor	Acute pancreatitis and joint pain
Thiazolidinediones	Hypoglycemia, weight gain, heart failure, edema, bone fractures raised LDL cholesterol, and risk of bladder cancer
Sulfonureids	Hypoglycemia and weight gain

Source: Datamonitor, Company presentation

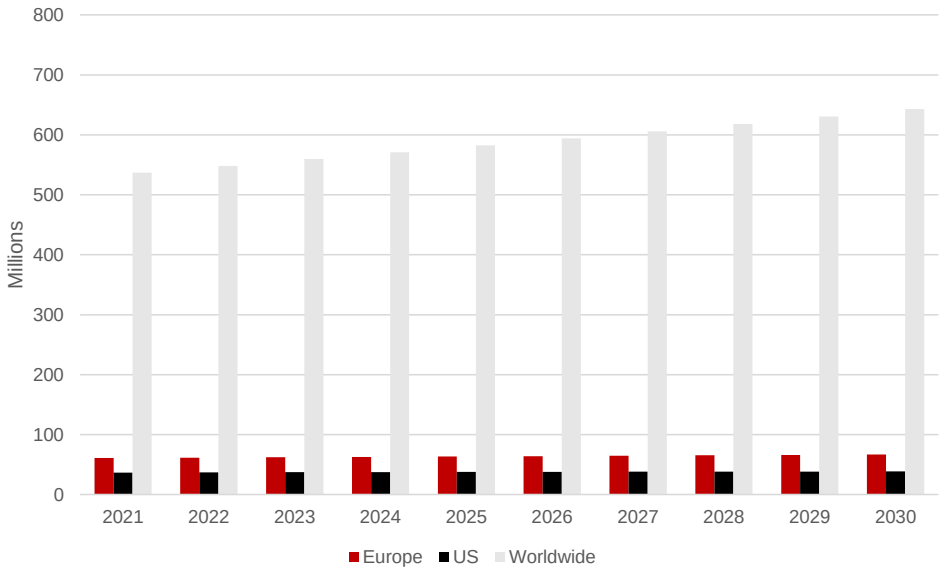
Summary

In our view, the so far discovered adverse events are by no means alarming given the safety profile of the currently approved drugs. The efficacy of XEN-D0501, potentially demonstrated in its phase IIb study, will be crucial for its competitiveness against the currently marketed drugs.

Epidemiology and Market Outlook

According to the International Diabetes Federation, there were ~540m prevalent cases of T2D worldwide in 2021, and it estimates this number to grow to ~643m by 2030, representing ~1.8 percent annual growth. Asia is believed to have had the most significant number of prevalent cases in 2018 at ~350m. Despite it being the region with the highest prevalence, the most significant market opportunities are found in the US and Europe, which we assume will be the regions that Pila targets. In a study published by the American Diabetes Association in 2018, care for people with diagnosed diabetes was estimated to account for one in four healthcare dollars spent in the US, with more than half of that expenditure directly attributable to diabetes.

Prevalent T2D cases in 20-85 year olds (millions)



Source: Datamonitor Healthcare, International Diabetes Federation

In 2021, there were roughly ~83m prevalent cases of T2D in the US and Europe, implying a significant market opportunity given a competitive drug profile. According to the International Diabetes Federation (IDF), the prevalence of T2D is expected to grow by around 20 percent until 2030. The broad range of therapeutics available and the significant prevalence indicates a continued substantial market opportunity for efficacious drugs.

According to research published by the American Diabetes Association, the global burden of diabetes in adults, including indirect causes, exceeded USD 1.5 trillion in 2015 and is expected to reach USD ~2.1-2.6 trillion in 2030. Billions of dollars are devoted to R&D within T2D annually by Big Pharma names such as Sanofi, Novo Nordisk, Merck & Co, and more – creating a challenging competitive landscape with an innovative pipeline.

At present, the highest-selling drugs for T2D includes several blockbusters, both in the form of subcutaneously injected drugs (GLP-1s and insulin) and orally administered small molecules. As illustrated below, Novo Nordisk has a strong position in the field, followed by other Big Pharma firms.

Highest-selling T2D drugs

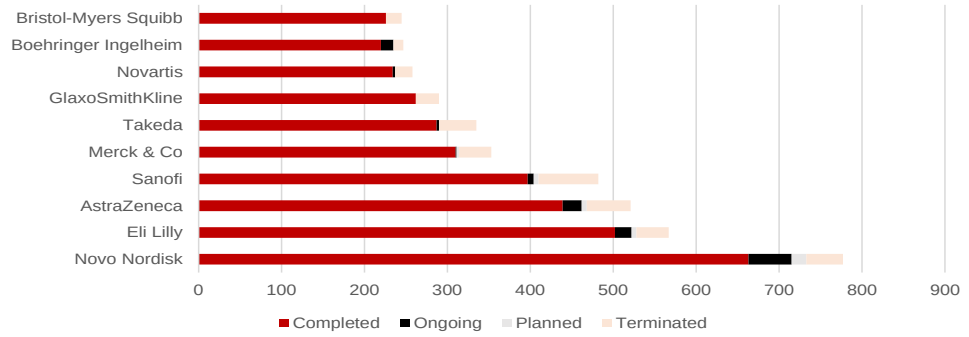
Worldwide sales (USDm)			2018	2019	2020
GLP-1 agonists					
Trulicity	Peptide	Eli Lilly	3 199	4 128	5 068
Ozempic	Peptide	Novo Nordisk	273	1 710	3 228
Victoza	Peptide	Novo Nordisk	3 703	3 338	2 853
Bydureon	Peptide	AstraZeneca	584	549	488
Rybelsus	Peptide	Novo Nordisk			285
Insulin					
Lantus	Peptide	Sanofi	4 034	3 408	3 011
Humalog	Peptide	Eli Lilly and Company	2 997	2 821	2 626
NovoLog	Peptide	Novo Nordisk	2 855	2 748	2 576
NovoLog Mix	Peptide	Novo Nordisk	1 443	1 459	1 466
Tresiba	Peptide	Novo Nordisk	1 223	1 409	1 365
Small Molecules					
Januvia	Small Molecule	Merck & Co	3 686	3 482	3 306
Jardiance	Small Molecule	Boehringer Ingelheim/Lilly	1 653	2 435	2 806
Janumet	Small Molecule	Merck & Co	2 228	2 041	1 970
Farxiga	Small Molecule	AstraZeneca	1 391	1 543	1 959
Tradjenta	Small Molecule	Boehringer Ingelheim/Lilly	1 581	1 764	1 711

Source: Biomedtracker

Clinical pipeline

The vast prevalence of T2D and the tremendous commercial opportunities have led to the development of dynamic and innovative pipeline projects. Looking at the contributors, Novo Nordisk is the giant in the field, followed by Eli Lilly, AstraZeneca, Sanofi, and other Big Pharma names.

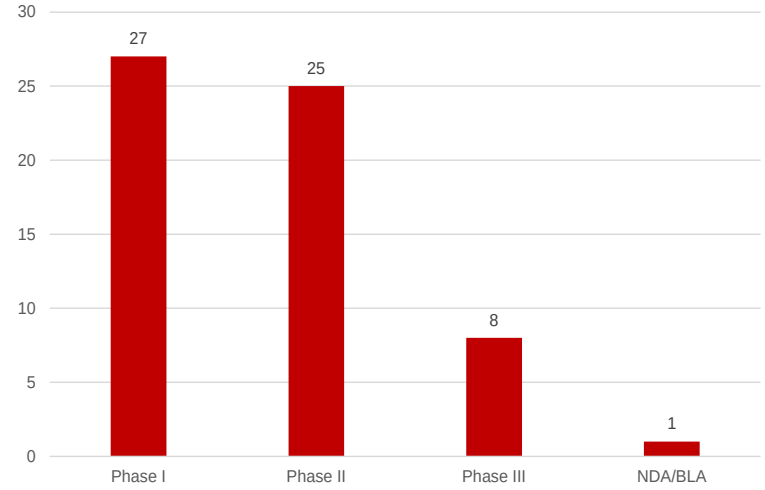
Conducted clinical studies

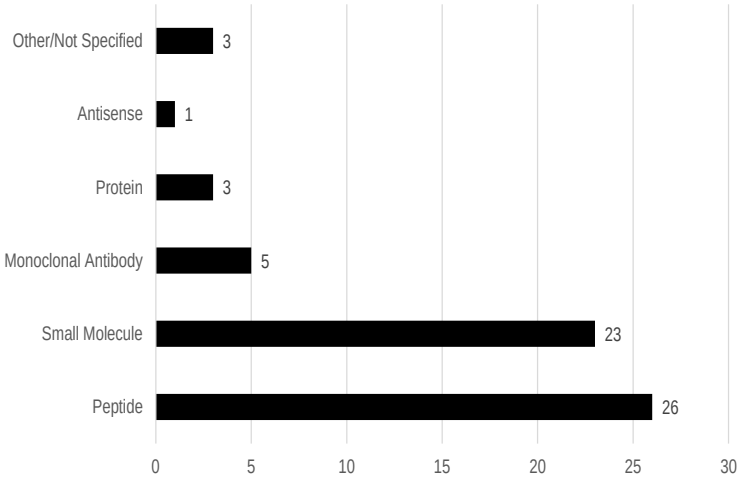


Source: Trialtrove October 2021

The clinical development pipeline is rich in content, with 45 companies currently conducting clinical studies on 61 assets. At present, Eli Lilly (six projects) and Novo Nordisk (four) have the widest presence. Below, we illustrate the current drug pipeline based on the development and drug class phase.

Current pipeline drugs





Source: Biomedtracker, October 2021

Comments on market possibilities

Based on our research of the T2D market and the clinical pipeline outlook, we consider the commercial landscape to be highly competitive with several established and widely used therapeutic options. In our view, XEN-D0501 will have to compete on two main attributes: efficacy and cost. As previously stated, this certainly creates a significant inflection point at the phase IIb trial readout, not least since TRPV1 antagonists are a new MoA for the treatment of T2D. However, due to the broad range of therapeutics and significant competition expected if XEN-D0501 reaches the market, we set our anticipated peak market share at five percent of diagnosed first-line patients, creating a substantial market opportunity.

Deals for T2D Projects and Deal Assumptions

Provided that XEN-D0501 presents positive efficacy data in its phase IIb study, Pila aims to sign a partnership deal with a larger pharmaceutical player that can take the compound through a phase III study. Moreover, in its Q3 2021 report, the company pointed out that it expects such a deal to be signed in 2024.

We have taken a deep dive into previous deals within the T2D space for small molecule new molecular entities (NMEs). Several deals have been signed in the field in recent years, and we list these for other small molecules, offering some insight into the prospects for XEN-D0501 from a deal point of view.

Relevant Small Molecule Deals T2D

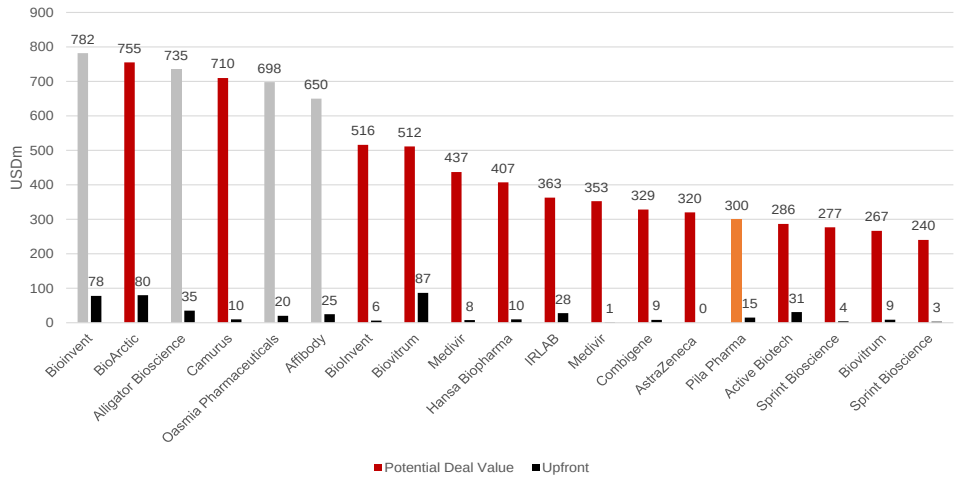
Licensee	Licensor	Phase	Molecule	Upfront (USDm)	Deal value (USDm)	Royalties
Sanofi	Lexicon Pharmaceuticals	III	Small molecule	300	1 720	low double digits
Roivant Sciences	Ligand Pharmaceuticals	II	Small molecule	20	549	10-16%
Islet Sciences	BHV Pharma	II	Small molecule	5	117	N/A
Sumitomo Dainippon	Poxel	II	Small molecule	42	299	escalating double-digit
Forest Laboratories	Transtech	II	Small molecule	50	1 110	N/A
Chiesi Farmaceutici	Phenomix	III	Small molecule	28	191	N/A

Source: Redeye Research, Datamonitor

Among these, there is a large variety of deal structures. However, the disclosure of terms is relatively scarce and some involved more than one asset or were in clinical development towards more than one indication, etc. Based on our findings and Pila's strong patent position, we find it reasonable to assume that the company could sign a deal in the range of low double-digit royalties (we assume 12 percent) with a deal value of some USD 250-350m (we assume USD 300m).

To add further context, we have compared our deal assumptions with previous licensing deals for Swedish biotechs, as illustrated below. (Those marked in grey were terminated prematurely.)

Largest licensing deals for Swedish biotechs, 2001-2021 (USDm)



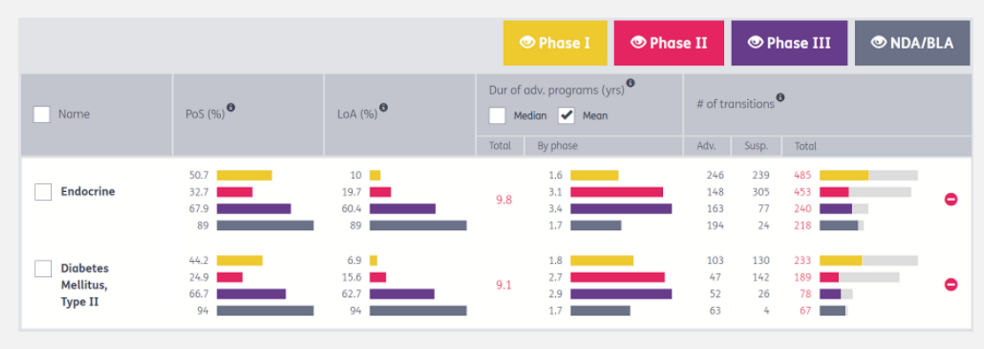
Source: Biomedtracker, Redeye Research

Probability of Success

Assessment of the probability of success (PoS) for a project is a process riddled with uncertainty, especially when factoring in Pila's novel approach towards T2D. We primarily base our assessment on the historical success rate for projects within T2D and endocrine diseases. The historical numbers for a phase II T2D project suggest a likelihood of approval (LoA) of ~16 percent, while the number is slightly higher at around 20 percent for endocrine diseases in general.

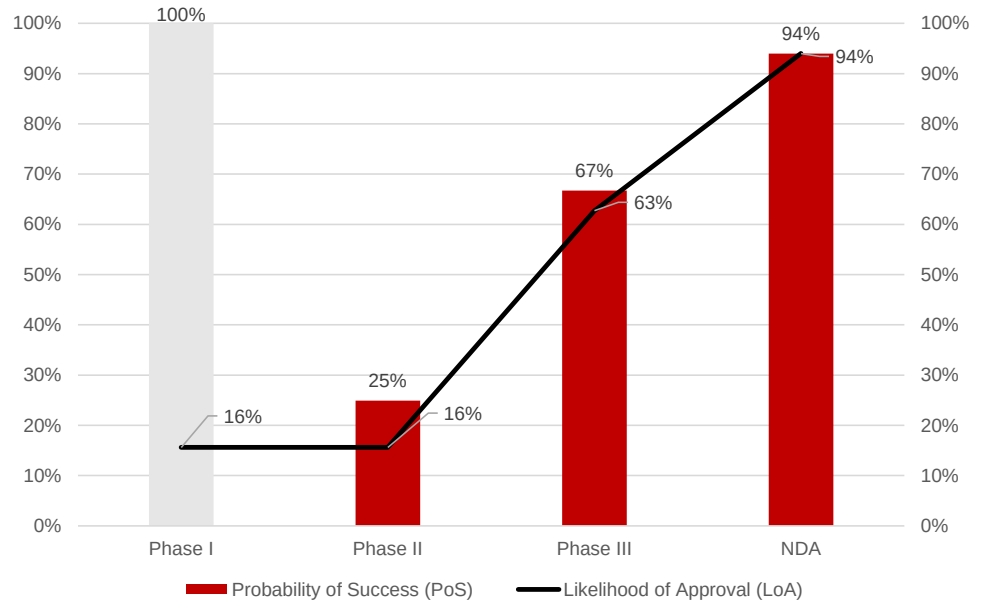
Based on the prospects for XEN-D0501, we have decided not to deviate from the historical PoS for T2D projects. We view this as a balanced approach, accounting for both the concluded solid safety profile and the elevated risk of being a first-in-class drug. We thus apply a PoS of 25 percent for the phase IIb trial, suggesting an LoA of 16 percent at the current stage, and we use this to risk-adjust our forecasted sales for Pila.

Probability of success in T2D pipeline



Source: Pharmapremia, October 2021

XEN-D0501's PoS/LoA



Source: Redeye Research, Pharmapremia

Financials

Operating Expenses (OPEX)

Operating expenses (OPEX) will primarily be driven by research and development in the coming years. Pila expects its phase IIb study to include 250-300 patients and to cost some SEK 120m. This implies that Pila is calculating costs of SEK ~0.45m per patient. These numbers are largely in line with historical figures for studies in endocrine diseases (see below). These figures should also include costs for preparation of the phase IIb trial (tox and API etc) and other costs related to study close and data analysis.

Total per-study costs by phase and therapeutic area (USDm)

Therapeutic Area	Phase 1	Phase 2	Phase 3	*Phase 1, 2, & 3 Subtotal [d]*	FDA NDA/BLA Review Phase [c]	Phase 4	Total [d]
Anti-Infective	$4.2 (5)	$14.2 (6)	$22.8 (5)	*$41.2 (3)*	$2.0	$11.0 (12)	**$54.2 (10)**
Cardiovascular	$2.2 (9)	$7.0 (13)	$25.2 (3)	*$34.4 (10)*	$2.0	$27.8 (4)	**$64.1 (6)**
Central Nervous System	$3.9 (6)	$13.9 (7)	$19.2 (7)	*$37.0 (6)*	$2.0	$14.1 (11)	**$53.1 (11)**
Dermatology	$1.8 (10)	$8.9 (12)	$11.5 (13)	*$22.2 (13)*	$2.0	$25.2 (7)	**$49.3 (12)**
Endocrine	$1.4 (12)	$12.1 (10)	$17.0 (9)	*$30.5 (12)*	$2.0	$26.7 (6)	**$59.1 (7)**
Gastrointestinal	$2.4 (8)	$15.8 (4)	$14.5 (11)	*$32.7 (11)*	$2.0	$21.8 (8)	**$56.4 (8)**
Genitourinary System	$3.1 (7)	$14.6 (5)	$17.5 (8)	*$35.2 (8)*	$2.0	$6.8 (13)	**$44.0 (13)**
Hematology	$1.7 (11)	$19.6 (1)	$15.0 (10)	*$36.3 (7)*	$2.0	$27.0 (5)	**$65.2 (5)**
Immunomodulation	$6.6 (1)	$16.0 (3)	$11.9 (12)	*$34.5 (9)*	$2.0	$19.8 (9)	**$56.2 (9)**
Oncology	$4.5 (4)	$11.2 (11)	$22.1 (6)	*$37.8 (5)*	$2.0	$38.9 (2)	**$78.6 (3)**
Ophthalmology	$5.3 (2)	$13.8 (8)	$30.7 (2)	*$49.8 (2)*	$2.0	$17.6 (10)	**$69.4 (4)**
Pain and Anesthesia	$1.4 (13)	$17.0 (2)	$52.9 (1)	*$71.3 (1)*	$2.0	$32.1 (3)	**$105.4 (2)**
Respiratory System	$5.2 (3)	$12.2 (9)	$23.1 (4)	*$40.5 (4)*	$2.0	$72.9 (1)	**$115.3 (1)**

Source: Report submitted to the U.S. Department of Health and Human Services

Assuming a similar cost per patient for a phase III study suggests a cost of some SEK ~2bn, assuming more than 4,000 patients. We thus argue that Pila needs to find a partner to finance a pivotal phase III study.

We make the following forecasts for Pila's opex in the coming years. Despite its development advancement, the company's slim structure should entail moderate opex growth. We expect opex for the coming years to primarily be driven by the R&D costs related to the PK study and phase IIb trial. We expect a larger cost expenditure with Pila as a listed company, but the rapid increase in 2021 is largely attributable to listing costs and preparation for the IPO (SEK 3.2m). We thus assume that Pila will hire more staff and see moderate SG&A growth in the coming years as development progresses.

2018-2024 OPEX Redeye Estimates

SEKm	2018	2019	2020	2021E	2022E	2023E	2024E
SG&A	2,0	2,6	4,2	8,8	8,3	10,0	12,5
Growth %	*N/A*	*28%*	*61%*	*110%*	*-5%*	*20%*	*25%*
R&D	2,9	2,4	0,5	0,0	24	84	12
Growth %	*N/A*	*-17%*	*-80%*	*-95%*	*88789%*	*250%*	*-86%*
Employees (Full Time)	1	1	3	5	7	9	10
OPEX	**5**	**5**	**5**	**9**	**32**	**94**	**25**

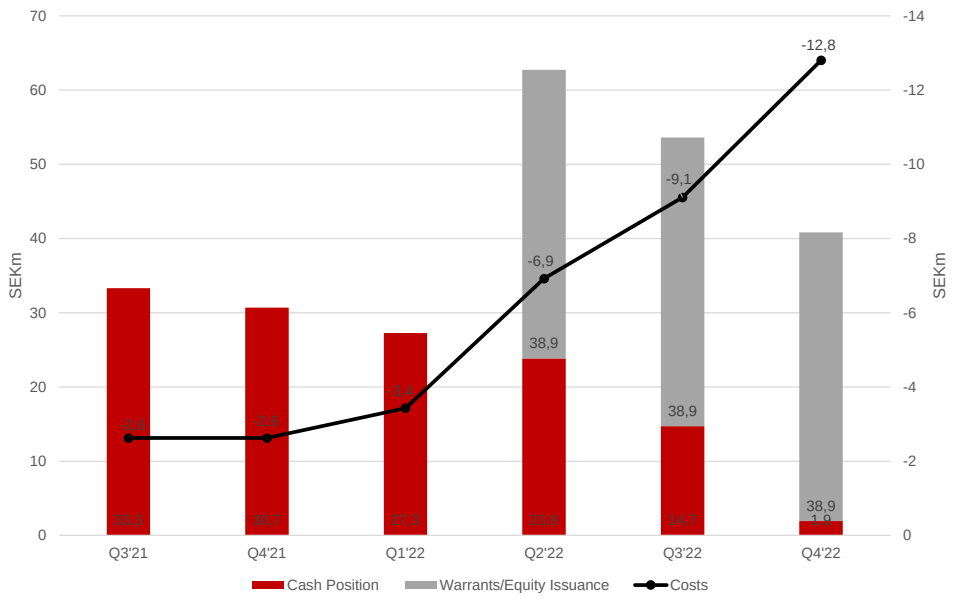
Source: Redeye Research

Cash Position

In its Q3 2021 report, Pila reported a cash position of SEK 33.3m. Based on its current prospects, we refrain from including the warrant exercise in our valuation of Pila because, despite our Base Case exceeding the subscription price, we cannot identify any particular catalyst to close the valuation gap before the exercise period in May/June 2022. We assume that it might not be subscribed and that Pila would then have to solve its financing needs via other options. Our valuation of Pila thus accounts for no dilution regarding the warrants or anticipated rights issue at the end of 2022 or in early 2023. Instead, we increase our WACC by one percent flat to account for the current financing uncertainty. Stronger biotech stock sentiment or unexpected good news could prompt us to review these assumptions.

Below we illustrate the estimated cash position until year-end 2022 and anticipate the potential cash position should the warrants be exercised.

Estimated capital need



Source: Redeye Research

The TO1 warrant program gives the right to subscribe to one new Pila share at a price of SEK 10 between 23 May and 3 June 2022, possibly raising another SEK ~39m before issuance costs.

XEN-D0501 Sales Model

Our sales model assumes that XEN-D0501 is launched in the US and EU5 (Germany, Italy, France, Spain, and the UK). These markets share a similar regulatory framework for bringing drugs to market. Based on Datamonitor's estimates, we assume that ~85 percent of prevalent T2D patients are diagnosed. We find support for 50 percent of diagnosed patients being eligible and needing first-line treatment in the US and EU5. This suggests an addressable population of ~21m patients in 2027, which is when we assume XEN-D0501 could be launched.

Pricing

To determine a price for XEN-D0501, we primarily look at the currently marketed other small molecule first-line treatments for T2D. In our view, the properties of XEN-D0501 will likely position it as a first-line treatment to be used with or after metformin. Due to the significant pricing range, considerable competition, and Pila's stated low-cost strategy, we take a conservative stance on pricing. We assume Pila will position XEN-D0501 at the lower end of the range so as to increase competitiveness. We regard reasonable annual pricing of around USD 1,500 in the US and some USD 400 in EU5, positioning it between metformin and other early-line small molecules.

Peer T2D pricing

Average annual drug cost $										
	Small molecules				GLP-1 Agonists			Insulin		
	Metformin	**Januvia**	**Jardiance**	**Janumet**	**Byetta**	**Ozempic**	**Victoza**	**Lantus**	**Humalog**	**NovoMix**
US	106	6 061	6 692	6 061	9 489	11 132	10 332	2 530	3 226	5 370
EU5	53	485	595	488	1 133	1 283	1 520	235	216	388

Source: Datamonitor Healthcare, Medical Expenditure Panel Survey 2013-2019

XEN-D0501 sales estimates model

XEN-D0501		2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
US																					
T2D prevalence			27,1	27,4	27,8	28,1	28,4	28,7	29,0	29,3	29,6	30,0	30,3	30,7	31,1	31,4	31,8	32,2	32,6	32,9	33,3
Treated patients	85%																				
First-line patients	50%																				
Adressable population			11,3	11,5	11,6	11,8	11,9	12,0	12,1	12,3	12,4	12,5	12,7	12,8	13,0	13,2	13,3	13,5	13,6	13,8	13,9
Launch curve								0,05	0,10	0,25	0,50	0,70	0,90	1,00	1,00	1,00	0,90	0,75	0,55	0,20	0,05
Market share	5%							0,2%	0,5%	1,2%	2,5%	3,5%	4,5%	5,0%	5,0%	5,0%	4,5%	3,7%	2,7%	1,0%	0,2%
Treated patients (mn)								0,03	0,06	0,15	0,31	0,44	0,57	0,64	0,64	0,65	0,59	0,50	0,37	0,14	0,03
Compliance Rate	80%																				
Annual drug cost ($)	1 500																				
Sales ($m)								**35,5**	**71,8**	**181,4**	**366,7**	**519,5**	**675,8**	**759,8**	**768,8**	**777,9**	**708,4**	**597,3**	**443,2**	**163,1**	**41,3**
Royalties	12%							4,3	8,6	21,8	44,0	62,3	81,1	91,2	92,3	93,3	85,0	71,7	53,2	19,6	5,0
EU 5																					
T2D prevalence			18,4	18,6	18,8	19,1	19,3	19,5	19,7	19,9	20,1	20,3	20,5	20,8	21,0	21,2	21,4	21,7	21,9	22,2	22,4
Treated patients	85%																				
First-line patients	50%																				
Adressable population			7,7	7,8	7,9	8,0	8,1	8,1	8,2	8,3	8,4	8,5	8,6	8,7	8,8	8,9	9,0	9,1	9,2	9,3	9,4
Launch curve								0,05	0,10	0,20	0,40	0,55	0,75	0,85	1,00	1,00	0,90	0,75	0,55	0,20	0,05
Market share	5%							0,2%	0,5%	1,0%	2,0%	2,7%	3,7%	4,2%	5,0%	5,0%	4,5%	3,7%	2,7%	1,0%	0,2%
Treated patients (mn)								0,02	0,04	0,08	0,17	0,23	0,32	0,37	0,44	0,44	0,40	0,34	0,25	0,09	0,02
Compliance Rate	80%																				
Annual drug cost ($)	400																				
Sales ($m)								**6,4**	**13,0**	**26,2**	**53,0**	**74,1**	**101,2**	**116,4**	**138,5**	**140,0**	**127,4**	**107,3**	**79,6**	**29,2**	**7,4**
Royalties	12%							0,8	1,6	3,1	6,4	8,9	12,1	14,0	16,6	16,8	15,3	12,9	9,5	3,5	0,9
Worldwide Sales($m)								**42**	**85**	**208**	**420**	**594**	**777**	**876**	**907**	**918**	**836**	**705**	**523**	**192**	**49**
Worldwide Royalties ($m)								5	10	25	50	71	93	105	109	110	100	85	63	23	6

Source: Redeye Research, Datamonitor

We assume that XEN-D0501 will be launched in 2027, with peak sales 8 years after launch after reaching some 5 percent market penetration. This sales ramp-up stems from the findings of Robey et al., 2017, which investigated the time required for different drugs to reach peak sales between 2000 and 2002. We assume a slightly lower sales ramp-up owing to a more fragmented market in Europe. We assume sales erosion before patent expiry because of the competitive nature of this area and ongoing competition from new drugs plus existing efficacious drugs going off patent.

Valuation

We perform a project-specific valuation of Pila Pharma based on a discounted cash flow (DCF) model with risk adjustments. Our model uses a weighted average cost of capital (WACC) of 14 percent, based on our proprietary Redeye Rating model and including additional premium of one percent due to future financing uncertainty. The premium is mainly attributable to the uncertainty regarding the subscription of the TO1, as we are concerned that no particular short-term catalyst is likely to close the valuation gap until the subscription period ends. However, once the phase IIb financing is taken care off we will lower our WACC to 13 percent.

Our assumptions suggests a fair value for Pila Pharma of SEK 189m or SEK 12 per share.

Pila Pharma: Valuation

XEN-D0501		2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
				Phase IIb		Phase III		NDA		>100m	>250m	>500m									
Sales (Worldwide)																					
Royalties ($m)						0	0	5	10	25	50	71	93	105	109	110	100	85	63	23	6
Probability	16%																				
Risk-adjusted sales ($m)						0	0	1	2	4	8	11	15	16	17	17	16	13	10	4	1
Risk-adjusted sales (SEKm)	**9,0**					**0**	**0**	**7**	**14**	**35**	**71**	**100**	**131**	**148**	**153**	**155**	**141**	**119**	**88**	**32**	**8**
Milestones / Grants ($m)					15		75	30		45	60	90									
Risk-adjusted milestones ($m)					4		12	5		7	9	14									
Risk-adjusted milestones (SEKm)	**9,0**				**34**		**112**	**42**		**63**	**84**	**126**									
COGS % of sales	10%																				
COGS								-1	-1	-3	-7	-10	-13	-15	-15	-15	-14	-12	-9	-3	-1
R&D			-24	-84	-12																
R&D, risk-adjusted			-24	-84	-12																
SG&A as % of sales	20%							-1	-3	-7	-14	-20	-26	-30	-31	-31	-28	-24	-18	-6	-2
Risk-adjusted value (SEKm)		0	-24	-84	22	0	112	47	10	88	134	196	92	103	107	108	99	83	62	23	6
tax		0	0	0	0	0	0	0	-2	-18	-28	-40	-19	-21	-22	-22	-20	-17	-13	-5	
Risk-adjusted value, post tax (SEKm)		0	-24	-84	22	0	112	47	8	70	106	156	73	82	85	86	78	66	49	18	6
WACC	14%																				
Net Present Value (rNPV)		0	-21	-64	14	0	57	21	3	23	31	40	16	16	15	13	10	8	5	2	0

Total rNPV	189
SO	16,1
Base case	**12**

Source: Redeye Research

Bear Case 2 SEK

In our Bear case, we assume that XEN-D0501 shows disappointing efficacy in the phase IIb-trial in T2D patients.

Consequently, we assume that the company will not take the asset through further development and so we value Pila equal to its current book value.

Base Case 12 SEK

In our Base Case, we apply the historical average PoS for XEN-D0501 and assuming that the asset shows an encouraging outcome in the phase IIb-trial, we assume that Pila will sign with a partner that can take XEN-D0501 through a phase III trial.

We make the following partnering assumptions.
Deal value: USD 300m
Upfront: USD 15m
Royalties: 12 percent

Bull Case 30 SEK

In our optimistic scenario, we assume that the previous clinical evidence for XEN-D0501 entails a higher likelihood for a positive outcome in the crucial phase IIb-trial in T2D patients and set the PoS at 50 percent. This substantially increases the LoA for XEN-D0501 to 31 percent. We also assume that a partner can finance the phase III-trial.

Partnering assumptions.
Deal value: USD 400m
Upfront: USD 20m
Royalties: 15 percent

Sensitivity Analysis

The discount rate (WACC) reflects risks related to the company and the market. The WACC is used when calculating the discounted cash flow and significantly impacts our DCF valuation. Below we illustrate the impact of WACC changes to our Base Case.

Sensitivity Analysis

Pila Pharma	WACC				
	12%	13%	**14%**	15%	16%
Base case	15	14	**12**	11	10

Source: Redeye Research

Peer Comparison

Despite its limitations, our peer comparison provides an additional take on Pila's valuation compared to other Swedish small cap biotechs targeting T2D/T1D or at a similar development stage.

A cohort of peer companies

Company name	Phase	Lead indication	Candidates*	Net debt	EV
Cereno Scientific	II	PAH	1	-19	508
Cyxone	II	RA	2	-43	145
Initiator Pharma	II	ED	3	-39	311
Respiratorius	II	DLBCL	1	-34	203
QuiaPEG Pharmaceutical	Preclin	T2D	-	-2	36
NextCell Pharma	II	T1D	1	-139	143
Scandion Oncology	II	Colorectal cancer	1	-160	282
		Median EV	**203**		
		Average EV	233		
Pila Pharma	**II**	**T2D**	**1**	**-32**	**84**

Source: Factset, Redeye Research

In our view, the peer comparison adds further support to our DCF valuation of Pila. The median EV of the peer group is SEK ~200m, aligning well with our DCF value for Pila Pharma of SEK ~190m, or SEK 12 per share.

Appendix

Use patents

Market	Description	Patent number	Acquired	Protectection
USA	Capsaicin-inhibitors for treatment of obesity and related diseases	7.879.866	2005-07-18	2026
EPO		1771162	2005-07-18	-
USA		8.455.504	2005-07-18	2026
France		1771162	2005-07-18	2025
Germany		1771162	2005-07-18	2025
UK		1771162	2005-07-18	2025

Product patents

Market	Description	Patent number	Acquired	Protectection
Australia	TRPV1-Agonists	2,003E+09	2003-04-28	2023
Canada		2.487.238	2003-04-28	2023
China		ZL 03815988.0	2003-04-28	2023
EPO		1506167	2003-04-28	-
India		252607	2003-04-28	2023
Japan		4335131	2003-04-28	2023
USA		7.612.113	2003-04-28	2024
France		1506167	2003-04-28	2023
Germany		1506167	2003-04-28	2023
Ireland		1506167	2003-04-28	2023
Italy		1506167	2003-04-28	2023
Netherlands		1506167	2003-04-28	2023
Spain		1506167	2003-04-28	2023
Switzerland		1506167	2003-04-28	2023
UK		1506167	2003-04-28	2023

Source: Pila Pharma

Currently, Pila has the use patents for capsaicin inhibitors to treat obesity and related diseases until 2026. This means that the company has a monopoly right to use these inhibitors for these diseases until 2026. In our view, this gives Pila a remarkably strong patent situation provided the authorities granted the company its substance patent for XEN-D0501 (recently filed). If approved in 2022, the company will have protection for the compound until 2042.

Summary Redeye Rating

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

Rating changes in the report

People: 3

Professionals with appropriate clinical and commercial experience populate Pila's management and board. Most notable is CEO Dorte X. Gram, who has devoted her career to research with TRPV1 antagonists for the treatment of T2D. Moreover, she demonstrates her conviction in Pila's trajectory with her ~30 percent ownership of the equity in the company.

Business: 2

The field of T2D is not short of competition. However, Pila has a novel approach and currently holds the patent for the use of capsaicin inhibitors to treat obesity and related diseases, which translates into a very strong IP position, provided it can demonstrate competitive and statistically significant efficacy for T2D patients.

Financials: 1

Pila is an unprofitable pre-revenue company with ongoing clinical development for several years before cash flow from product sales could become positive. Until operating cash flow can potentially finance the company's operations, Pila will be required to raise capital to fund its operations and development. Thus, investors should be aware that future dilution is expected. However, if approved and marketed, XEN-D0501 could generate significant cash flows and substantial profitability. In our estimates, Pila could become cash flow positive in 2027.

	2020	2021E	2022E	2023E
INCOME STATEMENT				
Revenues	0	0	0	0
Cost of Revenues	0	0	0	0
Gross Profit	0	0	0	0
Operating Expenses	3	9	32	93
EBITDA	-3	-9	-32	-93
Depreciation & Amortization	0	0	0	0
EBIT	-3	-9	-32	-94
Net Financial Items	0	0	1	1
EBT	-7	-9	-32	-93
Income Tax Expenses	0	0	0	0
Non-Controlling Interest	0	0	0	0
Net Income	-7	-9	-32	-93
BALANCE SHEET				
Assets				
Current assets				
Cash & Equivalents	2	25	25	25
Inventories	0	0	0	0
Accounts Receivable	0	0	0	0
Other Current Assets	0	0	0	0
Total Current Assets	2	25	25	25
Non-current assets				
Property, Plant & Equipment, Net	0	0	0	0
Goodwill	0	0	0	0
Intangible Assets	3	3	3	3
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	3	3	3	3
Total Assets	5	28	28	28
Liabilities				
Current liabilities				
Short-Term Debt	0	25	56	149
Short-Term Lease Liabilities	0	0	0	0
Accounts Payable	0	0	0	0
Other Current Liabilities	2	0	0	0
Total Current Liabilities	2	25	56	149
Non-current liabilities				
Long-Term Debt	0	0	0	0
Long-Term Lease Liabilities	0	0	0	0
Other Long-Term Liabilities	0	0	0	0
Total Non-current Liabilities	0	0	0	0
Non-Controlling Interest	0	0	0	0
Shareholder's Equity	3	3	-29	-121
Total Liabilities & Equity	5	28	28	28
CASH FLOW				
NOPAT	-3	-9	-32	-94
Change in Working Capital	2	-2	0	0
Operating Cash Flow	-2	-11	-31	-93
Capital Expenditures	0	0	0	0
Investment in Intangible Assets	0	0	0	0
Investing Cash Flow	0	0	0	0
Financing Cash Flow	0	34	31	93
Free Cash Flow	-2	-11	-31	-93

DCF Valuation Metrics	**Sum FCF (SEKm)**
Initial Period (2021–2040)	156
Firm Value	156
Net Debt	-33
Equity Value	188,6
Fair Value per Share	12

	2020	2021E	2022E	2023E
CAPITAL STRUCTURE				
Equity Ratio	95%	96%	neg	neg
Debt to equity	0,0	7,8	-2,0	-1,2
Net Debt	-1,9	-0,1	31,4	124,0
Working Capital Turnover	0,0	2,0	3,0	4,0
GROWTH				
Revenue Growth	N/A	N/A	N/A	N/A
Basic EPS Growth	N/A	N/A	N/A	N/A
Adjusted Basic EPS Growth	N/A	N/A	N/A	N/A
PROFITABILITY				
ROE	N/A	N/A	N/A	N/A
ROCE	N/A	N/A	N/A	N/A
ROIC	N/A	N/A	N/A	N/A
EBIT Margin (%)	N/A	N/A	N/A	N/A
Net Income Margin (%)	N/A	N/A	N/A	N/A
VALUATION				
Basic EPS	neg	neg	neg	neg
P/E	neg	neg	neg	neg
EV/Revenue	neg	neg	neg	neg
EV/EBIT	neg	neg	neg	neg

SHAREHOLDER STRUCTURE	**CAPITAL %**	**VOTES %**
Dorte X. Gram	31%	31%
Vimpu Intressenter AB	11%	11%
ALMI	10%	10%
Nordnet Pensionsförsäkring	3%	3%
Avanza Pension	2%	2%

SHARE INFORMATION	
Reuters code	PILA
List	First North
Share price	6,8
Total shares, million	16,10034

MANAGEMENT & BOARD	
CEO	Dorte X. Gram
CFO	Elna Lembrér Åström
Chairman	Fredrik Buch

ANALYSTS	Redeye AB
Filip Einarsson	Mäster Samuelsgatan 42, 10tr
Erik Nordström	111 57 Stockholm

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 people behind a business is a significant part of understanding the long-term drive 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

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Redeye Rating (2021-12-16)

Rating	People	Business	Financials
5p	32	15	4
3p - 4p	142	128	43
0p - 2p	5	36	132
Company N	179	179	179

Duplication and distribution

CONFLICT OF INTERESTS

Filip Einarsson owns shares in the company: No
Erik Nordström owns shares in the company: No
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