

Egetis Therapeutics

Sector: Biotech

An Attractive Late-Stage Orphan Drug Play

Redeye raises its base case for Egetis by almost 60 percent after a closer look at the project pipeline following the merger with Rare Thyroid Therapeutics (RTT). In our view, the current valuation does not fully reflect the transformation into a late-stage orphan drug developer or the quality of the portfolio. We see a high likelihood that flagship project Emcitate could become the first approved treatment for MCT8 deficiency, an ultra-rare severe thyroid hormone disorder, and a potential USD 1bn+ market.

Funded to Reach Critical Clinical Milestones

We are optimistic for the outlook for Emcitate based on i) convincing evidence in a proof of concept Phase II study, published in *The Lancet* in 2019 ii) a high unmet medical need iii) high pricing in the orphan drug space. We assume a 70 percent likelihood of approval and peak sales of USD 360m in our base case. Following the capital raise, Egetis has about SEK 300m in cash, which we predict is enough to run focused pivotal clinical trials for both the Emcitate and Aladote projects, with crucial readouts expected in H2 2022.

USD 100m “Prize” Looms at the Finishing Line

Suppose FDA approves Emcitate in the pediatric setting in the US. In that case, it will grant Egetis a Rare Pediatric Disease Priority Review Voucher (PRV), a transferable right to “cut the line” in the FDA review process with a market value of about USD 100m (Egetis share: 50 percent). In turn, a PRV sale could provide significant capital to finance the eventual commercialization of Emcitate starting in 2023-24.

Favorable Deal Characteristics

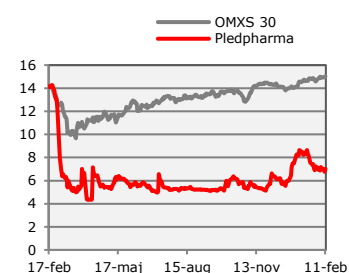
The small but experienced RTT team adds significant quality, and the former RTT CEO is now the largest owner of Egetis. We believe the deal structure sends a good signal as a large part of the payment to the RTT sellers is earnout contingent on regulatory milestones and sales volumes down the road. We calculate a risk-adjusted base case value of SEK 19, meaning 100+ percent upside, which we argue is supported to some extent by relative valuation. If the study readouts are positive, we see a potential of up to SEK 40 in 18-24 months (bull case). While the crucial catalysts for Emcitate are some time off, the expected initiation of the Aladote trial in H1 2021 (timing dependent on pandemic situation) could support share sentiment.

KEY FINANCIALS (SEKm)	2018	2019	2020E	2021E	2022E	2023E
Net sales	28	83	39	5	5	5
EBITDA	-93	-70	-121	-64	-119	-184
EBIT	-93	-70	-121	-64	-119	-184
EPS (adj.)	-1.7	-1.1	-0.7	-0.4	-0.7	-1.1

FAIR VALUE RANGE

BEAR	BASE	BULL
8.0	19.0	40.0

Pled.st VERSUS OMXS30



REDEYE RATING



KEY STATS

Ticker	Egtx.st
Market	Small Cap
Share Price (SEK)	6.9
Market Cap (MSEK)	1141
Net Debt 21E (MSEK)	-299
Free Float	70 %

ANALYSTS

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An Attractive Late-Stage Orphan Drug Play

We believe it is safe to say the tie-up with Rare Thyroid Therapeutics (RTT), announced on 5 October 2020 and closed on 3 November, was transformative for PledPharma. The future development of the previous flagship asset PledOx was already in the balance following the Phase III POLAR program's premature termination due to safety observations (severe allergic-hypersensitivity reactions observed after repeated treatment in a few cases). In December, the new entity renamed Egetis reported that the primary endpoint of reduced risk for chemotherapy-induced neuropathy was not met (at dose 5 µmol/kg). Egetis, together with partner Solasia, will review the plans for further development. Still, we fear the project has reached a dead-end and do not include it in our valuation assumptions going forward.

Our Valuation Focuses on Emcitate and Aladote

The acquisition of RTT brings in the late-stage project Emcitate, in development for the treatment of ultra-rare genetic hormone disorder MCT8-deficiency, alongside PledPharma's Aladote (calmangafodipir) for treatment of paracetamol poisoning. We will review these projects in further detail below.

PledPharma paid some SEK 400m upfront (SEK 60m in cash and 63.8m in newly issued stock at SEK 5.25 per share) for RTT. The sellers are also entitled to low single-digit royalties (three percent) on future net sales of Emcitate and 50 percent of the net proceeds from a potential sale of a so-called U.S Rare Pediatrics Disease Priority Review Voucher. We do not believe the transaction value is representative of the value of Emcitate in a well-financed structure. On the contrary, as we calculate a total addressable market of some USD 1bn for Emcitate, with no competition, we view the price tag as favorable for the old Pledpharma shareholders.

Looking into the details, we believe the deal structure sends a good quality signal. The sellers accepted an upfront payment mostly in stock in the combined entity. Following the directed issue and the subsequent capital raise of SEK 250m in the autumn of 2020, the three largest owners in former RTT will own some 35 percent of the new entity. Hence, they will share risk and upside with shareholders of the old PledPharma.

Orphan Drug Credentials

As in any merger situation, the people factor is an essential aspect. While RTT was a small organization, we think it adds vital experience in drug development and commercialization of, e.g., orphan drugs.

New Largest Owner Signals Commitment

Former CEO of RTT, Peder Walberg, is now the largest owner of Egetis (some 19 percent). Our impression is that he will be closely involved in the operations both as a board member of Egetis and currently acting Chief Medical Officer.

The second-largest owner is Avla Holding, controlled by Kennet Rooth, former Chairman of RTT. Both Kennet Rooth and Peder Walberg were part of the executive management team of Swedish Orphan and subsequently SOBI. Mr. Rooth was also the interim CEO of SOBI in 2011. He has a long career working for Bristol Myers-Squibb in various senior international positions, e.g., with the commercialization of psychiatry drug Abilify (peak sales over USD 7bn).

The three largest previous owners of RTT have agreed to a lock-up of twelve months for 100 percent of their holdings in Egetis and 24 months for 75 percent of the holdings.

Ownership

Ownership structure as of 31 Dec, 2020	Holdings	Capital
Peder Walberg	31 858 414	19.3%
Avla Holding AB	16 572 442	10.0%
Fjärde AP-fonden	14 311 300	8.7%
Peter Lindell	12 201 219	7.4%
Staffan Persson	11 300 629	6.9%
RegulaPharm AB	9 846 730	6.0%
Nyenburgh Holding B.V.	3 735 583	2.3%
Avanza Pension	3 571 010	2.2%
Thomas Eldered	2 251 674	1.4%
Mats Blom	1 988 227	1.2%
Others	57 431 332	34.8%
Total	165 068 560	100.0%

Source: Holdings

A Proven Track Record from the Orphan Drug Sector

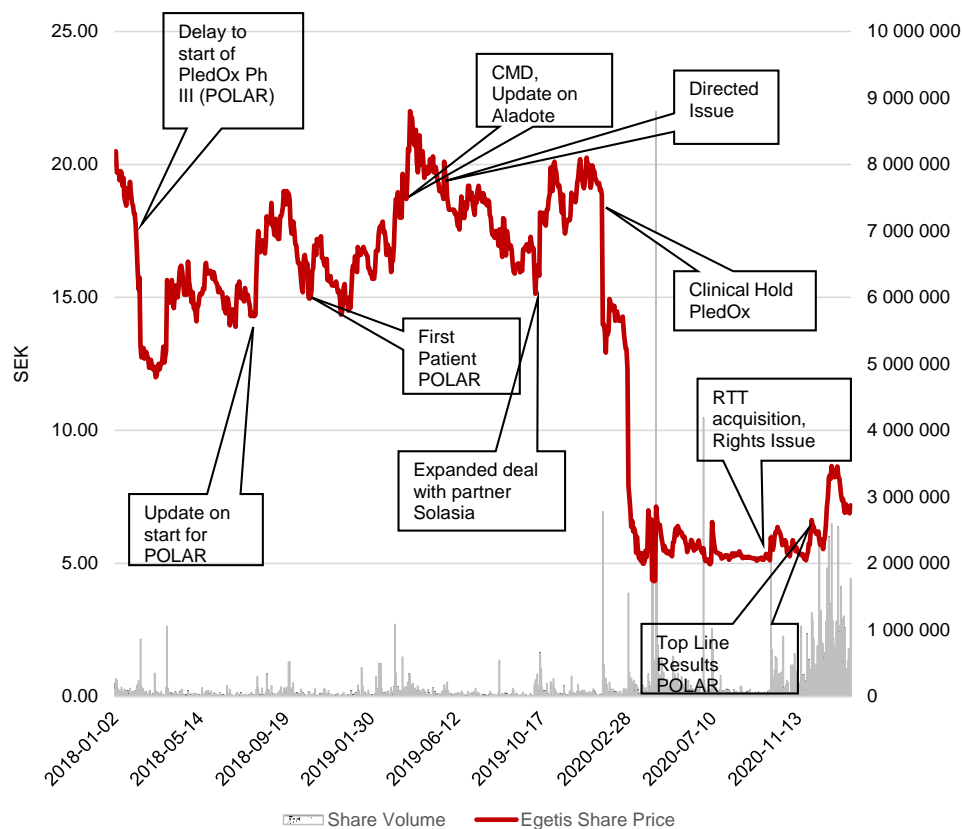
Peder Walberg has extensive experience from partnering, drug development, and commercialization in the orphan drug space, from Novartis, Swedish Orphan (head of business development), and Medical Need Europe (founder and CEO). At the time of the merger with Biovitrum, Swedish Orphan had a proven track record of commercialization in Europe. Walberg was involved in the European commercialization of orphan drugs such as Orfadin (treatment of rare metabolic disorder Tyrosinemia Type I) and Yondelis (soft tissue sarcoma) with European sales of about USD 100m. At Medical Need Europe, Walberg acquired the European rights to de-coppering agent Decuprate, repurposed it from oncology to the rare orphan condition Wilson's disease and later co founded and divested the rights to Wilson Therapeutics, who initiated Phase III development before Alexion acquired Wilson in 2018 for USD 855m.

In short, the RTT team has "done it before." Recently, Egetis also hired Henrik Krook as Vice President, Commercial Operations, previously at, e.g., Novartis, Medivir, and Alexion. Arguably, the organization still lacks commercialization experience from the U.S.

Share Price Performance

The last twelve months have been a bumpy ride for shareholders. The Phase III POLAR program for lead candidate PledOx in chemotherapy-induced neuropathy was discontinued due to safety observations, prompting shares to drop by some 75 percent. However, behind the scenes, the Egetis board and management had already planned to broaden into the orphan drug space and in October pulled a rabbit out of the hat and announced the acquisition of Rare Thyroid Therapeutics. In the months since shares have rebounded some 40 percent.

Egetis Share Price Development



Source: Bloomberg, Redeye

We believe the improved sentiment reflects a growing perception among investors that RTT brings significant business quality to Egetis. Further, the rights issue in November strengthened the financials.

Key Catalysts

Initiation of Pivotal Aladote Study. Egetis plans to initiate the Phase II/III trial for Aladote in H1, 2021, pending approval of clinical trial applications. As hospital resources are constrained due to the Covid-19 pandemic, and since Aladote will be studied in the acute/intensive care setting, there is a risk that Egetis will have to delay the start.

Clinical Updates. The investigators will conduct interim analyses halfway through both the Emticate and Aladote trials. We expect this will occur in H2, 2022. We view the interim readouts as crucial value inflection points, where our bull case scenario reflects a positive outcome.

Counter Thesis

Risk of Clinical Delays. Recruitment in rare/niche disorders is challenging. Egetis targets smaller subgroups (young children and high-risk paracetamol overdose patients) where the enrolment rate is difficult to predict. Despite a close collaboration with KOLs in the respective fields, recruitment may take longer and be more expensive than planned.

Market Potential May Materialize Slower than Expected. MCT8 deficiency is currently underdiagnosed, and there is a risk that the low diagnosis rates prevail until broader screening for thyroid disorders in infants is adopted.

Emcitate, The New Flagship Project

Emcitate (3,3',5-triiodothyroacetic acid; also known as tiratricol) is a natural thyroid hormone metabolite that works as an analog to the thyroid hormone triiodothyronine. It has been approved in France as an adjuvant therapy to thyroid cancer treatment. In 2018, Rare Thyroid Therapeutics acquired all rights to tiratricol and has subsequently pulled the drug off the market. Emcitate is off-patent but has been granted Orphan Drug Designation for the treatment of patients with MCT8 deficiency by the EMA and the FDA.

A Devastating Thyroid Disorder

Thyroid hormones are responsible for the regulation of metabolism. Two forms exist, triiodothyronine (T₃) and thyroxine (T₄). They act on almost all cells in the body. T₃ regulates, e.g., basal metabolic rate, cardiac rate and potentiates brain development and function via thyroid hormone receptors in the cells but cannot passively cross the cell membrane.

Thyroid Hormone Imbalance Affects Brain Development, Metabolism

In MCT8 deficiency, a genetic disease also known as Allan–Herndon–Dudley syndrome (AHDS), the influx of thyroid hormones into cells in the central nervous system is crucially impaired due to lack of the transmembrane transporter protein MCT8. In other parts of the body, there are several hormone transporters in the cell membranes; however, in the human brain, only MCT8 exists. Subsequently, a shortage of thyroid hormones (T₃) in the brain causes impaired brain development and very severe neurocognitive symptoms, including motor and intellectual disability, from a very early age. In contrast, thyroid hormones levels in the serum are instead compensatory high, leading to hyperthyroidism and a general loss of muscle volume. Most patients can never walk or talk and have a high pulse, hypermetabolism, low body weight, and a low life expectancy (about 35 years).

The prevalence of MCT8 deficiency is estimated at around 1 in 70,000 males (the deficiency is caused by a mutation in the X-chromosome and hence is almost exclusively prevalent in males) (Groenweg, S. et al., "Effectiveness and safety of the tri-iodothyronine analogue Triac in children and adults with MCT8 deficiency: an international, single-arm, open-label, phase 2 trial", *The Lancet Diabetes and Endocrinology*, 2019). While the symptoms have been described previously, the genetic defect was not identified until 2004. For this reason, the disease is still unknown in many areas, and not many patients have been diagnosed. According to Orphanet, there are 320 published cases worldwide. Egetis estimates the number of diagnosed cases at some 1,000.

Proof of Concept Published in *The Lancet*

Ideally, a therapy should ameliorate the peripheral hyperthyroidism while improving neurological development. Hallmarks of MCT8 deficiency are imbalances of thyroid hormones (T.H.s) in the serum (high levels of the active form, tri-iodothyronine (T₃), and low levels of the most common form in the blood, thyroxine (T₄)). In healthy subjects, the relationship should be the reverse as more active T.H.s should have entered the organs.

Emcitate, A Thyroid Hormone Analog Not Dependent on MCT8

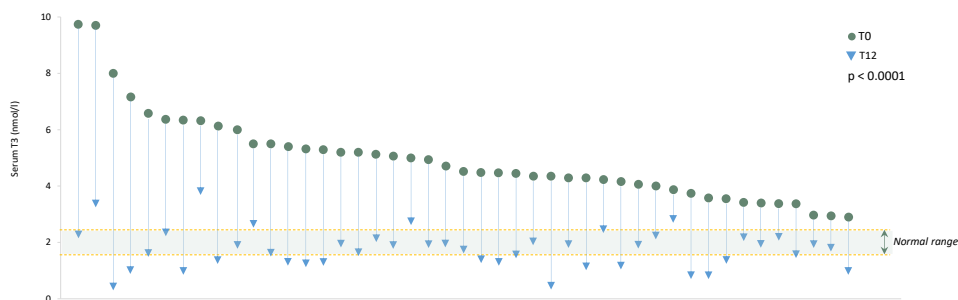
Tiratricol (the active substance of Emcitate) is a potential solution. It does not need the MCT8 transporter to cross the cell membranes and can mimic the activity of thyroid hormones by binding to thyroid hormone receptors in the cells. Thus, the mode of action is to bypass the MCT8 deficiency and restore thyroid hormone signaling in the brain. Tiratricol inhibits the secretion of thyroid-stimulating hormones, thereby lowering endogenous thyroid hormone production and reducing serum levels of T₃.

Normalizes Thyroid Hormone Levels and Reduces Toxicity

Preclinical results indicated that Emcitate enters MCT8-deficient human cells and had promising activity on neurocognitive development in early postnatal life in animal models. The observations prompted the Erasmus Medical Center in Rotterdam to investigate the safety and efficacy of Emcitate in a Phase II trial ("TRIAC I"). The investigators enrolled forty-six European and South African patients (median age seven years) with genetically confirmed MCT8 deficiency in a single-arm Phase II trial. Forty-five patients were treated, and 40 patients completed 12 months of treatment.

- The trial met the primary endpoint of reduction of T₃ in the serum and the T₃ level normalized in 78 percent of patients
- There was a significant effect on thyrotoxicosis, i.e., metabolic and cardiovascular symptoms such as body weight, heart rate, and blood pressure
- No dose reduction or discontinuation due to drug-related toxicity occurred. Adverse events that were suspected related to treatment were mild and transient (e.g., perspiration and irritability).

Emcitate Has Significant Effect on Thyrotoxicosis



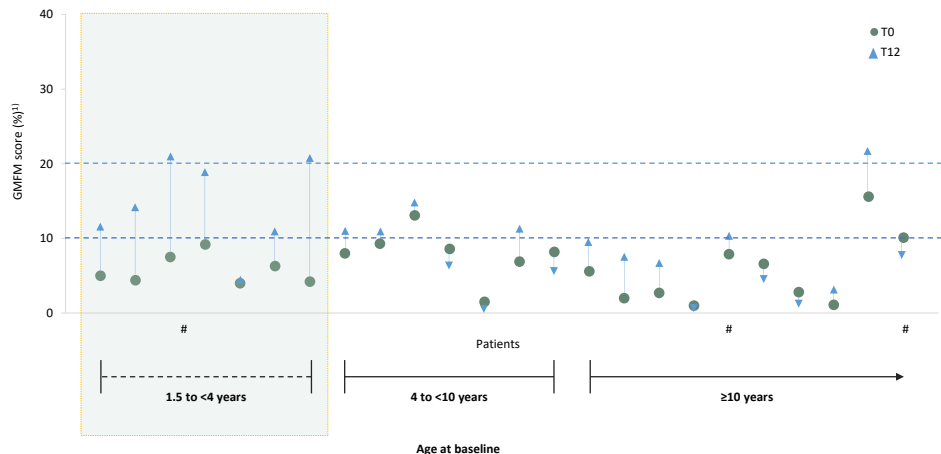
Endpoints	Baseline mean (± SD)	12 months mean (± SD)	Difference in means (95% CI)	p-value
Serum T3 (nmol/L)	4.97 (± 1.55)	1.82 (± 0.69)	-3.15 (-3.62, -2.68)	<0.0001
Weight to age (z score)	-2.98 (± 1.93)	-2.71 (± 1.79)	0.27 (0.03, 0.50)	0.025
Resting heart rate (bpm)	112 (± 23)	104 (± 17)	-9 (-16, -2)	0.01
Mean heart rate 24 h (bpm)	102 (± 14)	97 (± 9)	-5 (-9, -1)	0.012
SHBG (nmol/L)	212 (± 91)	178 (± 76)	-35 (-55, -15)	0.0013
Total cholesterol (mmol/L)	3.2 (± 0.7)	3.4 (± 0.7)	0.2 (0.0, 0.3)	0.056
CK (U/L)	108 (± 90)	161 (± 117)	53(27, 78)	<0.0001

Source: Egetis, Groenweg et al (2019)

Promising Signs of Neurological Effect in Young Children

Exploratory endpoints were neurophysiological tests, including gross motor function. Gross motor function increased in patients that started treatment before four years of age. Two out of seven patients in this subgroup achieved 20 percent on the function score, meaning they could sit and hold their head up independently. There was no discernible trend for older patients, which is consistent with what we know about how and when brain development can be affected. To our knowledge, these are the first clinical signs of efficacy from any treatment on neurocognitive development in MCT8 deficient patients. The results were published in *The Lancet Diabetes Endocrinology* (Groenweg et al. (2019)).

Indication of Positive Effect on Motor Function in Young Children



Source: Egetis, Groenweg et al (2019)

A Pivotal Trial is Underway

Egetis has recently started enrolling patients in a Phase IIb/III early intervention trial ("TRIAC II"). The plan is to recruit 18-22 patients among very young children 0-30 months of age in the USA and Europe. The trial will involve around ten centers in the USA and Europe. The primary endpoint is improved neurocognitive development as measured by Gross Motor Function 88 compared to baseline and natural history controls. There will be no prospective control in the study. Other secondary endpoints in neurodevelopment will be investigated. The purpose is also to confirm the effect on clinical and biomarkers measures of hyperthyroidism and thyrotoxicosis observed in the TRIAC I trial.

Patients will be treated for 24 months. Egetis will conduct an interim analysis after 12 months, which is planned serve as a basis for filing for approval.

Egetis will base the filings on both TRIAC I and TRIAC II trials. According to the prospectus, RTT was actually encouraged by the EMA to file in the E.U. based on the results in TRIAC I alone. However, the ongoing trial importantly serves to include U.S. patients, a likely prerequisite to eventually getting approval by the FDA. The study also further supports broadening the indication to a pediatric population, including a possible approval as a rare pediatric disease in the U.S. If the trial meets the neurological endpoint, the business case should also strengthen for early intervention. In a natural history study, patients who attained full head control by the age of five had a more than three times longer median survival than patients who did not achieve head control (Groeneweg, S., et al, Disease characteristics of MCT8 deficiency: an international, retrospective, multicentre cohort study, *Lancet Diabetes Endocrinology*, vol. 8, July 2020)

No Competition on the Horizon

There is no approved treatment for MCT8 deficiency. Hormone replacement therapy seems to aggravate hyperthyroidism. Antithyroids have been considered to treat hyperthyroidism but have proven either ineffective in MCT8-deficiency (thiamazole) or has unacceptable side effects (PTU). Besides Emcitate, another thyroid hormone analog, DITPA (diiodothyropropionic acid), has limited clinical evidence. Like Emcitate, it does not need the MCT8 transporter to enter cells. In an investigator-initiated small pilot trial in very young children, it normalized T₃ levels, and there was a positive effect on peripheral symptoms but no effect on psychomotor function. It is less potent in acting on hormone receptors than Emcitate and requires higher dosing. DITPA is not approved in any indication (it failed in

clinical trials as a congestive heart failure drug), and we are not aware of any ongoing clinical development.

Emcitate is already provided to some 100 AHDS patients annually on a named patient basis after individual consent from national regulatory bodies.

Emcitate Already Has a Strong Scientific Case

As mentioned, all MCT8 deficient patients need a safe and efficacious treatment to lower serum levels of T₃ and lessen symptoms of thyrotoxicosis. We believe the TRIAC I trial provides a compelling "proof of concept" in this perspective.

The safety profile seems generally favorable, and there is experience of long-term exposure in other indications (tiratricol was approved in France already some 40 years ago). In MCT8-deficient patients, some subjects included in TRIAC I have been on treatment for several years (the trial started in 2014).

Unless any unexpected safety issues present themselves, we believe that the case is convincing for Emcitate to eventually be approved solely based on its effect on hyperthyroidism due to the unmet medical need. Improving neurocognitive development in young children is arguably a more challenging task, but so far the preclinical and clinical evidence is promising. The clear reduction in serum thyroid hormone levels indicates that Emcitate permeates brain cells; however, the clinical effect on brain development needs to be further confirmed.

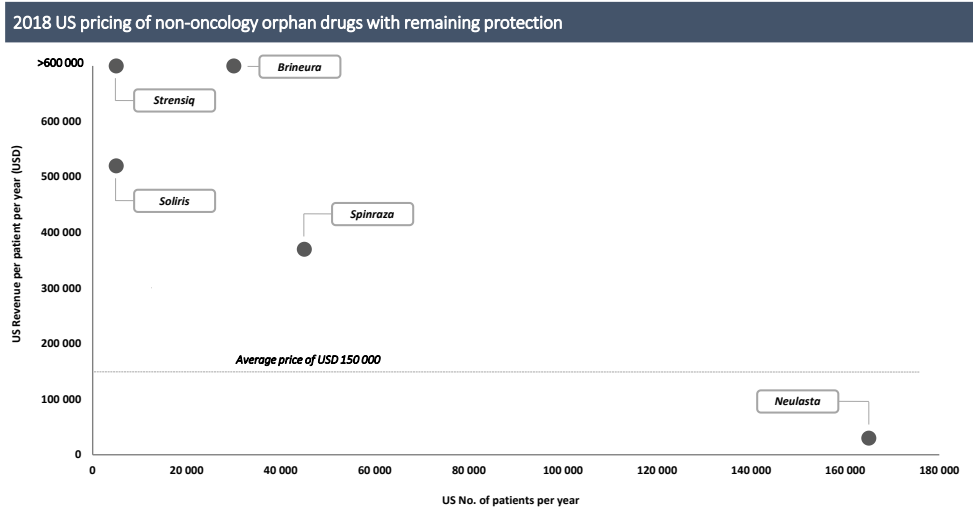
An Unserved Orphan Drug Market

The commercial opportunity for Emcitate depends on many factors, including diagnosis rate, penetration, and drug pricing.

Based on reported cases as cited above, it appears that less than ten percent of the estimated prevalence has a diagnosis. As newborns are not screened for the disease, early diagnosis is a significant challenge. Abnormally low T₄ combined with normal TSH is a biomarker hallmark of MCT8 deficiency. It is easily detected if the physician knows what they are looking for; however, since pediatricians rarely screen infants for T₄, the disease is undetected in most cases. However, if treatment is approved, the diagnosis rate will likely rise. Another rare disease that is more well-known than AHDS but where the diagnosis is difficult is Wilson's Disease. Wilson's Disease has a diagnosis rate of some 60 percent, according to Wilson Therapeutics. We assume a similar rate for Emcitate, long-term.

Orphan Drugs come with high pricing; the average cost is some USD 150,000 annually in the U.S. Egetis has estimated a list price of USD 300,000 for Emcitate in the U.S.. It appears a rather conservative figure compared to other drugs targeting rare diseases with similar prevalence as AHDS, such as Brineura and Strensiq.

U.S. Pricing of Orphan Drugs



Source: Egetis/Evaluate Pharma

- Brineura is an enzyme replacement therapy for CLN2/Batten Disease, a rapidly progressing fatal brain condition that presents at an early age. Prevalence is less than 1 in a million. BioMarin reported USD 72m (+80 %) in sales for 2019. Global Data forecasts Brineura sales of USD 358m in 2025. According to Endpoints, the list price is USD 700,000 per year in the U.S.
- Strensiq is indicated for perinatal/infantile- and juvenile-onset hypophosphatasia as an enzyme replacement therapy. Hypophosphatasia is a rare inherited disease of the bones, leading to early loss of teeth, malformed bones, frequent bone fractures, and difficulty breathing. The prevalence is not known. Alexion reported 2019 sales of USD 592m for Strensiq (+25%).

Simultaneously, we should recognize the significant differences between gross and net drug prices on the U.S. market in general (for example, Bristol-Myers Squibb reported a 40 percent gross-to-net adjustment for U.S. product sales in 2019). We assume a gross-to-net adjusted price of USD 180,000 in the U.S. and USD 138,000 in Europe. Hence, we see an addressable market of some USD 900m+ in these regions.

Due to the unmet medical need, we believe a high market share in diagnosed patients is feasible. Below we summarize our assumptions for peak sales estimates for Emcitate

Sales Estimates for Emcitate

Peak sales, Emcitate		
	USA	Europe
Peak sales year	2031	2035
Prevalence ('000)	2.3	4.0
Diagnosed population ('000)	1.3	2.0
% of prevalence	57%	50%
Treated with Emcitate, ('000)	1.0	1.6
% of diagnosed	76%	80%
Net cost/year (kUSD)	180	128
Sales Emcitate (USDm)	183	203

Source: Redeye Research

We have not yet included any “rest of the world” sales in our estimates. In China, there is no clear definition of orphan drugs and consequently no market exclusivity tied to orphan drug status. Since Tiratricol is off-patent, the economics in China are uncertain. For Japan, local clinical development is probably required, which we conclude effectively means that Egetis needs to find a Japanese partner.

Aladote – A Last Resort for The Liver?

Paracetamol is the world's best-selling drug by volume. Potential overdosing is a serious concern as there is a high risk for liver injury if not treated appropriately. Paracetamol overdose is the most common pharmaceutical poisoning in many developed countries. In the U.K., several studies estimate that there are about 100,000 hospital presentations annually (about half eventually admitted to hospital stay).

Liver toxicity from paracetamol arises from the fact that some drug metabolites are highly reactive and cause damage to liver tissue. An overdose occurs in two phases:

- Metabolic phase: Reactive paracetamol metabolites called NAPQIs are conjugated in the liver but predominantly binds to glutathione (a naturally occurring anti-oxidant), which detoxifies the metabolites
- Oxidative phase: NAPQI eventually depletes glutathione stores, and toxic NAPQIs instead bind to intracellular proteins, causing increased oxidative stress, mitochondrial injury, and cell death.

The first-line treatment is the antidote N-acetylcysteine (NAC), which replenishes the liver's glutathione reserves to alleviate oxidative stress on liver cells. NAC is generally effective if treatment begins within the first eight hours after overdosing. However, if the patient presents later, the risk of acute liver injury rises considerably. In an Australian study, late presenters treated with NAC had a 21-23 percent risk of developing acute liver injury compared to about three percent for early presenters.

Aladote mimics the naturally-occurring superoxide dismutase, which protects mitochondria from injury from oxidative stress. The idea is a rescue therapy when glutathione replenishing from NAC is not sufficient.

The incidence of paracetamol poisoning varies considerably from country to country. It seems much more common in the U.K. and Australia than in other countries due to significantly higher paracetamol overdose rates as a method for self-harm. According to a Danish study, differences in paracetamol availability in non-pharmacy outlets might be one explanation for the lower rates of paracetamol poisoning in, e.g., Germany and Austria compared to the U.K.

Incidence of Paracetamol Overdose and Treatments

Country, year	Reported POD	Treated	Late Presenters	Treated incidence
US (AAPCC), 2019	74027	37343		0.01%
Australia, 2017		11754	29%	0.05%
England+Scotland, 2013		50198		0.08%
Sweden, 2012		1500-2000		0.02%

Sources: Gummin D., et al, 2019 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPD) . POD: Paracetamol Overdose.

Initial Clinical Evidence Promising

The Phase Ib/IIa study (the "POP trial") was an open-label, randomized single-center study to explore the safety and tolerability of Aladote in combination with NAC for the treatment of paracetamol overdose. A secondary study objective was the measurement of clinical and exploratory biomarkers of acute liver injury.

The study screened 304 patients and recruited 24 at one center during eleven months. Patients admitted to the hospital within 24 hours of the paracetamol overdose were included. Aladote was administered as a bolus infusion after a first infusion of NAC (NAC is administered in 2-3 doses).

We believe the key takeaways were positive, motivating further clinical development:

- There were no serious adverse events deemed probably or definitely related to Aladote.
- The study was not powered to measure efficacy. However, a smaller share of patients (11 percent vs. 50 percent) showed increased risk of acute liver injury in the Aladote arms compared to the control arm only treated with NAC.

In our view, the major limitation was the small study sample. There was a difference in the time from an overdose to treatment between the arms. In the control group, 50 percent started treatment later than eight hours after overdosing (the threshold considered crucial for NAC effectiveness), compared to 28 percent for the Aladote arms. Arguably, this difference might have affected the outcome.

Increased-Risk Patients the Focus in Pivotal Trial

Following discussions with the FDA, the EMA, and the British MHRA, Egetis have finalized the study design for a pivotal Phase IIb/III trial. The primary endpoint is reducing liver injury measured as a composite measure of ALT and INR (biomarkers for liver injury) at 20 hours. Secondary endpoints include the percentage of patients needing further NAC treatment, length of hospital stay, and experimental biomarkers for liver injury K18, miR-122 and GLDH.

Initially patients will be randomized 1:1:1 to receive either NAC+placebo, NAC + Aladote low dose or NAC Aladote. Egetis high dose plans to recruit about 225 patients; however, an interim analysis after completing 50 percent of patients (i.e., 45 treated patients in each arm) will test for futility and determine the dose for the active treatment arm for the continued trial.

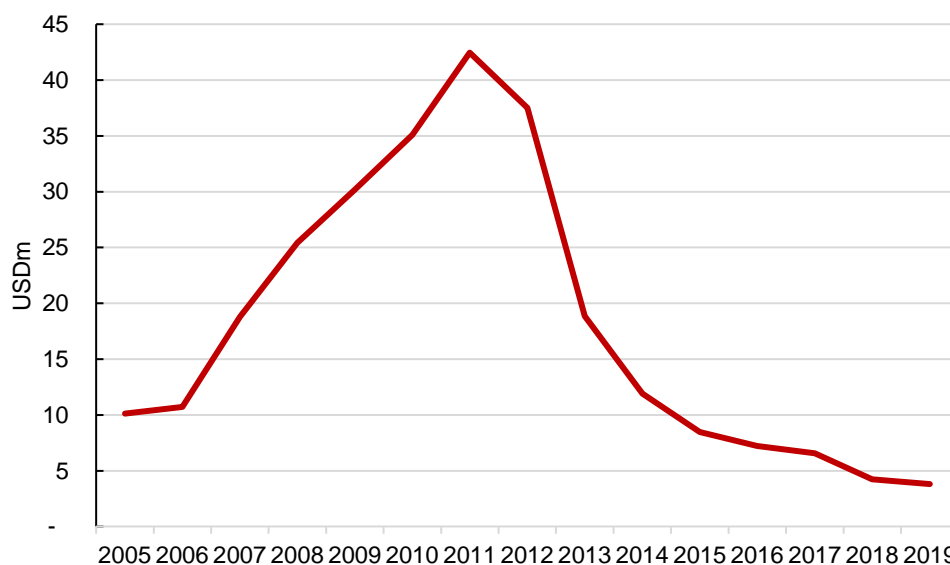
Compared to the POP trial, there are some essential differences: The study will only include patients presenting later than 8 hours, hence a much larger proportion of increased-risk patients. At the same, the criteria for efficacy are different and arguably tighter. For example, the ALT cut-off is 50 U/L compared to 100 U/L. The power of the test is increased, but it also raises the bar for Aladote, we believe.

Egetis plans to conduct the trial in the U.S., E.U., and the U.K. It expects to recruit the first patient in H1, 2021. While recruitment in an emergency room setting is challenging, the study is small as pivotal trials go, and there is minimal follow-up. Hence, we believe Egetis can run clinical development cost-efficiently.

A Niche Market Without Competition

We have no accurate estimate of the value of the current market for antidotes for paracetamol poisoning. In the US, Cumberland Pharmaceuticals markets Acetadote, i.e., branded injectable acetylcysteine. Historically, this product has sold for some USD 40m annually, but sales have dwindled in recent years, likely due to generic competition.

Historical U.S. Sales of NAC Product Acetadote



Source: Biomedtracker

The list price for Acetadote is about USD 910 per treatment; however generic versions sell for 20-25 percent of that price. Egetis has performed some initial market research indicating acceptance for a price level of up to USD 5,000 per dose in the U.S. According to Egetis, some 135,000 paracetamol overdose patients are admitted to the hospital each year in the U.S. and the five largest European markets.

The addressable market in terms of the number of patients is likely lower for Aladote than acetylcysteine. However, we believe higher pricing supports the view that the commercial market potential could be similar or larger for patients with increased risk (arriving in the hospital more than 8 hours after overdosing). Among those treated in hospital, some 25 percent are late presenters and likely eligible for Aladote. Assuming 37,000 treated patients annually in the U.S. (Gummin D., et al, 2019 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPD)), late presenters should correspond to about 9,300 cases. We believe that dose sales should exceed the number of

patients treated, as hospitals likely will have to stock to have the capacity to treat patients "around the clock." We use a factor of 2x in our calculations.

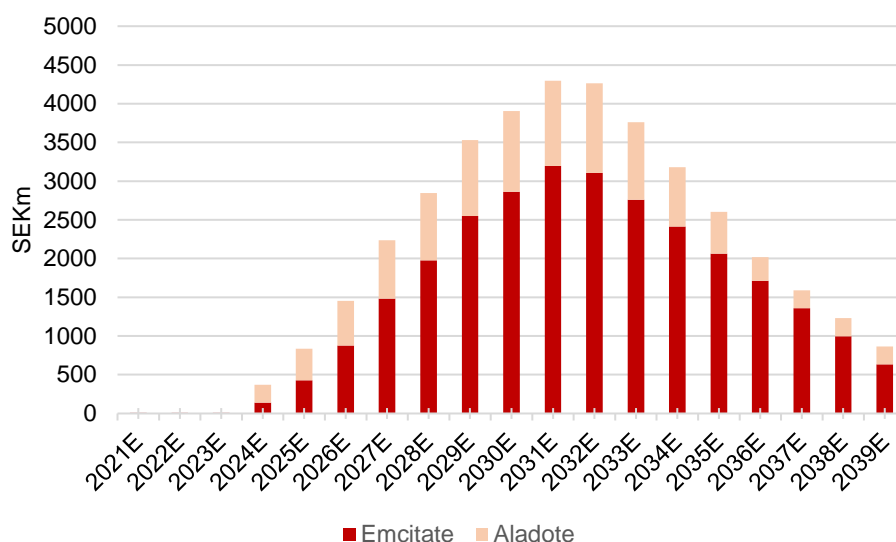
Assuming a U.S. gross list price of USD 5,000 per dose and a net worth of USD 4,000, the market potential in "late presenters" in the U.S. is some USD 75m. Including U.K. and E.U. markets, and assuming 50 percent lower price in these regions, we estimate a total market potential of about USD 185m.

We conclude that Aladote in POD represents a niche market opportunity combined with standard-of-care acetylcysteine. Since there are no good treatment alternatives available for increased-risk patients, we believe high penetration is feasible for a drug with proven effect of reduced liver injury. We still assume 70 percent penetration.

Estimates

Below we summarize our sales forecasts (non-risked) for Emcitate and Aladote.

Sales Forecasts



Source: Redeye Research

Following the POLAR program's conclusion, we expect project costs to come down in 2021, before picking up again in 2022 as clinical activity picks up. Overall, we expect lower project expenses compared to recent years due to fewer patients in the Aladote and Emcitate trials compared to the POLAR program.

Egetis Financial Estimates

FY Estimates (Risk-adjusted)							
(SEKm)	2017	2018	2019	2020E	2021E	2022E	2023E
Net sales	14	28	83	39	5	5	5
Other income	0	0	0	0	0	0	0
Revenue	14	28	83	39	5	5	5
Cost of goods sold					0	0	0
Project expenses	-77	-84	-112	-128	-29	-85	-57
Personel expenses	-11	-20	-19	-21	-23	-23	-51
Other expenses	-13	-11	-18	-10	-16	-16	-40
Depreciations	0	0	0	0	0	0	0
Other operating expenses	-1		0	-1	0	0	0
Operating expenses	-102	-115	-149	-160	-69	-124	-148
EBITDA	-88	-87	-66	-121	-63	-119	-143
EBIT	-88	-87	-67	-121	-64	-119	-143
Financial net	0	2	5	1	0		
EBT	-88	-85	-61	-120	-64	-119	-143
Tax	0	0	0	0	0		
Net profit	-88	-85	-61	-120	-64	-119	-143

Source: Redeye Research

Margin Assumptions

Egetis has a go-to-market strategy for Aladote and Emcitate and plans to establish in-house commercial capabilities for launch in E.U as well as the U.S. Commercialization in large markets is arguably a challenging task for a company that is still virtual. However, Egetis already works closely with key opinion leaders. For example, researchers from Erasmus Medical Centre, which is the leading center for MCT8 deficiency worldwide, have been instrumental in the clinical development of Emcitate (it is also entitled to royalties from future sales. We are not aware of any competition in the pipeline for neither Aladote nor Emcitate

We assume high gross margins with a low single-digit cost of goods as a percentage of sales. Erasmus Medical Centre is entitled to royalties of ten percent of net sales for ten years following market approval. In turn, the RTT sellers will receive royalties of three percent of net sales for the same period.

The Company estimates it needs a commercial organization of some 50 full-time employees or less to serve the U.S. and European markets. While we recognize the often very high productivity in the Orphan Drug space, we assume Egetis will eventually need a larger sales organization.

Costs as Percentage of Net Sales, Orphan Drug Companies

Orphan Drug Companies Cost Components			
Company	Gross Margin	SG&A	R&D
SOBI	77%	25%	10%
Alexion	91%	23%	17%
BioMarin	79%	40%	42%
Vertex	88%	12%	29%
Jazz Pharma	94%	34%	14%
Average	86%	27%	22%
Median	88%	25%	17%

Source: Thomson Reuters

For mature Orphan Drug companies, SG&A typically amounts to 25-30 percent of sales. We assume that relative costs for Egetis will correspond to the median of the peer group, some 25 percent on average.

Emcitate Likely Eligible for a Priority Review Voucher on Market Approval

At the end of November 2020, Egetis was granted a Rare Pediatric Disease Designation by the FDA for Emcitate for the treatment of MCT8 deficiency. The main advantage is that it opens for an application for a Rare Pediatric Disease Priority Review Voucher (PRV), which the FDA will grant in the event Emcitate is approved for a U.S. pediatric population.

Congress recently voted to extend the Rare Pediatric Disease Priority Review Voucher Program until 30 September 2026. As a reminder, a Priority Review Voucher can be redeemed to receive a priority review of a subsequent marketing application for a different product. A priority review means a commitment (however, no guarantee) by the FDA to complete a review of a marketing application within six months compared to about a year for the standard procedure. The voucher is transferable any number of times before it is redeemed.

Since 2009, FDA has granted 24 Rare Pediatric Disease Priority Review Vouchers. The market value is around USD 100m, according to the latest transfers.

Value of a U.S. Priority Review Voucher

Priority Review Vouchers Transactions			
Seller	Buyer	Year	USDm
Y-mAbs	United Therapeutics	2020	105
Lumos	Merck	2020	100
Argenx	Bayer	2020	98
Bavarian Nordic	Undisclosed	2020	95
Average			100

Source: Redeye Research

For a small company like Egetis, the possibility to raise funds by selling a voucher is a boon to finance the eventual commercialization of a new drug. According to the acquisition terms, the sellers of RTT are entitled to 50 percent of the net proceeds from a sale of PRV awarded for the market approval of Emcitate.

Likelihood of Approval

We have based our assumptions on the Likelihood of Approval (LOA) on statistics from relevant indications as reported by BIO and BioMedtracker.

For endocrine disorders, Biomedtracker estimates a historical LOA of 60 percent for Phase III projects. We see a lower than average attrition risk for Emcitate due to convincing clinical evidence, the experience of long-term use in patients, and the unmet medical need in MCT8 deficiency. According to Wong, Ch, et al, "Estimation of clinical trial success rates and related parameters", *Biostatistics* 2019, the LOA in for Phase III drug projects in metabolic/endocrinology orphan indications is estimated at 78 percent. For Emcitate, we assume some 70 percent as study population and primary endpoint (neurological) are different in the pivotal TRIAC II trial.

For Aladote, we stick with our previous assumption of a 35 percent LOA. The Phase Ib/IIa POP trial yielded promising results; however, it had broader inclusion criteria than the upcoming pivotal trial. For gastroenterology, Biomedtracker estimates Phase II and Phase III LOAs of 24 and 62 percent, respectively.

Assumed Project Risk and Development Phase

Project risks per development phase						
	Preclinical	Phase I	Phase II	Phase III	Reg	Total
Year	→ 2021					
Aladote						
Paracetamol poisoning	100%	100%	50%	78%	90%	35%
Year	→ 2021					
Emcitate						
MCT8-deficiency	100%	100%	100%	78%	90%	70%

Source: Redeye Research, BIO, BioMedtracker

Valuation

We have reviewed our valuation of Egetis primarily due to a closer look at the Emcitate asset.

- We have increased our peak sales assumptions by 80 percent to USD 360m as we believe Emcitate will likely be prescribed for patients of all ages and as there are no alternatives in clinical development.
- As stated above, we now see a considerably higher likelihood of approval for Emcitate than we initially calculated. An already well-demonstrated effect on serum levels of thyroid hormones and thyrotoxicosis combined with a favorable safety profile likely goes a long way to convincing regulators, given the very high unmet medical need for these patients.
- In contrast, we have lowered our valuation of Aladote on the back of more conservative assumptions regarding incidence and pricing in the U.S. We assume peak sales of USD 130m vs. USD 180m previously.
- We have also assumed higher SG&A costs relative to sales (on average 25 vs. 21 percent previously) to reflect the cost structure of mature orphan drug companies.
- We use a WACC of 13 percent and a USD/SEK of 8.8.

In total, we raise the base case by almost 60 percent to SEK 19 (12).

Egetis Sum of the Parts

Egetis - Valuation						
Sum-of-the-parts						
Project	Indication	LOA	Royalty	Peak sales USDm	Launch	NPV SEKm
Aladote	Paracetamol poisoning	35%	na	130	2024	560
Emcitate	MCT8 deficiency	70%	na	360	2024	2596
Tech value (SEKm)						3 156
Net cash (SEKm) (Q4 2020e)						300
Admin costs (SEKm)						-295
Fair value (SEKm)						3 162
No. Shares (million)						165.1
Base case per share						19.2

Source: Redeye Research

Scenario Analysis

Our valuation of Egetis is highly dependent on pricing and LOA assumptions.

To illustrate their potential impact, we also calculate optimistic and pessimistic scenarios for the Company.

Our **bear case** scenario, which gives a fair value of SEK 8, assumes these negatives:

- Egetis discontinues development of Aladote due to setbacks in clinical development
- We lower our peak sales estimation for Emcitate by 50 percent due to 25 percent lower pricing and diagnosis rates.

Our optimistic **bull case** scenario, which gives a fair value of SEK 6.5bn or SEK 40 per share in about 24 months, assumes:

- A positive interim readout in the TRIAC II trial, with a subsequent filing for marketing approval
- Also, a positive interim analysis for Aladote
- We calculate with a higher net price for Emcitate of USD 240,000 in the U.S. and USD 170,000 in Europe and peak sales of USD 490m.
- We lower the WACC to 12 percent.

Peer Group Valuation

The valuation of listed developers of orphan drugs varies considerably, from differences in project validation, potential, financial position, and risk. Below we present a sample of Nordic peers.

We base our relative valuation on the technology value (market value less net cash) of somewhat comparable drug development companies. Compared to other listed peers, Egetis' valuation appears attractive with a considerably lower E.V. than the average and median – though we acknowledge differences in project potential and risk.

A valuation in line with peers (median EV) suggests a potential of more than a doubling of the market cap to SEK 2.6bn or SEK 16 per share.

Peer Group Valuation – Mid To Late Stage Orphan Drug Companies

Peer group valuation (SEKm)	Market Cap	Share price	Net Cash	EV	No. Projects	Dev. Stage
Ascelia Pharma	1389	48.4	239	1150	2	Phase III
Calliditas	6672	133.6	1396	5276	3	Phase III
Oncopeptides	11550	170	1252	10298	2	NDA
Orphazyme	3802	80.6	864	2939	1	NDA
Saniona	1186	19.02	625	561	3	NDA
Vicore Pharma	2089	34.5	321	1768	3	Phase II
Average				3665		
Median				2353		
Egetis	1142	6.92	300	842	2	Phase III

Source: Redeye Research

Catalysts

Initiation of Phase II/III trial Aladote

Egetis plans to initiate a pivotal trial for Aladote in patients with paracetamol poisoning at high risk of liver injury in H1, 2021.

Downside			IMPACT			Upside	Time Frame
Significance		Likelihood	Significance		Likelihood		
Major		Unlikely	Moderate		Highly likely		Short

Emcitate Phase II/III study fully recruited

Egetis plans to recruit all patients (15-18) by the end of 2021. This milestone is important for the 12m follow-up in 2022 which could serve as the basis for a marketing application.

Downside			IMPACT			Upside	Time Frame
Significance		Likelihood	Significance		Likelihood		
Moderate		Possible	Moderate		Possible		Mid

Interim analysis Emcitate Phase II/III

The results from the 12m interim analysis of the Phase II/III early intervention trial is expected at the end of 2022. If successful, Egetis plans to file on this data.

Downside			IMPACT			Upside	Time Frame
Significance		Likelihood	Significance		Likelihood		
Major		Unlikely	Major		Highly likely		Long

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 points. The maximum score for a valuation key is 5 points.

Rating changes in the report

People: 4

Egetis have a small but experienced executive management team. The ownership structure has changed significantly after the merger with Rare Thyroid Therapeutics. The largest shareholder Peder Walberg is an operative board member.

Business: 2

Egetis does not yet market any products. However, it is in late-stage clinical development. It targets attractive rare disease/niche markets where we see an above-average likelihood of approval, high pricing, and no competition from approved treatments.

Financials: 1

Egetis have no history of profitability. Following the capital raise at the end of 2020, we estimate that operations are financed for more than two years.

INCOME STATEMENT	2018	2019	2020E	2021E	2022E
Net sales	28	83	39	5	5
Total operating costs	-121	-152	-160	-69	-124
EBITDA	-93	-70	-121	-64	-119
Depreciation	0	0	0	0	0
Amortization	0	0	0	0	0
Impairment charges	0	0	0	0	0
EBIT	-93	-70	-121	-64	-119
Share in profits	0	0	0	0	0
Net financial items	8	8	0	0	0
Exchange rate dif.	0	0	0	0	0
Pre-tax profit	-85	-61	-121	-64	-119
Tax	0	0	0	0	0
Net earnings	-85	-61	-121	-64	-119

BALANCE SHEET	2018	2019	2020E	2021E	2022E
Assets					
<i>Current assets</i>					
Cash in banks	230	255	299	238	119
Receivables	9	5	2	0	0
Inventories	0	0	4	1	1
Other current assets	3	10	10	4	4
Current assets	242	270	315	243	124
<i>Fixed assets</i>					
Tangible assets	0	0	0	0	0
Associated comp.	0	0	0	0	0
Investments	0	0	0	0	0
Goodwill	0	0	0	0	0
Cap. exp. for dev.	0	0	395	395	395
O intangible rights	0	0	0	0	0
O non-current assets	0	0	0	0	0
Total fixed assets	0	0	395	395	395
Deferred tax assets	0	0	0	0	0
Total (assets)	242	270	710	638	519
Liabilities					
<i>Current liabilities</i>					
Short-term debt	0	0	0	0	0
Accounts payable	15	11	10	0	0
O current liabilities	8	14	14	15	15
Current liabilities	23	25	24	15	15
Long-term debt	0	0	0	0	0
O long-term liabilities	0	0	0	0	0
Convertibles	0	0	0	0	0
Total Liabilities	23	25	24	15	15
Deferred tax liab	0	0	0	0	0
Provisions	0	0	0	0	0
Shareholders' equity	219	245	686	622	503
Minority interest (BS)	0	0	0	0	0
Minority & equity	219	245	686	622	503
Total liab & SE	242	270	710	638	519

FREE CASH FLOW	2018	2019	2020E	2021E	2022E
Net sales	28	83	39	5	5
Total operating costs	-121	-152	-160	-69	-124
Depreciations total	0	0	0	0	0
EBIT	-93	-70	-121	-64	-119
Taxes on EBIT	0	0	0	0	0
NOPLAT	-93	-70	-121	-64	-119
Depreciation	0	0	0	0	0
Gross cash flow	-93	-70	-121	-64	-119
Change in WC	5	0	-2	2	0
Gross CAPEX	0	0	-395	0	0
Free cash flow	-88	-70	-518	-62	-119

CAPITAL STRUCTURE	2018	2019	2020E	2021E	2022E
Equity ratio	91%	91%	97%	98%	97%
Debt/equity ratio	0%	0%	0%	0%	0%
Net debt	-230	-255	-299	-238	-119
Capital employed	-11	-10	387	384	384
Capital turnover rate	0,1	0,3	0,1	0,0	0,0

GROWTH	2018	2019	2020E	2021E	2022E
Sales growth	108%	193%	-53%	-87%	0%

DATA PER SHARE	2018	2019	2020E	2021E	2022E
EPS	-1.75	-1.15	-0.73	-0.39	-0.72
EPS adj	-1.75	-1.15	-0.73	-0.39	-0.72
Dividend	0.00	0.00	0.00	0.00	0.00
Net debt	-4.72	-4.77	-1.81	-1.44	-0.72
Total shares	48.67	53.53	165.07	165.07	165.07

VALUATION	2018	2019	2020E	2021E	2022E
EV	512.3	815.6	841.1	902.7	1 021.8
P/E	NA	NA	NA	NA	NA
P/E diluted	NA	NA	NA	NA	NA
P/Sales	NA	NA	NA	NA	NA
EV/Sales	NA	NA	NA	NA	NA
EV/EBITDA	NA	NA	NA	NA	NA
EV/EBIT	NA	NA	NA	NA	NA
P/BV	3.4	4.4	1.7	1.8	2.3

SHARE PERFORMANCE	GROWTH/YEAR	18/20E
1 month	-16.6 %	Net sales 16.9 %
3 month	27.0 %	Operating profit adj 14.5 %
12 month	-51.5 %	EPS, just -35.1 %
Since start of the year	-7.5 %	Equity 76.8 %

SHAREHOLDER STRUCTURE %	CAPITAL	VOTES
Peder Walberg	19.3 %	19.3 %
Avla Holding AB	10.0 %	10.0 %
Fjärde AP-fonden	8.7 %	8.7 %
Peter Lindell	7.4 %	7.4 %
Staffan Persson	6.9 %	6.9 %
RegulaPharm AB	6.0 %	6.0 %
Skandinaviska Enskilda Banken S.A	3.1 %	3.1 %
Abn Amro Global Custody Services Nv	2.3 %	2.3 %
Nyenburgh Holding B.V.	2.3 %	2.3 %
Avanza Pension	2.2 %	2.2 %

SHARE INFORMATION	
Reuters code	Pled.st
List	Small Cap
Share price	6.9
Total shares, million	165.1
Market Cap, MSEK	1140.6

MANAGEMENT & BOARD	
CEO	Nicklas Westerholm
CFO	Marie-Louise Alamaa
IR	
Chairman	Håkan Åström

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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 (2021-02-15)

Rating	People	Business	Financials
5p	23	18	3
3p - 4p	106	87	40
0p - 2p	5	29	91
Company N	134	134	134

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Niklas Elmhammer owns shares in the company : Yes
 Redeye performs/have performed services for the Company and receives/have received compensation from the Company in connection with this.