goetzpartners SECURITIES

COMPANY NOTE

Vicore Pharma Holding AB (VICO-SE)

Novel approach to tackle fibrotic orphan diseases

OUTPERFORM
Price target SEK43.00
Price SEK15.80

KEY TAKEAWAY

We initiate coverage of Vicore Pharma with an OUTPERFORM recommendation and a TP of SEK43, nearly three times the current share price. Vicore is a clinical-stage Swedish biotech company focused on fibrotic orphan diseases. The key driver is lead asset C21, a highly selective small molecule agonist of the angiotensin II type 2 receptor ("AT2R"), in development for idiopathic pulmonary fibrosis ("IPF"), a rapidly progressing, fatal lung disease with few, sub-optimal treatment options that nevertheless generated c.$1.8bn in 2017E sales. C21 is due to start a Phase IIa proof-of-concept trial in IPF in April / May and could enter a pivotal trial in 2020E, paving the way for regulatory approval in 2023E. We forecast peak sales of c.$1.4bn in 2030E and assume that Vicore enters a licensing deal in 2022E including $1bn in total upfront and milestone payments plus double-digit royalties on sales.

Stimulating the AT2R to enhance its tissue-protective and antifibrotic effects
Vicore focuses on stimulating the AT2R, a novel target within the blood pressure-regulating renin-angiotensin-system that mediates many tissue-protective, anti-inflammatory and antifibrotic effects. It opposes the actions of the AT1R, whose excessive activation causes high blood pressure, fibrosis and inflammation, and has therefore yielded many drug targets and therapies for over 40 years. C21 is the first metabolically stable agonist of the AT2R to have been synthesised in 2004 and has since revolutionised the field, leading to >200 peer-reviewed research papers.

Initial focus on the c.$1.8bn, high-growth IPF market
Characterised by the formation of fibrosis (scar tissue) in the lungs, IPF leads to the irreversible loss of lung function, with a prognosis worse than for most cancers. Only two drugs have been approved: Roche/InterMune's Esbriet (pirfenidone) and Boehringer Ingelheim's Ofev (nintedanib). Neither increases survival, with efficacy limited to a slowing of disease progression. Both cause debilitating gastrointestinal side effects which >30% of patients are unwilling to endure. Nevertheless, the drugs have been highly successful commercially. The need for novel therapies remains high and experts predict that future treatment will consist of combination therapy.

C21: first-in-class AT2R agonist with c.$1.4bn sales potential in IPF
C21 has demonstrated potent anti-inflammatory and antifibrotic effects in multiple preclinical disease models including pulmonary fibrosis, making it an ideal candidate for IPF. Favourable safety and tolerability were confirmed in three Phase I studies, and a Phase IIa proof-of-concept trial in IPF is due to start in April / May, with data expected in Q3/2019E. We model approval in 2023E and 2030E sales of c.$1.4bn, based on 15% penetration in the US and Europe and pricing in line with current therapies. Our valuation is entirely based on C21 revenues and hence the key risk to our recommendation is failure of the compound in Phase IIa.

SEK	2015A	2016A	2017A	2018E	2019E
Sales	2	2	4	5	7
EBIT	(5)	(7)	(9)	(10)	(12)
Net Profit	(5)	(7)	(22)	(10)	(12)
Net Cash/Debt ($M)					
FY Dec	25.2	4.3	24.0	(1.0)	(39.2)

FINANCIAL SUMMARY

Net Cash/Debt (M):	24.02

MARKET DATA

Price:	SEK15.80
Target Price:	SEK43.00
52 Week Range:	SEK40.00 - SEK14.85
Total Enterprise Value:	227
Market Cap (M):	251
Shares Out (M):	15.9
Float (M):	15.9
Average Daily Volume:	16,295

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PRICE PERFORMANCE



Source: Factset

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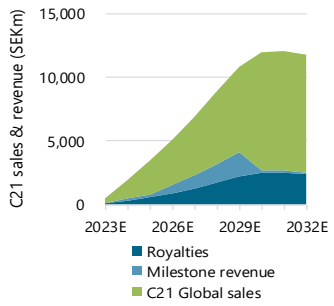
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Novel approach to tackle fibrotic orphan diseases

We initiate coverage of Vicore with an OUTPERFORM recommendation and a TP of SEK42. Vicore is a clinical-stage Swedish biotech company focused on fibrotic orphan diseases. The key driver for the shares is lead asset Compound 21 ("C21"), the first small molecule agonist of the angiotensin II type 2 receptor (AT2-receptor, "AT2R"). C21 is close to entering a Phase IIa proof-of-concept trial in idiopathic pulmonary fibrosis ("IPF"), a fatal lung disease with few treatment options. Despite their limited efficacy and poor tolerability, the two approved products generated combined sales of c.$1.8bn in 2017 – only three years after US launch. Experts believe that the IPF treatment paradigm will shift to combination therapy consisting of multiple compounds, which should lead to significant market expansion over the next decade. We believe that C21 could enter a pivotal trial in 2020E and receive regulatory approval in 2023E. We forecast peak sales of c.$1.4bn in 2030E and assume that Vicore enters a lucrative global licensing deal in 2022E following completion of a pivotal trial (Chart 1). Our sum-of-the-parts ("SOTP") valuation suggests that the shares could double on a one-year view.

CHART 1: C21 could reach peak sales of c.$1.4bn, with Vicore retaining value through a licensing deal

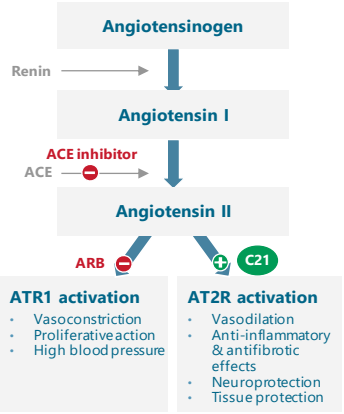


Source: goetzpartners Research estimates. Warning Note: Forecasts are not a reliable indicator of future performance or results.

Focus on drugs that enhance the protective effects of AT2R

The AT2R is a novel target within the blood pressure-regulating renin-angiotensin-system ("RAS") that mediates a range of anti-inflammatory, antifibrotic and tissue protective effects (Chart 2). It opposes the actions of the AT1R, its better-known sibling whose excessive activation causes hypertension (high blood pressure), fibrosis and inflammation. Historically, attention has largely been focused on the widely expressed AT1R, yielding many drug targets and blood pressure drugs for over 40 years, while the study of the AT2R was hampered by its low expression levels and the lack of a metabolically stable inhibitor. This was revolutionised by C21, the first non-peptide, small molecule AT2R agonist. Since its discovery in 2004, over 200 research papers have been published elucidating function and signalling of the AT2R on one hand and demonstrating the antifibrotic and anti-inflammatory properties of C21 on the other hand, which combined with its attractive drug-like properties makes it an ideal drug candidate for fibrotic diseases including IPF. Vicore is building on its strong heritage in the AT2R field to discover follow-on compounds that target other orphan and non-orphan indications with a fibrotic component.

CHART 2: C21 stimulates the AT2R within the RAS

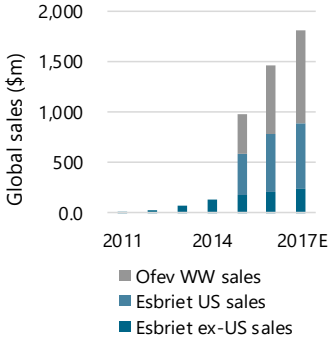


Abbreviations: ACE, angiotensin-converting enzyme; ARB, AT1R blocker; AT2R, angiotensin II type 2 receptor; RAS, renin-angiotensin system
Source: goetzpartners Research

IPF represents a c.$1.8bn, high-growth therapeutic market

Initially, the focus is to develop C21 in IPF, a progressive, fatal lung disease characterised by a destruction of the lungs' functional tissue due to the irreversible formation of fibrotic (scar) tissue. The prognosis is worse than for most cancers, with median survival of 2 - 3 years. Successful drug development has been hampered by the complex and multifactorial nature of the disease, with only two compounds approved to date: Ofev (nintedanib, Boehringer Ingelheim) and Esbriet (pirfenidone, Roche / InterMune). Neither cures the disease nor increases survival, with efficacy limited to a slowing of disease progression, and both cause debilitating gastrointestinal side effects which up to one-third of patients are unwilling to endure. Nevertheless, Esbriet and Ofev have been highly successful commercially, reaching combined sales of c.$1.8bn in 2017E (Chart 3), aided by high pricing (c.$96,000 p.a. in the US). The need for novel therapeutic options with improved efficacy and safety remains high, and experts predict that the future treatment paradigm will consist of combination therapy with multiple compounds.

CHART 3: The IPF market exceeded c.$1.8bn in 2017E

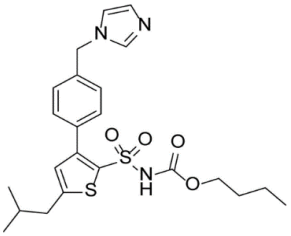


Source: Company data

C21 is a potential first-in-class AT2R agonist to treat IPF

C21 has demonstrated potent anti-inflammatory, antifibrotic and tissue-protective effects in multiple preclinical disease models including pulmonary, renal and vascular fibrosis. Key preclinical studies supporting its development in IPF showed that it prevented, attenuated and reversed pulmonary fibrosis in well-established animal models, and further lowered pulmonary blood pressure without affecting the systemic blood pressure. Its attractive drug-like properties include good solubility in water, oral bioavailability of 20% - 30% and a half-life of 4-6 hours in humans, allowing for once-daily dosing. Importantly, it has a >25,000-fold higher selectivity for the AT2R vs. the AT1R; hence, there is a low risk of side effects due to stimulation of the AT1R (K_i value of 0.4nM for AT2R vs. >10μM for AT1R).

CHART 4: C21 structure



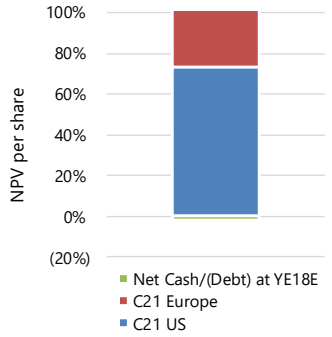
Source: Company data

Pivotal trials could start in 2020E following positive Phase IIa data in Q3/2019E

C21 has already shown favourable safety and tolerability in three Phase I studies in healthy volunteers and a Phase IIa trial in IPF is due to start in April / May, with data expected in Q3/2019E. The strategy is to go straight into a pivotal trial in 2020E – akin to the approach taken by key competitors Galapagos and Prometic – which could lead to approval in 2023E. Our c.$1.4bn peak sales estimate conservatively assumes that C21 shows similar efficacy but better tolerability than approved drugs, and is based on use in up to 15% of IPF patients in the US and Europe plus pricing in line with current therapies. Peak sales could be significantly higher than we currently forecast (potentially double) if C21 demonstrates a clinically meaningful survival benefit for what remains an incurable disease.

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CHART 5: Vicore SOTP valuation



Source: goetzpartners Research estimates. Warning Note: Past performance and forecasts are not a reliable indicator of future performance or results. The return may increase or decrease as a result of currency fluctuations.

SOTP valuation suggests shares could double

Since Vicore is a loss-making growth company that, if successful, will realise much of the value of its products in future years, we value the company using a SOTP valuation based on net present values ("NPVs") for C21 in the US and Europe, plus net debt at YE2018E (Chart 5 and Chart 6). The NPV for each product is derived from free cash flow ("FCF") forecasts until 2032E. We discount FCFs using our estimate for Vicore's weighted average cost of capital ("WACC") of 12.2% and set a zero-terminal value for all product NPVs. We adjust C21 by applying a probability of success of 15%, in line with the average success rate for a compound in early Phase II development. Our SOTP analysis yields a fair value of more than double the current share price, and we expect upside to be driven by pipeline milestones driven primarily by C21 in IPF.

CHART 6: Vicore sum-of-the-parts-valuation

Product	Indications	Stage	Peak sales ($m)	Year	NPV (SEKm)	Probability	Adj. NPV (SEKk)	NPV/share (SEK)
C21 US	IPF	Phase IIa	1,014	2030	3,461	15%	519	33
C21 Europe	IPF	Phase IIa	427	2031	1,086	15%	163	10
Net Cash/(Debt) at YE18E					(1)	100%	(1)	(0)
Fair value (TP)					**4,547**		**681**	**43**
Current Share Price (SEK)								15.8
Upside (Downside)								*172%*

Abbreviations: IPF, idiopathic pulmonary fibrosis; NPV, net present value; TP, target price
Source: goetzpartners Research estimates. Warning Note: Forecasts are not a reliable indicator of future results or performance. The return may increase or decrease as a result of currency fluctuations.

Positive Phase IIa data in Q3/2019E would increase fair value to SEK71 per share

Positive Phase II data for C21 in IPF in Q3/2019E would increase our valuation for Vicore to SEK71 per share (nearly 300% upside to the current share price), based on increasing the probability of success to market to 25% for both the US and Europe.

Survival benefit could drive much higher valuation

The holy grail in IPF drug development is to prolong survival, akin to the objective in most cancer trials. There is currently no precedent, since all compounds tested to date have only shown a modest slowing of disease progression, measured by the annual rate of decline in forced vital capacity ("FVC"), currently the preferred primary endpoint for IPF clinical trials. (FVC is a measurement related to lung size and represents the maximum volume of air in the lungs that can be exhaled following a deep inhalation.) We believe that a survival benefit could drive peak sales of at least $3bn and potentially a much more lucrative licensing deal, which would translate to a current valuation of SEK77 per share – c.3x the current share price.

The key risk is failure of C21 in clinical development

Since our entire valuation currently hinges on C21, the key risk for the shares is the potential failure of C21 in clinical development, which would become apparent at the latest in Q3/2019E when the Phase IIa proof-of-concept trial is due to report data. Other risks include slower than expected patient enrolment due to competing IPF trials; unexpected side effects leading to a premature halting of the trial; and Vicore failing to raise the necessary funds to complete the Phase II trial.

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Innovative approach for fibrotic orphan diseases

Vicore Pharma is a clinical-stage Swedish biotech company focused on rare fibrotic diseases with no or limited treatment options. Its lead asset is C21, a small molecule AT2R agonist in Phase IIa development for IPF. IPF is a rare, but ultimately fatal condition that causes lung scarring, stiffness and shortness of breath, with a prognosis worse than that of most common cancers. The AT2R is part of the RAS and mediates its protective effects, which counter those of the pro-inflammatory, pro-fibrotic AT1R, its better-known sibling and established target for anti-hypertensive therapy. AT2R agonists are a new class of potential drugs that enhance the beneficial effects of the AT2R. Vicore is leveraging its strong scientific heritage accumulated over the last ten years in discovering and developing AT2R agonists to both identify additional fibrotic orphan indications for C21 as well as novel follow-on compounds for development in non-orphan indications. The company completed its initial public offering ("IPO") on the Nasdaq First North Stockholm on 10th December 2015.

Orphan diseases have become a sought-after therapy area

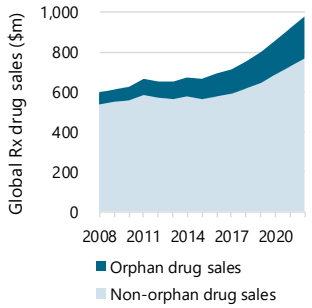
CHART 7: Leading companies focused on rare diseases

Company	Market cap ($bn)
Celgene	67.4
Vertex	43.3
Shire	40.3
Alexion	26.2
BioMarin	13.9

Source: goetzpartners Research

There are approx. 7,000 rare diseases. Recognising that the patient populations were too small for the biopharma industry to commit R&D dollars, the US and Europe introduced orphan drug legislation in 1983 and 2000, respectively, providing multiple regulatory and financial incentives. The most important is a period of market exclusivity from approval: seven years in the US and ten years in Europe. This attracted many companies into the field, initially small biotechs. However, this changed over the years following the success of multiple orphan drugs and there are now many large companies focused on orphan diseases (Chart 7). Another important factor are the premium prices orphan drugs can command: c.$140,000 p.a. on average (vs. c.$28,000 for non-orphan drugs), with some priced above $500,000. The top orphan drug in 2017 was Revlimid with sales of $8.2bn. According to EvaluatePharma, orphan drug sales are expected to grow to a staggering $290bn by 2022E, representing an 11% 2017-2022E CAGR and accounting for over one-fifth of total prescription drug sales (Chart 8).

CHART 8: Orphan drug sales, 2008-2022E (2017-2022E CAGR of 11%)

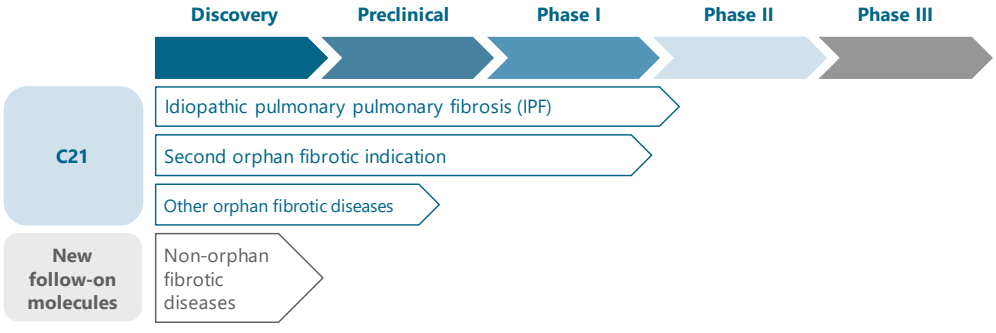


Source: EvaluatePharma

Pipeline focuses on C21 for orphan indications, initially IPF

Vicore is focusing its knowledge of and expertise with the AT2R, plus the strong preclinical data for C21 in multiple fibrotic disease models, to develop the compound for orphan diseases where protective signalling through the AT2R has been shown to produce benefits (Chart 9). C21 is the first non-peptide AT2R agonist to have been synthesised, causing a revolution in the study and hence understanding of the function and signalling of the AT2R. Over 200 research papers have been published, many of them demonstrating its antifibrotic and anti-inflammatory properties, making it an ideal drug candidate for fibrotic indications. C21 has cleared the Phase I hurdle and is in Phase IIa development for IPF, a disease with a high unmet medical need. We believe that pivotal trials could start in 2020 and market entry occurs in 2023.

CHART 9: Vicore's pipeline is focused on orphan indications for C21



Source: Company data

Second orphan indication for C21 to be disclosed in 2018, potentially PAH

Vicore is currently evaluating the development of C21 in a second orphan indication and intends to disclose its decision sometime in 2018. Additional orphan indications may follow in the coming years. A strong candidate is pulmonary arterial hypertension ("PAH"), a disease which shares similarities with IPF and where preclinical data generated with a view to support development in IPF also provided a strong rationale for PAH.

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Follow-on compounds to be developed for non-orphan indications

In parallel, Vicore is continuing its efforts to identify a new generation of AT2R agonists that could potentially be developed for larger, non-orphan diseases, such as complications of diabetes, rheumatoid arthritis and heart failure. This workstream is taking place in collaboration with Vicore's research partner Emeriti Bio, a small private biotech company based in Gothenburg, Sweden. The strategy would be to license these products out to partners at earlier stages of development to create separate, potentially lucrative revenue streams.

SEK81.5m raised since IPO, cash runway till YE/2018

Vicore has raised SEK81.5m in equity since becoming a public company (Chart 10). On our estimates, the SEK56m fundraise completed in Q1/2017 should allow Vicore to fund operations until YE/2018.

CHART 10: Financing events completed since IPO

Date	Event	Security	Proceeds (SEKm)	Price (SEK)	No. of securities issued
Dec-15	IPO	Equity	25.5	6.0	3.25
Jan-17	Loan agreement	Debt	2.4	n.a.	n.a.
Feb-17	Private placement	Equity	56	16	3.50

Source: Company data

Financial investment in I-Tech AB

In addition to the therapeutic business, Vicore's parent company, Vicore Pharma Holding, also has a 21.2% ownership in I-Tech AB, a Gothenburg, Sweden-based, privately-held highly innovative industrial biotech company that has developed and commercialised Selektope (medetomidine), an organic, non-metal compound for use as an antifouling ingredient in antifouling paints. Given the size of the shareholding, which surpassed the 20% threshold in 2017, I-Tech is accounted for using the equity method (applied to ownership of 20% - 50%, which is considered a controlling stake). Vicore's shareholding in I-Tech goes back in history, since both companies shared the same CEO (Per Jansson) for many years. Vicore increased its shareholding in 2017 and in February 2018, and intends to keep the investment until an inflection point leading to significant value creation has been reached before exiting.

News flow will be focused on C21 in the next 12-18 months

Chart 11 shows major news flow items for Vicore. The key share price driver will be the announcement of the results from the Phase IIa trial in IPF, in our view, expected in Q3/2019E. Prior to that, Vicore will be announcing the decision on the second indication for C21, probably in the H2/2018E. We expect this to be PAH, but there are other possibilities given the wealth of supportive preclinical data generated with the compound.

CHART 11: The key catalyst is Phase IIa data for C21 in IPF

Event	Timing
Annual report 2017	12th April 2018
Q1 interim report	8th May 2018
Decision and announcement on 2nd indication for C21	mid-2018 – H2/2018E
Q2 interim report	24th August 2018
Q3 interim report	19th October 2018
Results from C21 Phase IIa proof-of-concept trial in IPF	Q3/2019E

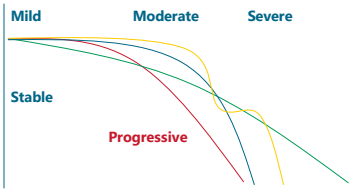
Source: Company data

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IPF treatment paradigm shifting to combo Tx

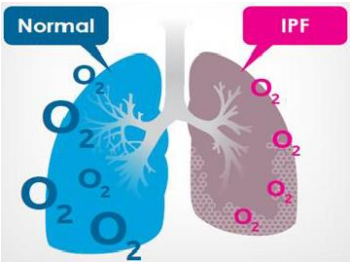
Idiopathic pulmonary fibrosis is a progressive, ultimately fatal lung disease of unknown cause with a highly variable clinical course (Chart 12). It is characterised by a shrinking of the lungs (Chart 13) due to the irreversible formation of fibrosis (i.e. scar tissue), causing stiffness, an irreversible loss of lung function and difficulty breathing. The prognosis is poor and worse than for most cancers. Only two drugs have been approved: Roche / InterMune's Esbriet (pirfenidone) and Boehringer Ingelheim's Ofev (nintedanib). Neither cures IPF nor increases survival, with efficacy limited to a slowing of disease progression, and both cause serious gastrointestinal side effects which up to one-third of patients are unwilling to endure. Access is also difficult due to high pricing. Nevertheless, Esbriet and Ofev have been highly successful commercially since their respective first launches in 2011 and 2014, reaching combined sales of c.$1.8bn in 2017E. The need for novel therapeutic options with improved efficacy and safety remains high, particularly due the multifaceted nature of the disease, with experts predicting that the future treatment paradigm will consist of combination therapy with multiple compounds.

CHART 12: IPF disease progression is highly variable and unpredictable



Source: goetzpartners Research

CHART 13: IPF causes shrinking of the lungs due to irreversible fibrosis



Source: Prometic investor and KOL event, 31 January 2018

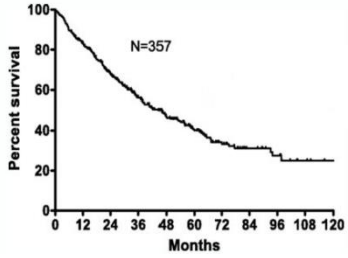
"Common" rare disease, prognosis worse than most cancers

While there is a consensus that IPF is a rare disease and therefore falls into the orphan drug category, the true prevalence of the disease is hard to estimate. This is due to IPF often being difficult to diagnose owing to the lack of specific diagnostic tools and the fact that many of the symptoms are shared with related respiratory diseases. Different studies have established a wide prevalence range of 14 - 43 per 100,000 in the US, equating to a total population of 45,000 to 140,000, and an incidence rate of 50,000 patients per year. In Europe, the prevalence is estimated at 80,000 to 110,000, with new patients accounting for 27% to 44% of the total patient pool each year. The disease affects mainly men between 60 - 70 years of age, where the prevalence is estimated to exceed 200 per 100,000. Hence, IPF is one of the most common of the known rare diseases.

Survival is worse than for all cancers except lung and pancreatic

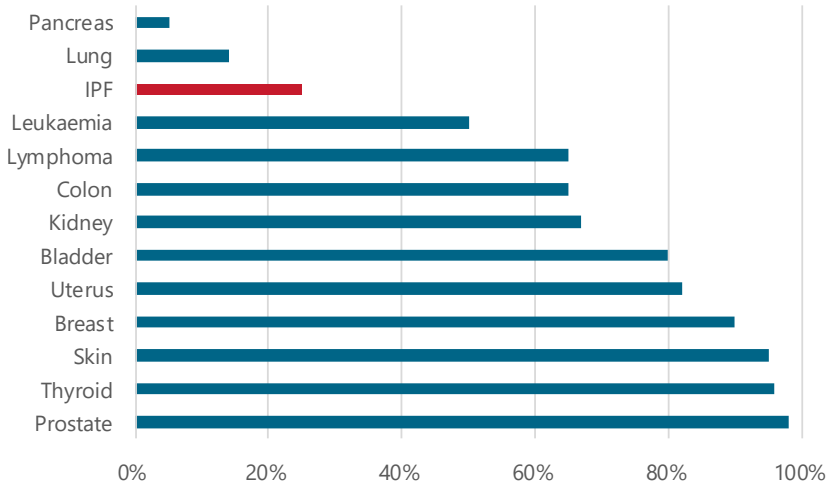
The prognosis of IPF is dismal: patients only live 3 - 5 years after diagnosis, with median survival estimated at 2 - 3 years (Chart 14) – worse than for most common cancers (Chart 15).

CHART 14: IPF is associated with a 50% chance of death three years following diagnosis



Source: Prometic investor and KOL event, 31 January 2018

CHART 15: Survival in IPF patients following diagnosis is worse than for most cancers



Source: Vancheri et al. (2009) European Respiratory Journal

Disruption to normal wound healing process

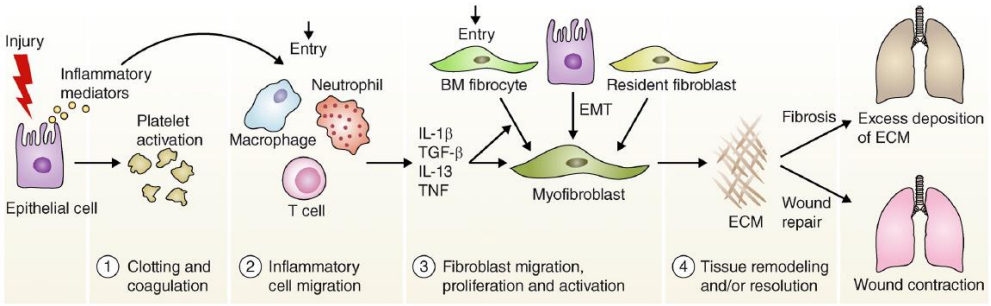
IPF is characterised by damage to the alveoli (the small "air bubbles" in the lungs) as well as the lung tissue surrounding the alveoli. The disease arises due to a disruption to the normal wound healing process, which causes thickening and damage to the walls of the alveoli, thus leading to fibrosis (scarring). This process occurs gradually and is accompanied by progressive loss of lung function, thus decreasing the amount of oxygen the lungs can supply to major organs of the body. This is why patients need to receive supplemental oxygen in advanced stages of the disease.

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Complex underlying cellular and molecular mechanisms

Fibrotic disease overall regardless of organ type affected is a complex process involving many cell types and molecular pathways. Wound healing generally occurs in the four distinct stages depicted in Chart 16: (1) a clotting phase; (2) an inflammatory cell migration phase; (3) a fibroblast migration, proliferation and activation phase; and (4) a tissue remodelling and resolution phase. The process starts with an initial injury to the lung, which triggers a cascade of inflammatory mediators that cause blood clotting, the removal of dead cells, proliferation of myofibroblasts (the main cellular culprit in fibrosis) that release extracellular matrix components, and ultimately wound repair. It is thought that either a disruption at any of these stages or persistent lung injury can lead to lung fibrosis. There are many different cytokines and other molecular mediators involved in this process, with transforming growth factor beta ("TGF-beta") known to play a central role in fibrogenesis.

CHART 16: IPF is caused by a disruption to the normal wound healing process



Source: Wynn (2011) *Journal of Experimental Medicine*

Treatment options have limited efficacy and poor tolerability

Key limitations of currently approved IPF therapies
1. Lack of survival benefit
2. Zero benefit in a sizeable proportion of patients
3. Poor safety and tolerability, leading many patients to discontinue treatment or abstain altogether

Until recently, IPF treatment was limited to oxygen therapy, pulmonary rehabilitation and lung transplant. While there has not been a shortage of attempts to develop a therapeutic agent for IPF, only two compounds have been approved to date, based on demonstrating a reduction in disease progression: Boehringer Ingelheim's Ofev (nintedanib) and Roche/InterMune's Esbriet (pirfenidone) (Chart 17). However, neither product prolongs survival, and both are associated with debilitating, predominantly gastrointestinal side effects. Consequently, up to 30% of patients are unwilling to initiate therapy, while many others discontinue treatment within a few weeks of starting.

… and yet have created a c.$1.8bn market

Nevertheless, both products are recommended by the most recent treatment guidelines and generated estimated combined sales of c.$1.8bn in 2017E, up from c.$1.46bn in 2016 (+48% YoY). The staggering growth of the IPF market in the short period of time since Esbriet was first approved has lured other companies into the field, which has led to some large licensing and M&A deals – the most prominent of which was the acquisition of InterMune by Roche on 24 August 2014 for $8.3bn in cash (c.38% premium), shortly before expected FDA approval later that year.

CHART 17: Two therapies are approved for IPF. Both affect multiple pathways implicated in fibrosis

Company	Product	Molecule	Class	MoA	FDA approval	EMA approval
Roche/InterMune	Esbriet	pirfenidone	Antifibrotic (pyridone)	Downregulates TGF-beta and regulates multiple other profibrotic and proinflammatory cytokines	15-Oct-14	3-Mar-11
Boehringer Ingelheim	Ofev	nintedanib	Tyrosine kinase inhibitor	Inhibits multiple tyrosine kinases. Targets multiple growth factor receptors, incl. VEGF, FGF and PDGF, all of which have been implicated in IPF	15-Oct-14	19-Jan-15

Abbreviations: FGF, fibroblast growth factor; PDGF, platelet-derived growth factor; TGF, transforming growth factor; VEGF, vascular endothelial growth factor
Source: Company data

FVC is the preferred and most commonly used primary endpoint for IPF trials

Esbriet and Ofev slow down lung deterioration, but do not prolong survival

Esbriet and Ofev, both orally available, were approved based on demonstrating a significant benefit on disease progression only, measured by the annual rate of decline in FVC. Neither drug demonstrated a significant benefit on mortality or acute exacerbation of IPF. FVC is currently the preferred primary endpoint for IPF clinical trials, since it is (1) by far the best validated clinical marker, (2) easy to measure and (3) highly reproducible. It is a measurement related to lung size and represents the maximum volume of air in the lungs that can be exhaled following a deep inhalation. During the normal ageing process, FVC declines by 20 - 25ml per year. In IPF patients, the decline is as high as 200ml per year.

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Esbriet: third pivotal trial requested by FDA prior to US approval

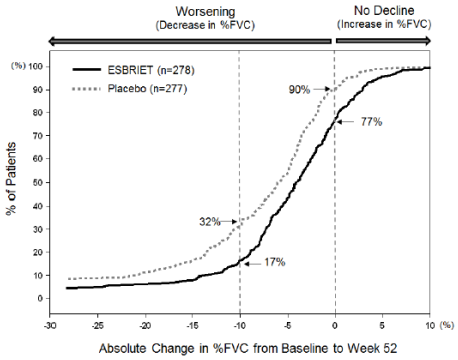
Esbriet was tested in three pivotal trials (Chart 18). Initially only the CAPACITY clinical trials were conducted. However, since CAPACITY 006 failed to meet the primary endpoint, the FDA requested an additional trial. InterMune then completed ASCEND, which together with CAPACITY 004 led to FDA approval. Both trials showed a similar reduction in decline in FVC (Chart 19 and Chart 20).

CHART 18: Pivotal Phase III trials completed for Esbriet

Trial name	No. of patients
CAPACITY 004	435
CAPACITY 006	344
ASCEND	555
Total patients	1,334

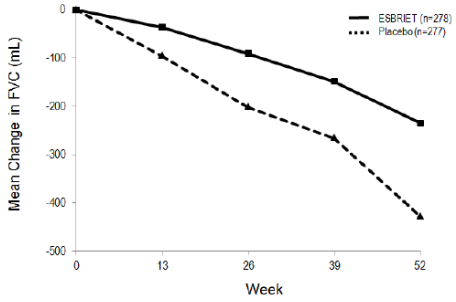
Source: Company data

CHART 19: Cumulative distribution of pts by change in % predicted FVC from baseline to week 52



The vertical lines indicate ≥0% decline or ≥10% decline.
Abbreviations: FVC, forced vital capacity
Source: CAPACITY 004 trial. Esbriet US prescribing information

CHART 20: Mean change from baseline in FVC



Abbreviations: FVC, forced vital capacity
Source: CAPACITY 004. Esbriet US prescribing information

Ofev was approved based on the two INPULSIS trials

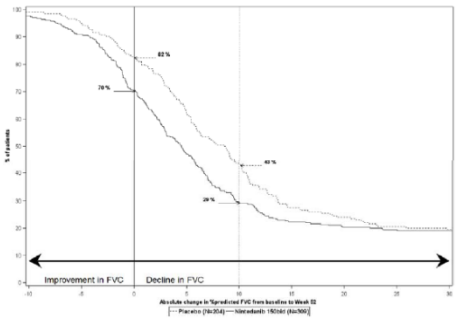
Ofev was tested in two replicate pivotal trials, INPULSIS-1 and INPULSIS-2 (Chart 21), which together enrolled 1,066 patients with a follow-up of 52 weeks. Both trials hit their primary endpoints (Chart 22 and Chart 23), with the results broadly similar to those from the Esbriet trials.

CHART 21: Pivotal Phase III trials completed for Ofev

Trial name	No. of patients
INPULSIS-1	515
INPULSIS-2	551
Total patients	1,066

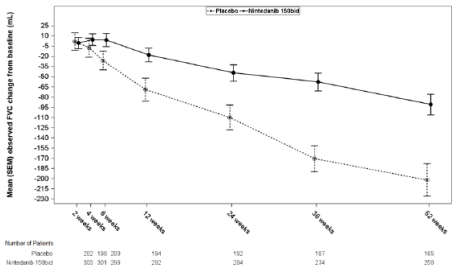
Source: Company data

CHART 22: Cumulative distribution of pts by change in % predicted FVC from baseline to week 52



The vertical lines indicate ≥0% decline or ≥10% decline.
Abbreviations: FVC, forced vital capacity
Source: Ofev US prescribing information

CHART 23: Mean change from baseline in FVC



Abbreviations: FVC, forced vital capacity
Source: Ofev US prescribing information

CHART 24: Esbriet (pirfenidone) and Ofev (nintedanib) are associated with gastrointestinal side effects



Source: Prometic investor and KOL event, 31 January 2018

Poor safety and tolerability, often leading to treatment discontinuation

Esbriet and Ofev are associated with many side effects (Chart 25 and Chart 26) that often lead to dose reduction or treatment discontinuation. Esbriet causes mainly upper gastrointestinal ("GI") issues such as vomiting, while Ofev triggers predominantly lower GI problems such as diarrhoea (Chart 24). These side effects are particularly challenging to tolerate because most patients suffer from multiple co-morbidities. In the pivotal Phase III programmes, dosage reduction or interruption for gastrointestinal events overall was required in 18.5% of patients receiving Esbriet, while diarrhoea due to Ofev therapy led to a permanent dose reduction in 11% and discontinuation in 5% of patients. In addition, patients need to undergo liver function tests prior to receiving therapy, as the drugs can cause elevated liver enzymes and drug-induced liver injury. This may be related to the high pharmacological doses at which they are administered: (1) for Esbriet, the recommended dose is 801mg three times daily, for a total of 2.4g per day; (2) for Ofev, it is 150mg twice daily, for a daily total of 300mg per day.

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CHART 25: Adverse events observed in Esbriet pivotal trials

Adverse reaction	Esbriet	Placebo
Nausea	36%	16%
Rash	30%	10%
Abdominal pain	24%	15%
Diarrhoea	26%	20%
Fatigue	26%	19%
Dyspepsia	19%	7%
Dizziness	18%	11%
Vomiting	13%	6%
Photosensitivity	9.0%	1%
Liver enzyme elevation	3.7%	0.8%

Source: Esbriet US prescribing information

CHART 26: Adverse events observed in Ofev pivotal trials

Adverse reaction	Ofev	Placebo
Diarrhoea	62%	18%
Nausea	24%	7%
Abdominal pain	15%	6%
Vomiting	12%	3%
Liver enzyme elevation	14%	3%
Decreased appetite	11%	5%

Source: Ofev US prescribing information

Conditional recommendation for Ofev and Esbriet in current treatment guidelines

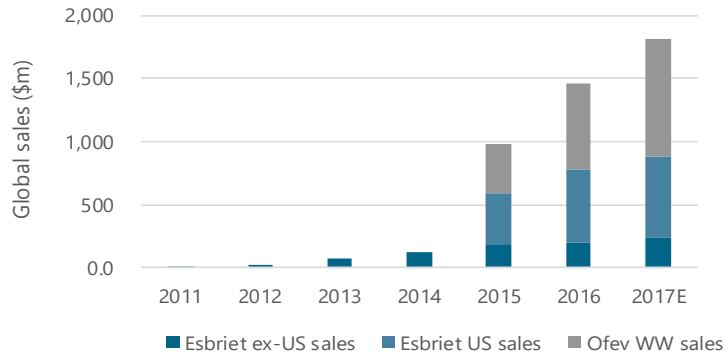
The most recent treatment guidelines (developed by a consortium consisting of the American Thoracic Society ["ATS"], the European Respiratory Society ["ERS"], the Japanese Respiratory Society ["JRS"] and the Latin American Thoracic Association ["ALAT"]) prudently recommend both Ofev and Esbriet for use in IPF patients, albeit with a conditional recommendation and highlighting both the poor side effect profile and the high prices (see below). The rationale for prescribing these therapies is the following: (1) IPF disease progression is highly variable and unpredictable, and lung tissue "lost" due to fibrosis cannot be recovered. Hence, the earlier therapy is initiated, the higher the potential benefit. Both Esbriet and Ofev have shown a reduction in the annual rate of decline in FVC, therefore addressing this goal; (2) it is not known *a priori* who will respond to treatment, so the only way to find out is for patients to start taking either Esbriet or Ofev. The only other approved therapeutic option is anti-acid medication, based on possible improved lung function and the low cost of therapy.

The US represented c.75% of the c.$1.8bn in 2017E

The IPF market grew at a 3-year CAGR of 144% since US launch in 2014.

Despite their limited efficacy, poor safety profiles and high prices, costing c.$95,000 per year in the US and c.€40,000 in Europe, Esbriet and Ofev have enjoyed strong sales growth since launch (Chart 27). We estimate that combined sales reached over $1.8bn in 2017E, +25% YoY, based on reported Esbriet sales of c.$883m and estimated Ofev sales of $935. This reflects the willingness of patients to cling to any therapy shown to provide some sort of efficacy, similar to what is observed for cancer drugs, where many drugs that provide limited survival benefits as low as 1 - 2 months achieve high sales. We estimate that c.75% of sales come from the US market, based on the sales split for Esbriet in 2017E. (Boehringer Ingelheim is a private company and does not provide the geographical sales split for Ofev.)

CHART 27: The IPF market was worth c.$1.8bn in 2017E



Source: Company data, goetzpartners Research estimates. Warning Note: Past performance and forecasts are not a reliable indicator of future performance or results. The return may increase or decrease as a result of currency fluctuations.

IPF pipeline: few compounds in late-stage development

Key opinion leaders ("KOL") believe that the future IPF treatment paradigm will be combination therapy consisting of as many as four molecules with different mechanisms of action – similar to the management of HIV

Before the modest clinical successes achieved with Esbriet and Ofev, multiple late-stage IPF trials had failed. Past failures have been attributed to multiple factors, particularly inadequate mechanisms of action. The large theoretical IPF market opportunity coupled with the commercial successes of both Esbriet and Ofev despite their sub-optimal clinical profiles continues to attract companies into the space. According to recent studies, the clinical IPF pipeline currently comprises over 100 therapeutic candidates, of which only one is in Phase III and nearly 20 are in Phase II development. Drugs in late-stage development include both oral agents and antibody drugs. Approaches include treatment of naïve patients, add-on to pirfenidone and / or nintedanib and 3rd-line therapy in patients who have failed Esbriet and Ofev.

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Chart 28 shows the most advanced and promising agents. Given the complex nature of the disease, experts believe that combination therapy with three or four drugs will be necessary to have a real impact on slowing disease progression and potentially extending survival. Hence, there is ample room for multiple additional novel agents in the IPF drug arsenal.

CHART 28: IPF pipeline includes three promising drugs expected to be in pivotal trials by YE 2018

Company	Molecule	Mechanism of action	Phase	Admin	Comment
Asahi Kasei	ART-123	Thrombomodulin-a	Ph III ongoing	IV	Focus on acute flares, endpoint is survival
Prometic	**PBI-4050**	**Anti-inflammatory/anti-fibrotic**	**Ph II completed**	**Oral**	**Pivotal Ph II/III trial design agreed with FDA on 29 Jan 2018. Two trials to start in mid-2018**
FibroGen	**Pamrevlumab/FG-3019**	**anti-CTGF human mAb**	**Ph IIb completed**	**IV**	**Ph III is being planned**
Galapagos	**GLPG1690**	**Autotaxin inhibitor**	**Ph IIa completed**	**Oral**	**Ph III is being planned**
Kadmon	KD025	ROCK2 inhibitor	Ph II ongoing	Oral	Trial recruiting as of Mar 2018
Biogen	BG00011/STX-100	Anti-alpha v beta 6 integrin	Ph II completed	SC	Next step unclear
BMS	BMS-986202	LPA1 Antagonist	Ph II	Oral	Status unclear
Medicinova	MN-001/tipelukast	Anti-fibrotic	Ph II ongoing	Oral	Results possible in H2/2018

Abbreviations: CCL2, chemokine (C-C motif) ligand 2; CTGF, anti-connective tissue growth factor; ERS, European Respiratory Society; IV, intravenous; LOXL-2, lysyl oxidase-2; LPA, lysophospholipid; mAb, monoclonal antibody; Ph, clinical phase of development; ROCK, Rho-associated kinase coiled-coil kinase
The three leading companies in the space are highlighted in bold.
Source: Company data

Three companies vying for pole position: Prometic, Galapagos, Fibrogen

The most advanced company is Prometic, having disclosed on 29th January 2018 that it had agreed the design of the adaptive Phase II / III pivotal trial programme with the FDA. Patient enrolment into two pivotal trials is expected to start in mid-2018. One trial will enrol patients already receiving nintedanib (patients on pirfenidone will be excluded due to a known drug-drug interaction between pirfenidone and PBI-4050), while the other trial will select patients who are treatment naïve, thus allowing for a broad label irrespective of background therapy ("for the treatment of IPF"). Patients will be randomised to receive PBI-4050 800 mg or 1,200 mg, or placebo for 52 weeks, with an interim analysis planned at 26 weeks to determine which dose to take forward into the Phase III portion of the trial. The primary endpoint is the annual rate of decline in FVC. The other two most advanced companies are Galapagos and FibroGen, who are currently planning their pivotal trials with a view to starting enrolment this year.

Recent Phase III failures reflect difficulty in tackling disease complexity

There have been multiple Phase II and Phase III in IPF in recent years, such as Gilead's simtuzumab (anti-LOXL2), Roche's lebrikizumab (anti-IL-13), AstraZeneca's tralokinumab (anti-IL-13) and Sanofi's SAR156587 (dual anti-IL13/anti-IL4). Reasons for the high failure rate in this rapidly progressing disease include: (1) heterogeneous pathogenesis of the disease, (2) inappropriateness of study designs and endpoints used in clinical trials, and (3) lack of merit of the products studied due to their high level of specificity for one or a few molecular pathways, an approach which is unlikely to work in a complex, multifactorial disease such as IPF. Most of the ineffective drugs developed in the more distant past were repurposed as a potential line extension and had very narrow mechanisms of action (Chart 29).

CHART 29: Past late-stage IPF failures include drugs developed as line extensions

Company	Brand name	Molecule	Mechanism of action	Primary indication
J&J/Actelion	Tracleer	bosentan	Dual ER-A & ER-B antagonist	PAH
J&J/Actelion	Opsumit	macitentan	Dual ER-A & ER-B antagonist	PAH
Gilead	Letairis	ambrisentan	Selective ER-A antagonist	PAH
Pfizer	Revatio (Viagra)	sildenafil	PDE-5 inhibitor	PAH
Novartis	Gleevec	imatinib	Tyrosine kinase inhibitor	Multiple leukaemias

Abbreviations: ERA, endothelin receptor; PAH, pulmonary arterial hypertension; PDE, phosphodiesterase-5 inhibitor
Source: Raghu *et al.* (2015) *Am J Respir Crit Care Med*

Few, but high-value deals have been announced in the IPF space

Deal activity has been limited in the IPF space, but the few deals that were completed have been lucrative for the seller / licensor (Chart 30).

CHART 30: Select recent deals in the idiopathic pulmonary fibrosis space

Date	Target	Acquirer/licensee	Compound	Stage	Deal value ($m)	Comments
Jun-16	Afferent	Merck & Co	AF-219	Ph II	1,250	For symptomatic treatment (persistent cough)
Aug-15	Promedior	BMS	PRM-151	Ph II	1,250	$150m upfront, remainder contingent on +ve Ph II
Nov-14	Galecto	BMS	TD139	Ph Ib	444	Option to acquire company following +ve Ph Ib data
Aug-14	InterMune	Genentech/Roche	Esbriet	Marketed (EU)	8,300	Acquired 3 months prior to FDA approval
Feb-12	Stromedix	Biogen	STX-100	Ph I	563	Compound was Ph II ready

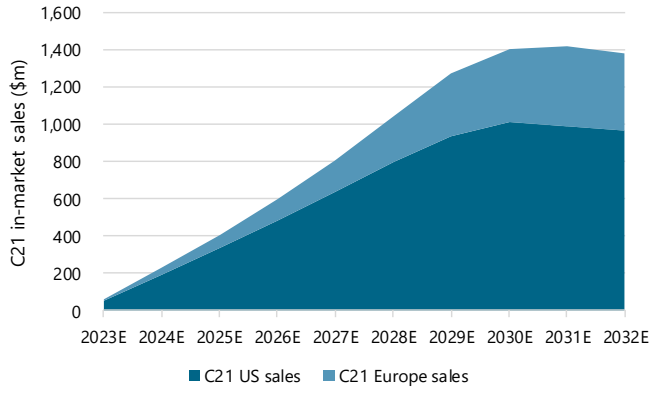
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First-in-class AT2R agonist in Phase II for IPF

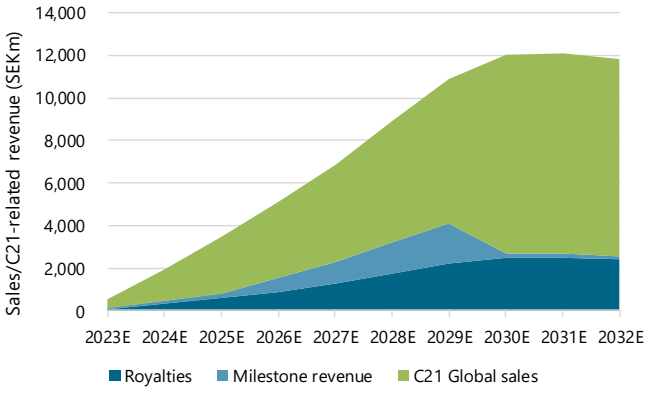
Vicore's lead drug C21, the first (and only) selective, non-peptide small molecule AT2R agonist to have been synthesised, is being developed for IPF, based on demonstrating potent anti-inflammatory and antifibrotic effects in multiple preclinical disease models including pulmonary, renal and vascular fibrosis. C21 has already shown favourable safety and tolerability in three Phase I studies in healthy volunteers. A Phase IIa trial in the target patient population is due to start in April / May 2018, and the strategy is to go straight into a pivotal trial, which could lead to approval in 2023E. We estimate peak sales for C21 of c.$1.4bn (Chart 31), based on use in up to 15% of IPF patients in the US and Europe and pricing in line with current therapies. We assume that Vicore enters a lucrative licensing deal following Phase IIb data consisting of upfront and milestone payments plus royalties on sales, which would allow the company to retain a significant share of C21's value (Chart 32).

CHART 31: C21 global sales to exceed $1.4bn by 2030E



Source: goetzpartners Research estimates. Warning Note: Forecasts are not a reliable indicator of future performance or results. The return may increase or decrease as a result of currency fluctuations.

CHART 32: Vicore would retain a significant share of C21's value from a global licensing deal



Source: goetzpartners Research estimates. Warning Note: Forecasts are not a reliable indicator of future performance or results. The return may increase or decrease as a result of currency fluctuations.

Renin-angiotensin-system: a tale of two receptors

The AT2R is part of the RAS, a central system of the body to regulate blood pressure and which has yielded several important targets for (cardiovascular) drug therapy for over 40 years. It has been known since the 1980s that angiotensin II ("Ang II") mediates its action via two major receptors, AT1R and AT2R (Chart 33). The consequences of the RAS system depend on the circumstances and to which receptor Ang II binds. AT1R is associated with the regulation of blood pressure, fluid and electrolyte balance, but its activation also mediates negative effects causing hypertension (high blood pressure), fibrosis and inflammation. In contrast, the AT2R mediates opposing anti-inflammatory, antifibrotic and tissue protective effects. Historically, most attention focused on the widely expressed AT1R, yielding many drug targets and consequently hypertension drugs, while the study of the AT2R was hampered by its low expression levels and the lack of a metabolically stable agonist. The synthesis of C21 in 2004 provided researchers with the necessary tool to elucidate the AT2R's role, while its attractive drug-like properties made it suitable for therapeutic development.

Binding of angiotensin II can have both beneficial and detrimental consequences

Under normal circumstances, the RAS is in a baseline-level state. In a situation of injury and rapid blood loss, the kidneys release the enzyme renin, leading to angiotensin being converted to angiotensin I, which is then converted into Ang II by the angiotensin converting enzyme ("ACE"). The octapeptide Ang II binds to the AT1R, mediating vasoconstriction and prompting the kidneys to retain more salt and water, leading to a rise in blood pressure to keep the individual alive. However, in a disease state, this life-saving system can be highly detrimental and pathogenic, causing unnecessary high blood pressure and damage to the heart's left ventricle, which pumps oxygenated blood from the heart to the body.

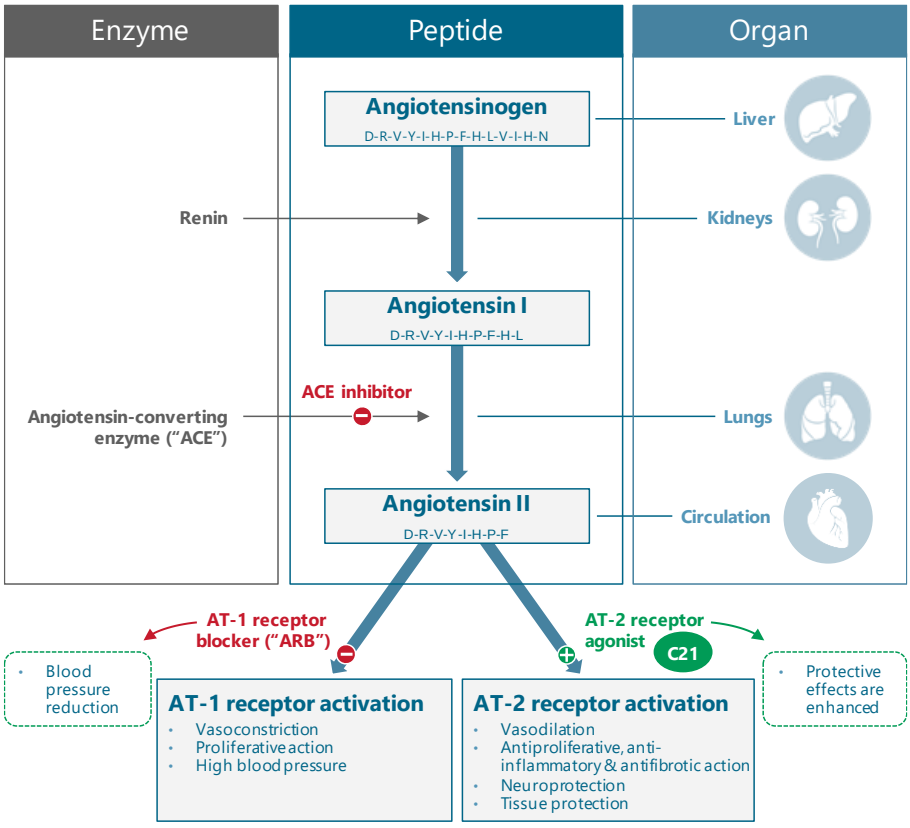
Drug therapy has focused on blocking the damaging effects of the AT1-receptor

AT1R is the most widely studied of the two Ang II receptors and drug therapy has largely focused on blocking its actions, with the aim of lowering blood pressure. There are three drug targets: ACE, AT1R, and renin. The first antihypertensive drug to reach the market was ACE inhibitor Capoten captopril, first launched by BMS in 1978. The first ARB, Novartis's Cozaar losartan, was launched almost 20 years later, followed by many other "sartans". It took almost another decade for the first renin inhibitor, Novartis's/Speedel's Tekturna aliskiren to be launched in 2007.

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The ARBs in particular have proven to be very effective in lowering blood pressure with benign safety profiles. To further improve the therapeutic benefit, combination therapy with two different targets within the RAS system was tested. However, this approach unexpectedly caused harm in patients and dual therapy is therefore not recommended. This led to the search for alternative therapeutic strategies to enhance the protective effects of the RAS.

CHART 33: Renin-angiotensin system mediates its actions via two receptors with antagonistic effects



Source: goetzpartners Research

Stimulation of the ATR2 mediates tissue-protective actions

The AT2R was identified in 1989. Early characterisation of its signalling and function revealed that it mediated opposite effects to those mediated by the AT1R, with later studies elucidating its multiple tissue-protective actions such as anti-inflammation, anti-fibrosis and anti-apoptosis.

Low expression levels in healthy adults, upregulation in disease situations including IPF

A detailed understanding of the AT2R was hampered by its low expression levels in adults. Despite being highly expressed at the embryonic stage and in most foetal tissues (including the brain), the AT2R / AT1R receptor ratio falls rapidly after birth. In healthy adults, high expression levels of the AT2R can only be found in specific tissues such as the adrenal glands, renal and cardiovascular tissue, as well as certain areas of the brain. However, expression has been scientifically shown to be upregulated in pathological conditions such as brain lesions, vascular injury, wound healing and in the lungs of IPF patients. Its stimulation results in a broad range of protective effects, ranging from vasodilation and inhibition of cell proliferation to extracellular matrix remodelling.

Structure sheds light on unusual signalling

It has long been known that the AT2R shares its structure with "classical" G-protein-coupled receptors ("GPCR"), the largest membrane receptor family in humans and which are implicated in a range of diseases including high blood pressure and cancer. However, a puzzle that has taken many years to solve was why the signalling and functions of the AT2-receptor, particularly its protective nature, are so distinct from "classical" "GPCR" signalling, which usually contributes to inflammation and fibrosis. The recent description of the AT2R's crystal structure (Zhang *et al.* 2017) sheds some light on this. The authors discovered that the receptor changes its conformation in a highly unusual way upon binding of an agonist, which causes that an extension of the receptor within the cell flips over, thus blocking the binding sites for key ligands involved in the activation of "classical" GPCR.

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C21 is a highly selective small molecule AT2R agonist

C21 profile

- First small molecule AT2R agonist
- Water soluble
- Oral bioavailability of 20-30%
- $t_{1/2}$ of 4-6 hours in humans
- >25,000-fold higher selectivity for AT2R vs. AT1R
- Antifibrotic, anti-inflammatory, anti-proliferative properties
- Improves elasticity of surrounding tissue

C21 is the first selective, non-peptide small molecule AT2R agonist to be synthesised, work which was carried out under Prof. Anders Hallberg at the University of Uppsala, Sweden in 2004. The discovery of C21 was not due to serendipity as is often the case in fundamental and clinical research, but the result of dedicated medicinal chemistry efforts focused on synthesising a selective AT2R agonist with high oral bioavailability. The starting point was the non-selective AT1R and AT2R agonist L-162,313, which was chemically modified through many steps to yield the highly selective AT2R agonist C21, which has c.25,000-fold higher selectivity for AT2R than for AT1R (K_i value of 0.4nM for AT2R vs. >10μM for AT1R. The lower the K_i, the higher the affinity for the receptor).

C21 attacks the fibrotic process from multiple angles

IPF is characterised by continuous remodelling of lung tissue to fibrotic tissue following lung injury. C21 inhibits this process by stimulating the AT2R, thus initiating a series of tissue-protective processes that block the fibrotic process from many different angles, which is important given the multifactorial nature of the disease and the high degree of biological redundancy. Both pirfenidone and nintedanib are thought to be active against IPF due to interfering with / blocking *multiple* molecular pathways, in contrast to failed compounds which were highly specific for only one or a few pathways. The pleiotropic actions of C21 were confirmed in multiple in vitro and preclinical studies.

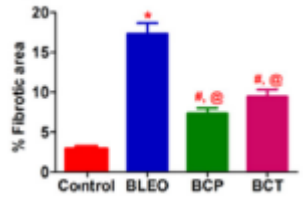
Extensive preclinical data supports development in IPF

Fundamental research groups in many labs worldwide have used C21 to characterise the AT2R and over 200 journal papers have been published. Collectively, they (1) elucidate the tissue-protective properties of the AT2R in various disease models and (2) describe the potent antifibrotic and anti-inflammatory properties of C21 in many fibrotic conditions in lungs, kidneys, heart, blood vessels and skin in animal studies. The evidence strongly supports the development of C21 for fibrotic diseases such as IPF.

Prevention, attenuation and reversal of fibrosis; lowering of pulmonary blood pressure

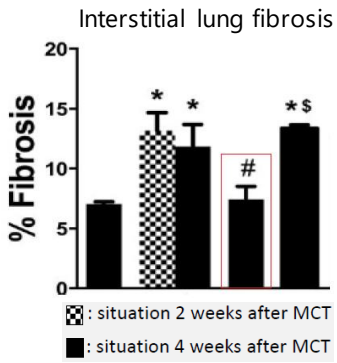
Key preclinical studies supporting the development of C21 in IPF showed that C21: 1) prevented and attenuated the progression of lung fibrosis in the well-established model of bleomycin-induced lung injury (Chart 34); (2) reversed fibrosis in the monocrotalin model of induced fibrosis (Chart 35); and (3) lowered pulmonary blood pressure (Chart 36) without affecting the systemic blood pressure (Chart 37) in both models. Blood pressure in the pulmonary circulation is often elevated in IPF patients and meaningfully worsens the prognosis, and neither of the two approved drugs has shown a benefit. Reassuringly, the EMA was very complimentary about this particular effect of C21 and based their decision to grant C21 orphan drug designation for IPF on the additive, beneficial effect on pulmonary hypertension associated with lung fibrosis.

CHART 34: C21 attenuates lung fibrosis in the bleomycin model



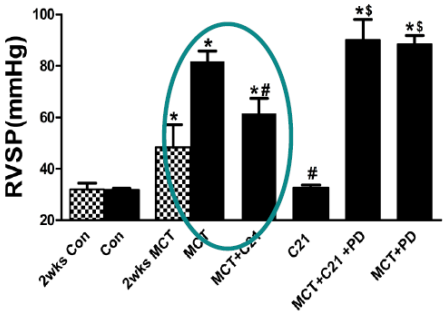
*, #, @: indicates a p-value of <0.05
Source: Rathinasabapathy *et al.* (2018) *frontiers in Physiology*

CHART 35: C21 reverses fibrosis in the monocrotalin model



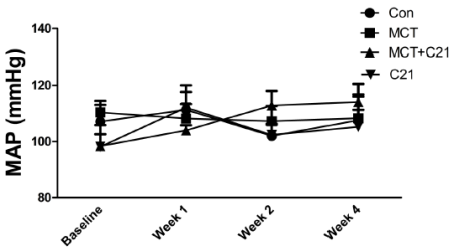
Source: Bruce *et al.* (2015) *Br J Pharmacol*

CHART 36: C21 lowers right ventricular systolic pressure (a measure for pulmonary blood pressure)



Source: Bruce *et al.* (2015) *Br J Pharmacol*

CHART 37: C21 has no effect on systemic blood pressure



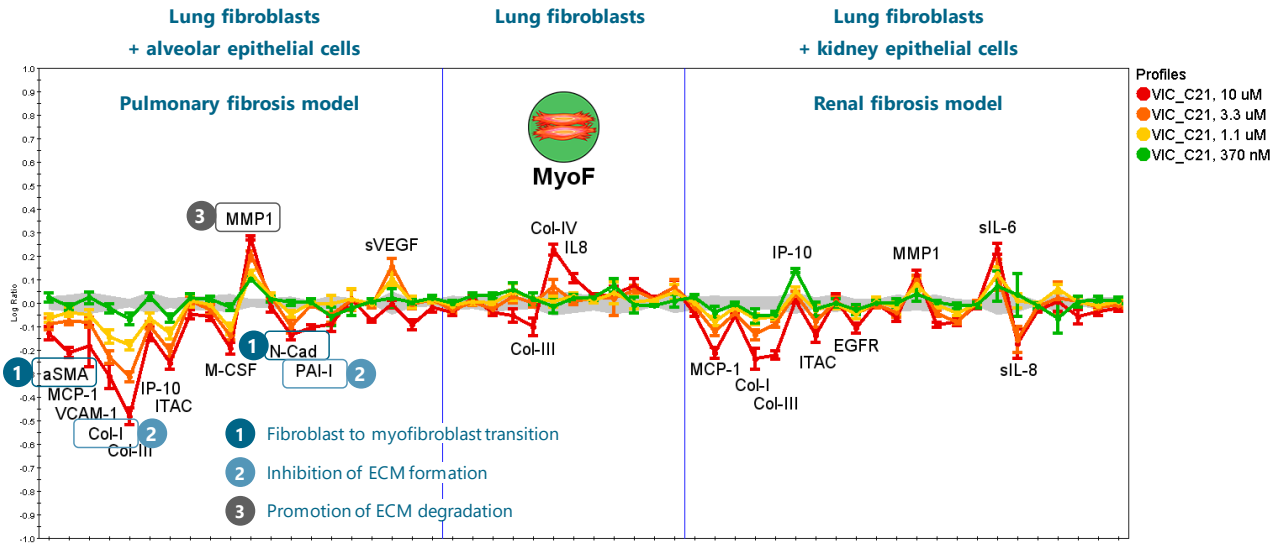
Source: Bruce *et al.* (2015) *Br J Pharmacol*

Reversal of fibrotic markers in primary human cells

Vicore conducted a BioMAP study (Chart 38) on fibrotinised human epithelial cells from lungs and kidneys aimed at benchmarking C21 vs. established IPF drugs. BioMAP is a screening study where human primary cells in co-culture (kidney or lung epithelial cells cultured together with fibroblasts) are exposed to fibrosing and pro-inflammatory compounds to create a milieu that mimics the disease of interest for testing of new drug candidates. The results showed favourable effects for C21 vs. pirfenidone and nintedanib, building on the large body of evidence from animal models by showing that C21 also exerts positive antifibrotic effects in primary human cells. Key findings are summarised in Chart 39.

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CHART 38: C21 lowers pro-fibrotic, raises anti-fibrotic markers in BioMAP human primary cell assay



➢ **Cells are treated with TGF-beta and TNF-alpha to induce a pro-fibrotic milieu**

Source: Company data

CHART 39: Key findings for C21 in the BioMAP study

▪ C21 was most active in the fibrotic lung disease model where it positively affected several markers indicative of inflammation and fibrosis in a dose dependent manner
▪ C21 exerted stronger effects than the currently approved drugs
▪ Positive effects on both matrix- and inflammation-related readouts demonstrated by C21 may translate to a stronger clinical impact than current therapies
▪ C21 was shown to be active and non-cytotoxic in the BioMAP panel for the concentration range tested

Source: Company data

Pivotal trials could start as early as 2020E following Phase IIa

C21 has already cleared the Phase I hurdle, showing good safety and tolerability. A Phase IIa proof-of-concept trial in IPF patients focused on finding robust efficacy signals will start enrolling patients in April / May, with data expected in Q3/2019E. Depending on the strength of the data, the plan is to go straight into a pivotal trial with the goal of filing for regulatory approval in 2022E. This would be in line with key competitors Galapagos and Prometic who went from small Phase IIa studies straight into registration trials.

Phase I hurdle passed with flying colours; beneficial effect seen on fats in the blood

Three Phase I trials in healthy adults completed in 2016 with the help of Finnish Contract Research Organisation ("CRO") Clinical Research Services Turku ("CRST") showed that C21 was safe, well tolerated and exhibited constant blood levels (Chart 40). One study was conducted in obese men and additionally showed unexpected, but beneficial effects on blood lipids, with C21 demonstrating a clinically relevant and consistent protective effect on blood lipids: low density lipoprotein ("LDL") (bad cholesterol) decreased while high density lipoprotein ("HDL") (good cholesterol) increased.

CHART 40: C21 successfully completed three single and multiple-ascending-dose Phase I studies

Trial & design	Objectives	Study period	N	Population	Dosing	Key findings
Phase I	Safety, tolerability, investigate if markers of metabolic dysfunction are affected by C21	Jan- Aug 2017	16	Overweight men (risk group), BMI 30-35	100mg C21 vs. placebo for 8 days (1:1)	C21 well tolerated and safe, no adverse readings for any biomarker, evidence for lowering of plasma LDL
Phase I	Safety, tolerability, PK	May-Nov 2016	48	Healthy adults	Ascending oral doses (25-100mg)	All objectives for Phase I met. C21 was well tolerated, safe in high doses and exhibited constant blood levels. MTD not reached
Phase I Double-blind, randomised, placebo-controlled	Safety, tolerability, PK	Apr-Jun 2016	24	Healthy adults	Six ascending oral doses (0.3mg-100mg)	

Abbreviations: IPF, idiopathic pulmonary fibrosis; LDL, low density lipoprotein; MTD, maximum tolerated dose; PK, pharmacokinetics
Source: Company data

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Start of proof-of-concept Phase IIa imminent, data expected in Q3/2019E

The Phase IIa proof-of-concept trial is being conducted under the supervision of Dr Joanne Porter at the UK's University College London ("UCL") and in partnership with Parexel, a leading CRO. Approval from the UK's Medicines and Healthcare Products Regulatory Agency ("MHRA") should be granted in the coming weeks and enrolment of the first patient is therefore imminent. The primary objectives of the trial are to (1) show that C21 is safe and well tolerated in IPF patients and (2) identify the efficacy signals required to start a pivotal trial. The study is expected to take 15 - 18 months, with data expected in Q3/2019E. The design of the trial is shown in Chart 41. We would like to highlight the following points:

- **C21 monotherapy in treatment-naïve patient population:** following consultation with Parexel, a top 10, highly experienced and reputable CRO, Vicore decided to conduct the trial in the UK and Eastern Europe. The aim is to access treatment-naïve patients in order to test C21 as monotherapy, rather than combination therapy as add-on to pirfenidone or nintedanib. Although the region is often associated with a high placebo effect, this is not a concern in IPF as the primary and key exploratory endpoints are based on robust efficacy signals and not subjective assessments;

- **1-month treatment period sufficient to see expected treatment effect:** the short treatment period was chosen over the more standard three months (as selected by Prometic and Galapagos for Phase IIa trials) based on extensive consultation with KOL in the IPF field. The rationale is that the efficacy signals that Vicore expects to see will most likely either become apparent after one month or not at all, with an extra two months of treatment not materially changing the outcome. The treatment duration in the ensuing Phase IIb trial would be the standard 24 - 48 weeks;

- **Key efficacy signals focused on fibrosis-specific biomarkers:** the focus will be on a few highly specific plasma biomarkers – C1M, C3M and PRO-C3 – which were selected through collaboration with Nordic Bioscience, a company specialised on extracellular matrix biomarkers that develops disease-specific biochemical markers for diagnosis and prognosis of many diseases including IPF, based on large patient databanks. All three biomarkers are extracellular matrix protein fragments that have been shown to strongly correlate with IPF disease progression. Vicore will also assess some of the standard efficacy endpoints including lung function, measured through changes in FVC (currently the primary endpoint in most late-stage IPF trials), although it is unlikely that a significant effect will be seen during the 1-month treatment period.

CHART 41: Phase IIa proof-of-concept trial design

Parameter	Description
No. of participants	30
Comparator	Placebo
Randomisation	1:1 (15x C21 vs. 15x placebo)
Target population	Treatment-naïve IPF patients
Dosing	Single 100mg dose given 1x daily
Study duration	4 weeks
Study locations	UK and Eastern Europe
Primary endpoint	Safety and tolerability
Secondary / exploratory endpoints	▪ Analysis of key biomarkers, incl. C1M, C3M, PRO-C3 ▪ Lung function (FVC)
Post hoc analyses	Key markers of fibrosis and inflammation, e.g. TGF-beta
Timing of trial results	Q3/2019

Source: Company data

Pivotal trial may be the next step

Galapagos, Prometic and FibroGen are all competing to be first in launching a novel drug into the IPF market. Of these, only Fibrogen completed a larger Phase IIb trial in over 100 patients over a period of 48 weeks before deciding to move into pivotal trials (Chart 42). In contrast, both Prometic and Galapagos based their decisions to progress their antifibrotic compounds into pivotal trials based on small Phase IIa trials involving 40 or fewer patients. To remain competitive and catch up with these potential new agents, Vicore's goal is to identify efficacy signals in a small Phase IIa proof of concept trial as quickly as possible and then move straight into a Phase IIb pivotal trial that could be used for regulatory filing. Since IPF is a cancer-like disease with a high unmet need and limited treatment options, we see this as a plausible approach. The field is evolving rapidly and Vicore will continue to monitor the strategies of its competitors to bring C21 to market in the shortest possible timeframe.

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CHART 42: IPF clinical trials completed by leading companies before embarking on pivotal trials

Company	Prometic	Fibrogen	Galapagos
Compound name	PBI-4050	Pamrevlumab	GLPG1690
Class / MoA	GPR40 agonist/GPR84 antagonist	Anti-CTGF mAb	Autotaxin inhibitor
Phase II trial	Phase II	Phase IIb	Phase IIa (FLORA)
Design	Open label, single arm	Randomised, double-blind, pcb-controlled	Randomised, double-blind, pcb-controlled
Results reported	17 Nov 2016 (first 30 pts)	7 Aug 2017	9 Aug 2017
No. of IPF patients	40	▪ 103 main efficacy and safety trial ▪ 57 safety combination sub-study	▪ 23
Randomisation	PBI-4050 vs. PBI-4050/nintedanib vs. PBI-4050/pirfenidone (9:16:15)	▪ Main trial: pamrevlumab vs. pcb (1:1)	▪ GLPG1690 vs. pcb (17: 6)
Treatment period	12 weeks	48 weeks	12 weeks
Dosing	1x daily oral dose of 800mg (4x200mg)	30 mg/kg IV every three weeks	1x daily oral dose
Primary objectives	Safety and tolerability	Change of FVC percent predicted	Safety, tolerability, PK, PD
Secondary objectives	Evaluation of lung function, imaging of thorax, changes in disease biomarkers	n.a.	Evaluation of lung function, changes in disease biomarkers, FRI, QoL
Other criteria	Nintedanib or pirfenidone background therapy	For the safety sub-study, pamrevlumab was combined with pirfenidone or nintedanib	Nintedanib or pirfenidone had to be discontinued for ≥4 weeks prior to initiating treatment with GLPG1690
Key efficacy findings	▪ FVC remained stable in pts receiving PBI-4050 (ΔFVC of -12ml) or PBI-4050/nintedanib (ΔFVC of +2ml) ▪ FVC declined in pts receiving PBI-4050/pirfenidone (ΔFVC of -102ml), suggesting a drug-drug interaction	▪ Average decrease in FVC: 129 ml for pamrevlumab vs. 308 ml pcb	▪ FVC increase of 8 mL for GLPG1690 vs. reduction of 87 mL pcb ▪ FRI confirmed disease stabilization for GLPG1690 vs. disease progression in pcb ▪ Clear reduction of serum LPA18:2, (biomarker for autotaxin inhibition)
Safety / tolerability	▪ "Highly compelling" safety and tolerability	▪ Well tolerated	▪ Generally well tolerated. Similar rates of discontinuation due to AEs for GLPG1690 and pcb
Next steps	Pivotal trial design finalised on 29 Jan 2018. Enrolment starts mid-2018E	Phase III study design in progress	Phase III study design in progress

Abbreviations: AEs, adverse events; CTGF, connective tissue growth factor; FRI, functional respiratory imaging; mAb, monoclonal antibody; MoA, mechanism of action; pcb, placebo; PD, pharmacodynamics; PK, pharmacokinetics; QoL, quality of life
Source: Company data, goetzpartners Research

Shorter treatment duration than currently the norm may be possible

In our opinion, it is possible for Vicore to opt for a shorter pivotal trial than is currently the norm, i.e. 24 weeks rather than 48 weeks, further shortening the clinical development timeline. The rationale is that both Esbriet and Ofev showed a separation vs. placebo on the FVC curves as soon as three months (see Chart 20 and Chart 23), and the effect further increased after 6 months. This will of course depend on the results of the Phase IIa trial and discussions with experts in the IPF field.

Conservative forecasts suggest c.$1.4bn market opportunity

CHART 43: C21 has received orphan drug status in the US and Europe

Region	Date
US	January 2017
Europe	August 2016

Source: Company data

We envisage three potential scenarios for C21 (Chart 44), depending on whether the compound demonstrates a survival benefit as well as its safety and tolerability profile compared to current therapies. In our base case, where C21 shows similar efficacy, but better safety than current therapies, we estimate peak sales of c.$1.4bn. Superior efficacy equating to a survival benefit could drive both premium pricing and higher uptake, in our view, driving sales of >$3bn. Similar efficacy and safety to current therapy would limit sales to $500m - $1bn. C21 has received orphan designation in the US and Europe (Chart 43), which grants seven and ten years of market exclusivity, respectively. This is important in light of the composition of matter patents for C21 in the US and Europe expiring around 2023E / 2024E. Since C21 is an innovative compound backed by a large body of robust preclinical and Phase I data, there is a chance that Vicore could receive a fast track or breakthrough designation from the FDA. Management intends to revisit this option once Phase IIa data become available. (Competitor PBI-4050 has received fast track designation.)

CHART 44: Three possible sales scenarios for C21. Our estimates are built around the Base case

Scenario	Description	Peak sales potential
Best case	Halting of fibrosis plus significant survival benefit	>$3bn
Base case	Delay in disease progression, but no survival benefit. Better side effect profile vs. marketed therapies	c.$1.4bn
Worst case	Delay in disease progression, but no survival benefit. Side effect profile similar to or worse than marketed therapies	$0.5-1.0bn

Source: goetzpartners Research estimates. Warning Note: Forecasts are not a reliable indicator of future performance or results. The return may increase or decrease as a result of currency fluctuations.

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CHART 45: Potential licensing deal for C21 following Phase IIb data in 2022E

Milestone	Amount ($m)
Upfront	125
Regulatory	75
Sales-based	800
Sales threshold	
$250m	50
$500m	100
$750m	150
$1,000m	200
$1,500m	300
Total milestones	1,000

Source goetzpartners Research estimates. Warning Note: Forecasts are not a reliable indicator of future performance or results. The return may increase or decrease as a result of currency fluctuations.

Base case assumes similar efficacy, but better tolerability than standard of care

Our base case is based on the following key assumptions. Our bottom-up sales model for C21 including a potential partnering deal is signed following Phase IIb data is shown in Chart 45.

- Clinical profile slightly better than current therapies, including similar efficacy (delay in disease progression, but no survival benefit), but better safety and tolerability;
- Launch in 2023E, based on pivotal trials starting in 2020E after completion of the Phase IIa proof-of-concept trial due to start in April / May 2018;
- Use in up to 15% of IPF patients in the US and Europe, based on patient pools of c.131,000 in each region at the time of launch;
- US pricing in line with Esbriet and Ofev, equating to c.$96,000. We assume an average price of €40,000 in Europe, where prices are variable ranging from c.£26,000 in the UK to over €50,000 in Germany. We further assume no price inflation;
- The average income per patient is based on 6 months of therapy due to patients starting therapy at different times during the year.

Lucrative commercialisation deal likely following late-stage trial

Vicore's strategy is to enter a licensing deal for C21 following Phase IIb data, although the company is open to considering earlier partnering approaches at the right valuation. With our base case scenario in mind, we assume that Vicore enters a global licensing deal in 2022E worth $1bn in total upfront and milestone payments (Chart 46), plus tiered double-digit royalties on sales, which we estimate to be in a range of 16% - 25% yielding a blended rate of 16% - 21%. The overall value of the deal as well as the size of the upfront payment will depend on the strength of the data and the level of competitive tension in the process. There is room for a more valuable deal if C21 demonstrates a survival benefit, in our view.

CHART 46: C21 global sales model and licensing deal

Dec YE (SEKm)		2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2028E	2030E	2032E
C21 | Idiopathic Pulmonary Fibrosis (IPF)													
US IPF patients		125,000	126,250	127,513	128,788	130,076	131,376	132,690	134,017	135,357	138,078	140,853	143,684
growth			1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%
C21 penetration							0.8%	3.0%	5.3%	7.5%	12.0%	15.0%	14.0%
Patients treated with C21 per year							1,051	3,981	7,036	10,152	16,569	21,128	20,116
growth								278.8%	76.8%	44.3%	24.3%	8.2%	(2.5%)
Price per year	$	96,000	96,000	96,000	96,000	96,000	96,000	96,000	96,000	96,000	96,000	96,000	96,000
Average duration of treatment	months	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0
Average revenue per patient	$	48,000	48,000	48,000	48,000	48,000	48,000	48,000	48,000	48,000	48,000	48,000	48,000
US sales reported by partner	$m						50.4	191.1	337.7	487.3	795.3	1,014.1	965.6
growth	%							278.8%	76.8%	44.3%	24.3%	8.2%	(2.5%)
EU IPF patients		125,000	126,250	127,513	128,788	130,076	131,376	132,690	134,017	135,357	138,078	140,853	143,684
growth			1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%
C21 penetration							0.4%	1.5%	2.5%	4.0%	9.0%	14.0%	14.5%
Patients treated with C21 per year							526	1,990	3,350	5,414	12,427	19,719	20,834
growth								278.8%	68.3%	61.6%	51.5%	17.8%	(2.4%)
Price per year	$	40,000	40,000	40,000	40,000	40,000	40,000	40,000	40,000	40,000	40,000	40,000	40,000
Average duration of treatment	months	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0
Average revenue per patient	$	20,000	20,000	20,000	20,000	20,000	20,000	20,000	20,000	20,000	20,000	20,000	20,000
Europe sales reported by partner	$m						10.5	39.8	67.0	108.3	248.5	394.4	416.7
growth	%							278.8%	68.3%	61.6%	51.5%	17.8%	(2.4%)
US & Europe sales reported by partner	$m						61.0	230.9	404.7	595.6	1,043.9	1,408.5	1,382.2
growth	%							278.8%	75.3%	47.2%	29.9%	10.7%	(2.4%)
Royalty rate (blended)	%						16.0%	16.0%	16.8%	17.5%	19.3%	20.7%	20.7%
Royalties to Vicore	$m						9.8	36.9	67.9	104.1	201.0	292.1	285.6
Royalties to Vicore	SEKm						83.3	315.6	579.8	889.6	1,717.2	2,496.1	2,440.0
growth	%							278.8%	83.7%	53.4%	36.9%	13.2%	(2.9%)
Upfront payment (deferred over 10 yrs)	$m	-	-	-	-	6.3	12.5	12.5	12.5	12.5	12.5	12.5	6.3
Regulatory milestones	$m					0.3	4.2	10.7	10.7	10.7	10.7	6.5	-
Sales-based milestones	$m								50.0	100.0	200.0		
Milestones	$m	-	-	-	-	6.5	16.7	23.2	73.2	123.2	223.2	19.0	6.3
Milestones	SEKm	-	-	-	-	55.9	142.4	198.4	625.6	1,052.8	1,907.3	162.7	53.4
Total revenue to Vicore	SEKm	-	-	-	-	55.9	225.7	514.0	1,205.3	1,942.4	3,624.4	2,658.8	2,493.4

Source: goetzpartners Research estimates. Warning Note: Forecasts are not a reliable indicator of future results or performance. The return may increase or decrease as a result of currency fluctuations.

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Please see analyst certifications, important disclosure information, and information regarding the status of analysts on pages 24 - 26 of this research report.

Board of Directors and Executive Management

Vicore is led by CEO Per Jansson, a seasoned life sciences entrepreneur who has been with the company since 2006. The other key members of the management team are Chief Scientific Officer Ulrike Steckelings, an internationally respected expert in the AT2R field, and Chief Financial Officer Hans Jeppsson, a scientist turned finance professional with extensive capital markets experience.

Leif Darner | Chairman of the Board of Directors

Leif Darner has been Chairman of the Board since May 2017. He is the owner of consulting firm Darner Asset Management AB. Prior to this role, Mr Darner was an Executive Director on the Board of Management at AkzoNobel, where he was responsible for Performance Coatings from 2008 and for Chemicals from 2004. Before this he was Managing Director BU Marine and Protective Coatings. Until 1999 he held various positions such as Chief Executive Northern Europe and Chief Executive Protective Coatings Europe at Courtaulds plc. Prior to this he was Managing Director for International Färg AB, Sweden. Other assignments include Board member at LKAB AB (Sweden), Flowserve Corporation (Dallas, US) and I-Tech AB, the company Vicore is invested in.

Per Jansson | Chief Executive Officer

Per Jansson has served as CEO of the holding company since November 2013, following a 7-year tenure when he held parallel CEO positions in Vicore Pharma AB and I-Tech AB. Prior to that, Mr Jansson acted as an investment manager with CIMON Medical and later with GU Holding, the Gothenburg University holding company. He serves as chairman of the board of Taurus Energy AB, a Swedish biotech company in the ethanol fuel industry. Mr Jansson has a dental degree from the University of Lund, Sweden.

Hans Jeppsson | Chief Financial Officer

Hans Jeppsson has served as CFO since June 2017. Mr. Jeppsson brings more than 10 years of experience in various fields, including roles as healthcare equity research analyst (Danske Bank), post-doc researcher (Haas School of Business at UC Berkeley), and research scientist working with both small molecules and biologics (AstraZeneca). Mr Jeppsson is an Assistant Professor of Finance at the University of Gothenburg in parallel with his role at Vicore Pharma. He has a PhD degree in Finance from the University of Gothenburg, Sweden.

Ulrike Steckelings | Chief Scientific Officer

Ulrike Steckelings joined as CSO in September 2017. Her official employment was preceded by a close collaboration over 10 years, which started when Vicore was acquired by the current owners. Ms. Steckelings is a physician with a specialisation in dermatology from Charité, Berlin and a “habilitation” degree from Charité in experimental pharmacology. She has worked in academia in pharmacology for most of her career and holds a position as Professor of Integrative Pharmacology at the University of Southern Denmark (Odense). Ms. Steckelings has authored 94 peer-reviewed publications in scientific journals, 14 book chapters, and co-edited the book “Protective arm of the renin-angiotensin-system”. She has delivered more than 50 invited presentations at conferences and academic institutions.

Peter Ström | Board Member

Peter Ström held senior positions in the period 1979-2005, including at KabiPharmacia UK (CEO) and IMSHealth Europe (VP). Since 2003, Peter has also been a director of several listed companies such as Wnt Research. Other assignments include Chairman of WntResearch AB, Board member of Stockholm Corporate Finance AB, Dentosystem Scandinavia AB, and Deputy Board member of Comtax Support Limited. Mr Ström holds an MBA from the Stockholm School of Economics.

Kjell Stenberg | Board Member

Kjell Stenberg has extensive board experience in several companies that are active across a range of industries. Other assignments include Board member of WntResearch AB, Kjell Stenberg AB and CN Stenberg AB.

Göran Wessman | Board Member

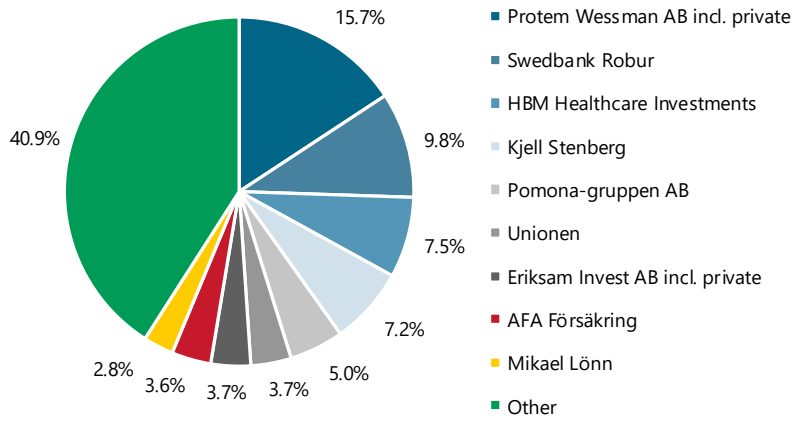
Göran Wessman has over twenty years’ experience in management positions in pharma and medical device companies, as well as in the clinical research organisation sector. Mr Wessman has held senior leadership positions at Nobel Biocare, Boule Group and Carmel Pharma. Other assignments include Board member of ITIN Holding AB (publ), Vicore Pharma AB, Protem Wessman AB and Protem Företagsförvaltning AB. Mr Wessman has a degree from biomedicine and chemistry at Uppsala and Gothenburg.

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Largest shareholders

Chart 47 shows Vicore's largest shareholders as of 31 December 2017.

CHART 47: Vicore shareholders



Source: Vicore 2017 Annual Report

Financial assumptions and models

Profit and Loss statement

- **Revenues:** The key driver is revenue related to C21 from a licensing deal, driven by upfront and regulatory milestone payments in the early years, and royalties plus sales-based milestones in out-years. Our forecasts assume that Vicore signs a global licensing deal in 2022E;
  - Net turnover: related to exchange of services between Vicore Pharma with I-Tech
  - Own work capitalised: capitalised R&D and patent expenses
  - Other income: small grants

- **Operating expenses:** we expect all cost lines to increase over the years as Vicore progresses C21 in IPF and earlier-stage pipeline programs through (pre)clinical development. Research expenses are booked in "Other external expenses", while development expenses are capitalised in the balance sheet as intangibles (see below);

- **Operating profit / loss:** we assume that Vicore becomes profitable in 2022E following the signing of a licensing deal with a biopharmaceutical company in mid-2022E. We model a $125m upfront payment amortised over 10 years starting in mid-2022E, a $25m filing milestone received at YE2022 and amortised over 7 years, and a $50m approval milestone received in H2/2023 and amortised over seven years;

- **Income tax:** Vicore is accumulating tax loss carry forwards and we therefore assume that the company starts paying taxes in 2022E at a rate below the 22% corporate tax rate in Sweden.

Balance Sheet and Cash Flow statement

- **Cash position:** with Vicore looking to spend around SEK15m on R&D in 2018, we estimate that the company has sufficient cash to fund operations until YE/2018. We therefore assume that Vicore takes on loans of SEK50m in 2018E, 2019E and 2021E;

- **Capitalised expenditures for development and similar work:** this line in the balance sheet reflects capitalised development expenses, with the yearly flows shown in the cash flow statement under "Acquisition of capitalised expenditure for research". We understand that the Phase IIa trial for C21 will cost up to SEK23m and assume that about one-third is incurred in 2018E and the remainder in 2019E. We further assume SEK9m – SEK10m other R&D expenses in each 2018E and 2019E.

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CHART 48: Vicore Profit and Loss model

Profit & Loss Statement		2014A	2015A	2016A	2017A	2018E	2019E	2020E	2021E	2022E	2024E	2026E
Dec YE (SEKk except EPS)	units	31-Dec-14	31-Dec-15	31-Dec-16	31-Dec-17	31-Dec-18	31-Dec-19	31-Dec-20	31-Dec-21	31-Dec-22	31-Dec-22	31-Dec-22
Revenue	**SEKk**	**1,578**	**1,677**	**2,133**	**3,674**	**5,128**	**6,851**	**8,653**	**10,244**	**67,214**	**527,631**	**1,958,907**
growth	%		6.3%	27.2%	72.2%	39.6%	33.6%	26.3%	18.4%	556.1%	121.6%	60.5%
C21 revenues	SEKk						-	-	-	55,946	513,996	1,942,409
% sales	%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	83.2%	97.4%	99.2%
growth	%									#DIV/0!	2.8%	0.4%
Net turnover	SEKk	851	840	852	932	1,044	1,159	1,275	1,402	1,542	1,866	2,258
% sales	%	53.9%	50.1%	39.9%	25.4%	20.4%	16.9%	14.7%	13.7%	2.3%	0.4%	0.1%
growth	%		(1.3%)	1.4%	9.4%	12.0%	11.0%	10.0%	10.0%	10.0%	10.0%	10.0%
Own work capitalised	SEKk	720	816	1,221	2,645	3,968	5,555	7,221	8,665	9,532	11,533	13,955
% sales	%	45.6%	48.7%	57.2%	72.0%	77.4%	81.1%	83.4%	84.6%	14.2%	2.2%	0.7%
growth	%		13.3%	49.6%	116.6%	50.0%	40.0%	30.0%	20.0%	10.0%	10.0%	10.0%
Other income	SEKk	7	21	60	97	116	137	158	177	195	235	285
% sales	%	0.4%	1.3%	2.8%	2.6%	2.3%	2.0%	1.8%	1.7%	0.3%	0.0%	0.0%
growth	%		200.0%	185.7%	61.7%	20.0%	18.0%	15.0%	12.0%	10.0%	10.0%	10.0%
Other external expenses	SEKk	(4,042)	(3,360)	(5,006)	(5,431)	(5,974)	(6,452)	(6,839)	(7,113)	(7,255)	(7,548)	(7,853)
% sales	%	256.1%	200.4%	234.7%	147.8%	116.5%	94.2%	79.0%	69.4%	10.8%	1.4%	0.4%
growth	%		(16.9%)	49.0%	8.5%	10.0%	8.0%	6.0%	4.0%	2.0%	2.0%	2.0%
Personnel costs	SEKk	(2,464)	(2,810)	(3,770)	(6,209)	(9,068)	(12,390)	(15,739)	(18,665)	(21,222)	(25,658)	(31,024)
% sales	%	156.1%	167.6%	176.7%	169.0%	176.8%	180.9%	181.9%	182.2%	31.6%	4.9%	1.6%
growth	%		14.0%	34.2%	64.7%	46.0%	36.6%	27.0%	18.6%	13.7%	10.0%	10.0%
Depreciation and write-downs	SEKk	(36)	(6)	(6)	(628)	(7)	(8)	(9)	(10)	(10)	-	-
% sales	%	2.3%	0.4%	0.3%	17.1%	0.1%	0.1%	0.1%	0.1%	0.0%	0.0%	0.0%
growth	%		(83.3%)	0.0%	10366.7%	(98.9%)	14.3%	12.5%	11.1%	0.0%		
Other operating expenses	SEKk	(376)	(44)	-	-	-	-	-	-	-	-	-
% sales	%	23.8%	2.6%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
growth	%		(88.3%)	(100.0%)								
Operating expenses		**(6,918)**	**(6,220)**	**(8,782)**	**(12,268)**	**(15,049)**	**(18,850)**	**(22,588)**	**(25,788)**	**(28,486)**	**(33,206)**	**(38,877)**
Operating Profit/Loss	**SEKk**	**(5,340)**	**(4,543)**	**(6,649)**	**(8,594)**	**(9,922)**	**(12,000)**	**(13,934)**	**(15,544)**	**38,728**	**494,425**	**1,920,030**
% sales	%	(338.4%)	(270.9%)	(311.7%)	(233.9%)	(193.5%)	(175.2%)	(161.0%)	(151.7%)	57.6%	93.7%	98.0%
growth	%		(14.9%)	46.4%	29.3%	15.4%	20.9%	16.1%	11.6%	(349.1%)	138.4%	62.1%
Profit/loss from financial items	**SEKk**	**19,027**	**(27)**	**(3)**	**(13,691)**	**(63)**	**(65)**	**(66)**	**(67)**	**(68)**	**(71)**	**(74)**
Interest income from group companies	SEKk	19,081	-	-	-	-	-	-	-	-	-	-
Other interest income from group	SEKk	51	-	-	-	-	-	-	-	-	-	-
Interest expenses	SEKk	(105)	(27)	-	-	-	-	-	-	-	-	-
Interest expense to group companies	SEKk	-	-	(3)	(62)	(63)	(65)	(66)	(67)	(68)	(71)	(74)
Loss from financial assets	SEKk	-	-	-	(13,629)	-	-	-	-	-	-	-
Profit before tax	**SEKk**	**13,687**	**(4,570)**	**(6,652)**	**(22,285)**	**(9,985)**	**(12,064)**	**(14,000)**	**(15,611)**	**38,659**	**494,353**	**1,919,955**
Income taxes	SEKk	-	-	-	-	-	-	-	-	(3,866)	(108,758)	(422,390)
Tax rate	%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	22.0%	22.0%
Net income	**SEKk**	**13,687**	**(4,570)**	**(6,652)**	**(22,285)**	**(9,985)**	**(12,064)**	**(14,000)**	**(15,611)**	**34,794**	**385,596**	**1,497,565**
EPS calculation												
Earnings/Loss per Share (Basic)	**SEK**	**1.69**	**(0.37)**	**(0.54)**	**(1.80)**	**(0.81)**	**(0.98)**	**(1.13)**	**(1.26)**	**2.81**	**31.18**	**121.08**
growth	%		(121.9%)	45.6%	235.0%	(55.2%)	20.8%	16.0%	11.5%	(322.9%)	125.4%	62.1%
Earnings/Loss per Share (Diluted)	**SEK**	**1.69**	**(0.37)**	**(0.54)**	**(1.80)**	**(0.81)**	**(0.98)**	**(1.13)**	**(1.26)**	**2.81**	**31.18**	**121.08**
growth	%		(121.9%)	45.6%	235.0%	(55.2%)	20.8%	16.0%	11.5%	(322.9%)	125.4%	62.1%
Number of Shares (basic)	k	8,120	12,369	12,369	12,369	12,369	12,369	12,369	12,369	12,369	12,369	12,369
Number of Shares (diluted)	k	8,120	12,369	12,369	12,369	12,369	12,369	12,369	12,369	12,369	12,369	12,369

Source: goetzpartners Research estimates. Warning Note: Past performance and forecasts are not a reliable indicator of future performance or results. The return may increase or decrease as a result of currency fluctuations.

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CHART 49: Vicore Balance sheet model

Balance Sheet	2014A	2015A	2016A	2017A	2018E	2019E	2020E	2021E	2022E	2024E	2026E
Dec YE (SEKk)	31-Dec-14	31-Dec-15	31-Dec-16	31-Dec-17	31-Dec-18	31-Dec-19	31-Dec-20	31-Dec-21	31-Dec-22	31-Dec-22	31-Dec-22
ASSETS											
CURRENT ASSETS	**2,095**	**26,346**	**4,799**	**24,726**	**49,776**	**61,732**	**21,219**	**28,543**	**35,301**	**527,965**	**2,858,863**
Cash and bank	1,710	25,175	4,266	24,019	48,984	60,836	20,213	27,440	31,065	498,478	2,750,927
Receivables from group companies	-	-	-	-	-	-	-	-	-	-	-
Trade receivables	92	146	122	206	281	375	474	561	3,683	28,911	107,337
Other receivables	147	973	223	337	344	351	358	365	372	387	403
Prepaid expenses and accrued income	146	52	188	164	167	171	174	178	181	188	196
FIXED ASSETS	**57,273**	**62,879**	**76,851**	**85,373**	**100,413**	**126,469**	**153,060**	**180,203**	**208,456**	**272,943**	**363,862**
Tangible assets	59	8	2	28	68	124	195	287	950	8,587	40,360
Equipment, tools, fixtures and fittings	59	8	2	28	68	124	195	287	950	8,587	40,360
Goodwill	-	-	-	-	-	-	-	-	-	-	-
Intangible assets	**37,104**	**42,761**	**56,239**	**77,377**	**92,377**	**118,377**	**144,897**	**171,947**	**199,539**	**256,388**	**315,534**
Capitalised expenditures for development and similar work	19,108	23,792	36,190	56,243	70,153	95,057	120,475	146,419	172,898	227,506	284,388
Patents	17,996	18,969	20,049	21,134	22,224	23,320	24,422	25,529	26,641	28,882	31,146
Financial assets	**20,110**	**20,110**	**20,610**	**7,968**	**7,968**	**7,968**	**7,968**	**7,968**	**7,968**	**7,968**	**7,968**
TOTAL ASSETS	**59,368**	**89,225**	**81,650**	**110,099**	**150,189**	**188,201**	**174,278**	**208,746**	**243,758**	**800,908**	**3,222,724**
LIABILITIES											
CURRENT LIABILITIES	**3,694**	**5,317**	**4,075**	**4,582**	**4,657**	**4,733**	**4,810**	**4,889**	**5,107**	**5,609**	**6,067**
Accrued expenses and deferred income	1,329	1,063	1,617	1,408	1,422	1,436	1,451	1,465	1,480	1,510	1,540
Trade payables	562	2,312	2,184	2,780	2,836	2,892	2,950	3,009	3,069	3,193	3,322
Current tax liability	127	126	86	143	143	143	143	143	143	143	143
Other liabilities	1,676	1,816	188	251	256	261	266	272	415	763	1,062
NON-CURRENT LIABILITIES	**1,978**	**1,978**	**1,978**	**1,978**	**51,978**	**101,978**	**101,978**	**151,978**	**151,978**	**151,978**	**151,978**
Long-term debt	-	-	-	-	50,000	100,000	100,000	150,000	150,000	150,000	150,000
Deferred tax liability	1,978	1,978	1,978	1,978	1,978	1,978	1,978	1,978	1,978	1,978	1,978
TOTAL LIABILITIES	**5,672**	**7,295**	**6,053**	**6,560**	**56,635**	**106,711**	**106,788**	**156,867**	**157,085**	**157,587**	**158,045**
EQUITY											
SHAREHOLDERS EQUITY (DEFICIT)	**53,696**	**81,930**	**75,597**	**103,539**	**93,554**	**81,490**	**67,490**	**51,879**	**86,672**	**643,321**	**3,064,680**
Share capital	3,428	6,184	6,184	7,934	7,934	7,934	7,934	7,934	7,934	7,934	7,934
Other contributed capital	46,258	76,306	76,625	130,875	130,875	130,875	130,875	130,875	130,875	130,875	130,875
Other capital incl. profit/loss for the year	4,010	(560)	(7,212)	(35,270)	(45,255)	(57,319)	(71,319)	(86,930)	(52,137)	504,512	2,925,871
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	**59,368**	**89,225**	**81,650**	**110,099**	**150,189**	**188,201**	**174,278**	**208,746**	**243,758**	**800,908**	**3,222,724**
GEARING											
Gross debt	**-**	**-**	**-**	**-**	**50,000**	**100,000**	**100,000**	**150,000**	**150,000**	**150,000**	**150,000**
Total ST debt	-	-	-	-	-	-	-	-	-	-	-
Total LT debt	-	-	-	-	50,000	100,000	100,000	150,000	150,000	150,000	150,000
Cash and cash equivalents plus investments	**1,710**	**25,175**	**4,266**	**24,019**	**48,984**	**60,836**	**20,213**	**27,440**	**31,065**	**498,478**	**2,750,927**
Net debt/(cash)	**(1,710)**	**(25,175)**	**(4,266)**	**(24,019)**	**1,016**	**39,164**	**79,787**	**122,560**	**118,935**	**(348,478)**	**(2,600,927)**

Source: goetzpartners Research estimates. Warning Note: Past performance and forecasts are not a reliable indicator of future performance or results. The return may increase or decrease as a result of currency fluctuations.

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CHART 50: Vicore Cash Flow model

Cash Flow Statement	2014A	2015A	2016A	2017A	2018E	2019E	2020E	2021E	2022E	2024E	2026E
Dec YE (SEKk)	31-Dec-14	31-Dec-15	31-Dec-16	31-Dec-17	31-Dec-18	31-Dec-19	31-Dec-20	31-Dec-21	31-Dec-22	31-Dec-22	31-Dec-22
OPERATING CASH FLOW											
Operating profit/loss	(5,340)	(4,543)	(6,649)	(8,594)	(9,922)	(12,000)	(13,934)	(15,544)	38,728	494,425	1,920,030
Depreciation and writedowns	36	6	6	628	7	8	9	10	10	10	10
Loss on sale of fixed assets	-	44	-	-	-	-	-	-	-	-	-
Share of results in group companies	376	-	-	-	-	-	-	-	-	-	-
Interest received	51	-	-	-	-	-	-	-	-	-	-
Interest paid	(105)	(27)	(3)	(62)	(63)	(65)	(66)	(67)	(68)	(71)	(74)
Other	(2)	-	-	57	-	-	-	-	(3,866)	(108,758)	(422,390)
Change in operating assets/liabilities											
Accounts receivable	268	(54)	24	(84)	(75)	(94)	(99)	(87)	(3,122)	(15,862)	(40,470)
Other receivables	89	(731)	614	(90)	(10)	(10)	(10)	(11)	(11)	(11)	(12)
Accounts payable	(127)	1,750	(128)	596	56	57	58	59	60	63	65
Other current liabilities	1,929	(127)	(1,115)	(154)	19	19	20	20	158	183	158
NET CASH USED IN OPERATING ACTIVITIES	**(2,825)**	**(3,682)**	**(7,251)**	**(7,703)**	**(9,988)**	**(12,085)**	**(14,023)**	**(15,620)**	**31,889**	**369,977**	**1,457,317**
CASH FLOW FROM INVESTING											
Acquisition of capitalised expenditure for research	(8,329)	(4,684)	(12,397)	(19,116)	(13,910)	(24,904)	(25,419)	(25,944)	(26,479)	(27,583)	(28,731)
Acquisition of concessions, patents, licences	(1,161)	(973)	(1,080)	(1,085)	(1,090)	(1,096)	(1,101)	(1,107)	(1,112)	(1,124)	(1,135)
Acquisition of equipment, tools, fictures and fittings	-	-	-	(34)	(47)	(63)	(80)	(102)	(672)	(5,276)	(19,589)
Loans granted during the year to group companies	-	-	-	-	-	-	-	-	-	-	-
Acquisition of long-term securities	-	-	-	-	-	-	-	-	-	-	-
Sale of long-term valuable document	7,100	-	(500)	(2,545)	-	-	-	-	-	-	-
Net cash provided by investing activities	**(2,390)**	**(5,657)**	**(13,977)**	**(22,780)**	**(15,047)**	**(26,063)**	**(26,600)**	**(27,153)**	**(28,264)**	**(33,982)**	**(49,455)**
CASH FLOW FROM FINANCING											
Paid options/New issue for the year	-	32,804	319	50,236	-	-	-	-	-	-	-
Long-term loans	-	-	-	-	50,000	50,000	-	50,000	-	-	-
Amortization of long-term loans	(7,100)	-	-	-	-	-	-	-	-	-	-
Net cash provided by financing activities	**(7,100)**	**32,804**	**319**	**50,236**	**50,000**	**50,000**	**-**	**50,000**	**-**	**-**	**-**
Net change in cash and cash equivalents	(12,315)	23,465	(20,909)	19,753	24,965	11,852	(40,623)	7,227	3,626	335,995	1,407,862
Cash and cash equivalents, beginning of period	14,025	1,710	25,175	4,266	24,019	48,984	60,836	20,213	27,440	162,483	1,343,064
Cash and cash equivalents, end of period	**1,710**	**25,175**	**4,266**	**24,019**	**48,984**	**60,836**	**20,213**	**27,440**	**31,065**	**498,478**	**2,750,927**
Cash generation/(burn)	**(12,315)**	**(9,339)**	**(20,728)**	**(27,938)**	**(25,035)**	**(38,148)**	**(40,623)**	**(42,773)**	**3,626**	**335,995**	**1,407,862**

Source: goetzpartners Research estimates. Warning Note: Past performance and forecasts are not a reliable indicator of future performance or results. The return may increase or decrease as a result of currency fluctuations.

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COMPANY DESCRIPTION

Vicore Pharma is a clinical-stage Swedish biotech company focused on the development of orphan drugs for rare fibrotic diseases with no or limited treatment options. Vicore has designed, synthesized and patented a unique collection of small, non-peptide molecules that stimulate the AT2R within the Renin Angiotensin System. The RAS plays a critical role in maintaining blood pressure, as well as fluid and salt balance. The lead asset is C21, a small molecule AT2R agonist in Phase IIa development for IPF, a rare, but fatal condition that causes lung scarring, stiffness and shortness of breath, with a prognosis worse than for most common cancers. Vicore is leveraging its strong scientific heritage in discovering and developing AT2R agonists to both identify additional fibrotic orphan indications for C21 as well as novel follow-on compounds for development in non-orphan indications. The company completed its initial public offering on the Nasdaq First North Stockholm on 10 December 2015.

SCENARIOS

Base Case - GP Investment Case

C21 successfully completes the Phase IIa proof-of-concept trial in Q3/2019E and enters a pivotal trial in 2020E, leading to US and European approval in 2023E. C21 demonstrates similar efficacy to current treatments but an improved safety profile and achieves peak sales of c.$1.4bn. A global licensing deal is signed in 2022E consisting of $1bn in upfront and milestone payments plus royalties on sales.

Bluesky Scenario

C21 demonstrates a survival benefit in the pivotal trial in IPF and becomes standard of care with peak sales >$3bn. Vicore signs a more lucrative licensing deal than we currently model.

Downside risk

C21 fails in Phase IIa or the trial needs to be stopped early due to safety issues. Vicore is unable to raise equity or debt before the current cash balance is exhausted by YE2018E.

Peer Group Analysis

Peer Group - Grid 1

Galapagos, Prometic Life Sciences, Fibrogen, Kadmon, Medicinova

Peer Group - Grid 2

Roche, Boehringer Ingelheim

SWOT

Strengths: Novel, patented approach for the treatment of fibrotic orphan diseases; strong scientific rationale and preclinical data supporting the development of C21 in IPF.

Weaknesses: limited resources; need to raise equity or debt before YE2018E.

Opportunities: develop C21 for other fibrotic orphan indications beyond IPF; develop follow-on compounds in non-orphan indications with support from partners.

Threats: a key competitor drug demonstrates a survival benefit in pivotal trials and enters the market before C21, potentially limiting its market opportunity.

INDUSTRY EXPECTATIONS

Idiopathic pulmonary fibrosis is a relatively "common" orphan disease with high unmet medical need, since the two current treatment options are associated with limited efficacy and poor tolerability. The IPF market was worth c.$1.8bn in 2017E (up c.25% YoY) and has experienced high growth since Esbriet (pirfenidone) and Ofev (nintedanib) were approved in 2011 and 2014, respectively. Experts predict that the future treatment paradigm will consist of combination therapy, which should allow multiple therapies with complementary mechanisms of action to be successful.

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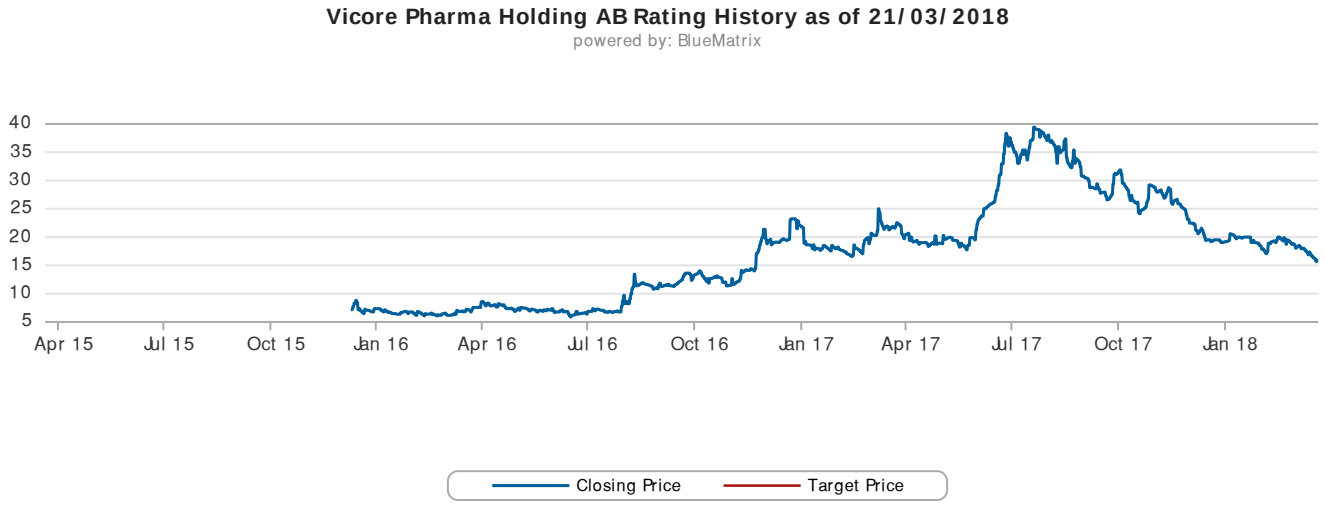
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