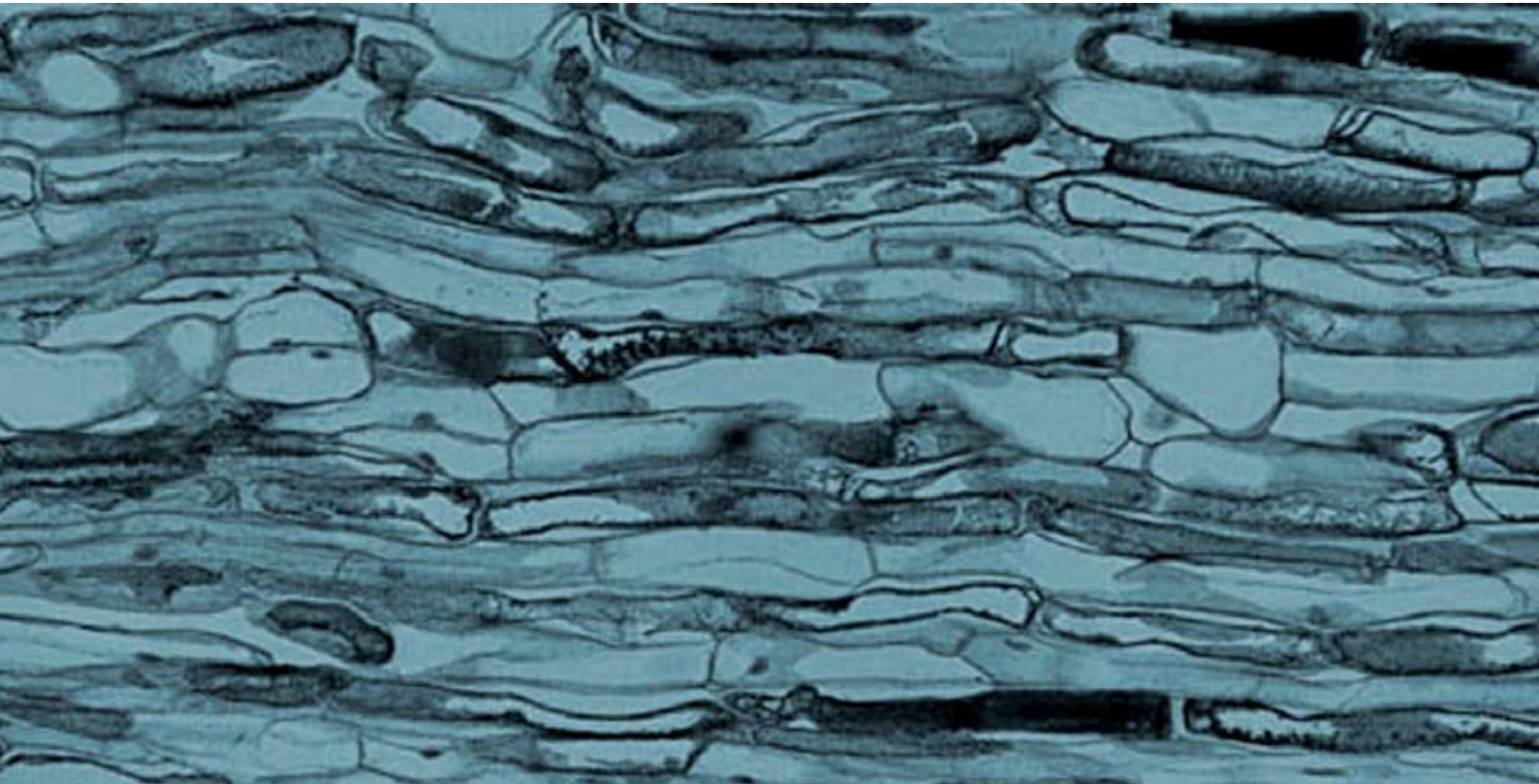


York Pharma (YRK)



York Pharma aims to capture a significant slice of the dermatological market for major indications such as fungal infections, eczema and psoriasis.

Objective Capital Limited
Token House
11-12 Tokenhouse Yard
London EC2R 7AS
Tel: +44-(0)870-080-2965
Fax: +44-(0)870-116-0839
US toll-free: 1-888-802-7215
editor@objectivecapital.com

Initiation Report

Corporate: www.ObjectiveCapital.com
Research: www.ObjectiveCapital.co.uk

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I certify that this report represents my own opinions.

Steven Zimmer, *Analyst*
steven@objectivecapital.co.uk

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Key Points

3 November, 2006

Price: 95p

A second shot at the Big Prize

York Pharma is an emerging speciality Pharma company with its sights set firmly on dermatology. It aims to capture a significant slice of the market for major indications such as fungal infections, eczema and psoriasis, with innovative products offering a superior safety and efficacy profile.

- **Abasol™ and a phoenix rising from the ashes**

Chastened by his experience with Bioglan but imbued with characteristic Northern grit and determination, Terry Sadler has returned to take a second shot at the big prize. This serial entrepreneur, like the proverbial phoenix, is determined to build York Pharma into a sizeable international business and has been given the opportunity by investors, both past and present, to do so.

- **Stick to the knitting: go for the Derm market**

Dermatology is a fragmented, focused market in which Terry and his team is well versed. It is best served by a small detailing force and crying out for new and more effective treatments. If you can show that you've got what it takes, dermatologists and their patients will be happy to make room for you!

- **A strong portfolio of products covering 75% of Derm by value**

York Pharma is going to market with Abasol, a broad-spectrum antifungal, the atopic dermatitis and psoriasis portfolio acquired along with Molecular Skin Care Ltd and the rights to commercialise Sphingosine-1-Phosphate for acne. These products give York Pharma the critical mass to build a significant market presence using a flexible combo of self-directed sales and regional licensees.

- **Look out for news flow on the registration of Abasol**

With what equates to an 'approvable letter', albeit conditioned on the submission of additional data on Abasol, York is working to complete the approval process over the next few months. Once Marketing Authorisation is granted, York will be able to roll out approval across the EU and get down to the business of licensing the drug for key markets and its registration run in the US and Japan.

- **Sabarep™ and Vampex™ could be significant winners**

We are particularly impressed with the concepts behind Sabarep (YP001) for atopic dermatitis; and are intrigued by the hijacking of an age-old anti-ulcer drug (YP003) to treat Psoriasis. If the target profiles can be achieved, York could make significant market inroads.

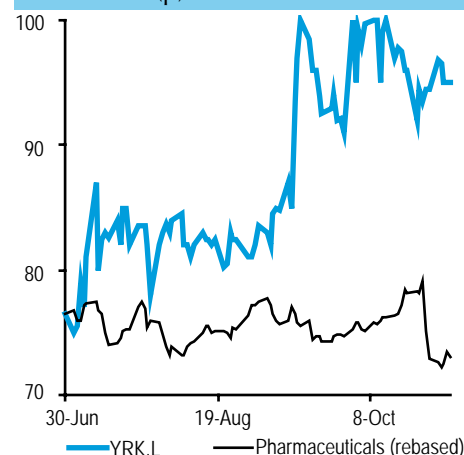
- **Caveat Lector!**

Our package warning is that it is rare for dermatological products to exceed the £150 million mark. Past offerings have not been constrained by demand, but by their efficacy/safety profile. Our projections assume that both the target profile and the ensuing capture of a significant share of the market are achievable.

- **The proof will be execution, execution and more execution!**

Whatever regulatory hurdles it jumps; clawing up market share is the real race. Management have something to prove, but we see success as ripe for the picking. Finances are tight but as evidenced by the latest financing round, available. Our analysis indicates that York appears to offer investors plenty of value to go around!

Price chart (p)



Value of Equity

Core Scenario	£96.2m
Pessimistic Scenario	£54.0m
Value per share:	£2.13 - £3.79

Company details

Quote

Shares	
-London AIM	YRK.L
Hi-Lo last 12-mos. (p)	74.0 - 120.0
Shares issued (m)	25.4
Fully diluted (m)	31.8
Market Cap'n (£m)	24.1
Stockbroker:	Collins-Stewart www.collins-stewart.com JMF Corporate www.jmfinn.com

Financial PR: Northbank Communications
www.northbankcommunications.com
Website: www.yorkpharma.com

Miles Saltiel

Research Director
miles@objectivecapital.com
0870 080 2965

Analyst:

Steven Zimmer, Analyst
steven@objectivecapital.co.uk

Overview

York Pharma is aiming to be a speciality company focused on dermatology

Dermatology is one of the few areas in medicine begging for safer, more effective products. The diseases are not necessarily life-threatening but nonetheless carry significant morbidity and a high degree of social stigma and resultant psychological trauma. This market is valued by IMS at around £7.5 billion — one of the smaller pharma sub-markets — but that does not make it less attractive. To the contrary, the limited number of dermatologists in most markets makes it easier to promote and sell drugs. As it has evolved as a niche market, it is less attractive to big Pharma who focus elsewhere. This leaves room for pure specialty plays like Medicis in the US to fill the gap, representing a niche where development companies such as York Pharma and others (Barrier Therapeutics, Connectics, Collagenex and the like) can make their mark.

It has constructed a portfolio of products aimed at filling market safety/efficacy gaps

Management is well-versed in dermatology and this serves the company well. It has a portfolio of products covering about 70% of the dermatology market, after raising less than £12 million from the market. The lead product, Abasol, is a novel antifungal from a new class of drugs. It is in registration in the UK and the company last month received word of 'approvability' from the UK's MHRA. Subject to the provision of further data, which should be forthcoming in relatively short timeframe York Pharma, should gain its first Marketing Authorisation, a major milestone and value driver for the business. Once licensed, this product should enable York Pharma on a relatively modest outlay of capital to fund the construction of its sales and marketing teams in the UK and Germany, and to initiate an international network of partnerships and licensees to gain full coverage of the world market.

A leveraged platform ready for action with other pipeline constituents!

The sales and marketing platform under construction should be in a position to serve as the base from which a full portfolio of drugs can be launched. The platform is intended to generate sufficient capital through upfronts, milestones and royalty payments to enable the company to develop its current pipeline and seek out new drugs to funnel through its business in true Specialty Pharma form. Once such a platform is set up, the company need only pile on incremental sales and marketing costs to bring the other pipeline constituents to market.

Portfolio developments and news flow are in ample prospect over the next three years

The nature of the products in York's portfolio will give rise to an intense period of clinical and business development news flow from late 2006 onwards. Vampex is a 35-year-old anti-ulcer drug hijacked for use as a new, patented topical treatment for psoriasis. Sabarep for atopic dermatitis is a 'gemisch' of GRAS (Generally Recognised as Safe) substances, which should only require clinical validation of efficacy to gain approval and enter into widespread clinical use. As these are all topicals (i.e., applied to the skin), the biggest barrier to further development is final formulation. Assuming this can be overcome with relative ease, the clinical pathway for these drugs should not be onerous. All of this points to a development timeline, which is relatively compressed in the 2007-2010 period.

Business development and execution are essential to complement fund raising

York Pharma's model calls for marketing counterparties to take on products in return for upfront, milestone and royalty payments. The ability of the company to pull this off is central to its finances and reputation. Success with the registration of Abasol as an antifungal agent should give the company some breathing space, but it will then have to source licensees in the Rest of the World, Euroland, the US and Japan – probably in that order. Successful execution of this part of York's strategy should add to the company's buzz in the market and transform its paper into an acquisition currency not to be sneezed at in fragmented markets like dermatology.

The key here is focus and not getting sidetracked!

We do not expect management to get sidetracked from their current highly focused plans. We take the view that they have learnt all too well from previous experience that unfocused portfolios and excessive leverage must be avoided at all cost. We believe that York Pharma will stay the course by focusing on its current promising pipeline without becoming diverted by far-flung adventures. If we are right, this holds out the prospect of a treasure trove of value and significant returns to shareholders.

Comparable companies sell at lofty valuations

As seen in the accompanying table, comparable companies, in the US and elsewhere, are selling at valuations which are far beyond what York has achieved: the difference lies in the stage of development. These companies either have product sales (Medicis and Connetics), demonstrated an ability to partner, or more cash at hand.

Valuation in the eye of the beholder

It is all too easy to generate specious valuations, which are multiples of the current level; we have tried to stay away from this path. As seen in the attached table, we have simply taken the target profile of the drug as advertised — we have no valid scientific or clinical reason to do otherwise — and sought to construct a realistic scenario of market share, pricing and market expansion. This yields a peak sales figure 5 to 6 years after launch.

Can't get away from significant upside!

Using this methodology, we have arrived at a number of projections, which give the total potential revenue of the portfolio. We estimate the potential peak sales of the total portfolio at around £1.2 billion. Stripping out any royalty-generating sales, this comes to some £240 million. We add revenues from upfront and milestone payments at £230 million. This yields a potential revenue stream of £470 million through to peak sales in 2015. We apply industry standard probabilities for the stage of development of each pipeline constituent. This analysis yields a valuation such that the equity is good value if the company achieves the market penetration we have projected. We know what that depends on: execution, execution and a dollop of good fortune on top!

Bottom line *Redux*

On balance, York Pharma has done a great job from a standing start in 2003 in constructing a company with such resilient dynamics and exciting prospects. To be sure, the experience brought to bear from the past has enabled this jump-start and, assuming that all goes to plan, patient investors should reap the benefits.

Valuation

York Pharma's strategy takes a two-pronged approach to the development of its business. On the one hand, it wishes to control its sales and marketing in two major European markets (the UK and Germany) and all that this entails by way of G&A, sales & marketing costs and the like. On the other hand, it plans to license out its products at the latest stage possible so as best to control the timing of launch and maximise upfront and milestone payments and royalties. We have therefore applied a mixed valuation methodology whereby:

- The trading business is valued with a P&L in its own right in the classic fashion; and
- The licensing streams are valued separately focusing on the NPV's of upfront & milestone payments plus royalty streams.
- We have only included licensing streams where the stage of development of the product triggers a clear path to revenue. While we have summarised the market potential for the other applications, they are not yet included in our valuation analysis

Our analysis suggests an expected value of £107.8 million of York Pharma's drug portfolio. Allowing for the value of tax losses and outstanding options, this would result in a net value of the business of around £96.2 million or 379p a share

Estimating market potential

We have analysed the potential sales of each component of York Pharma's development portfolio. This led us to size up total market for the indication in question, review the products now treating the condition, and estimate what would happen to the market if a safer and more effective treatment emerged. The detailed analysis set out below based on our review of the literature and discussions with York Pharma's scientific team have given us no reason to doubt the validity of the underlying scientific and clinical claims which give rise to the target clinical profiles. Our analysis of the current market confirms that the target profile would be attractive to it. We have kept in mind that few drugs achieve blockbuster status in this market and that competitive approaches are certain to emerge. In consequence, we have estimated modest market penetrations for each of the lead drugs in the portfolio.

Treatment of risks

As is common with pharmaceutical companies, we have applied significant probability-based discounts based on industry standard development-based probabilities of success, discounted even further where appropriate.

Valuation

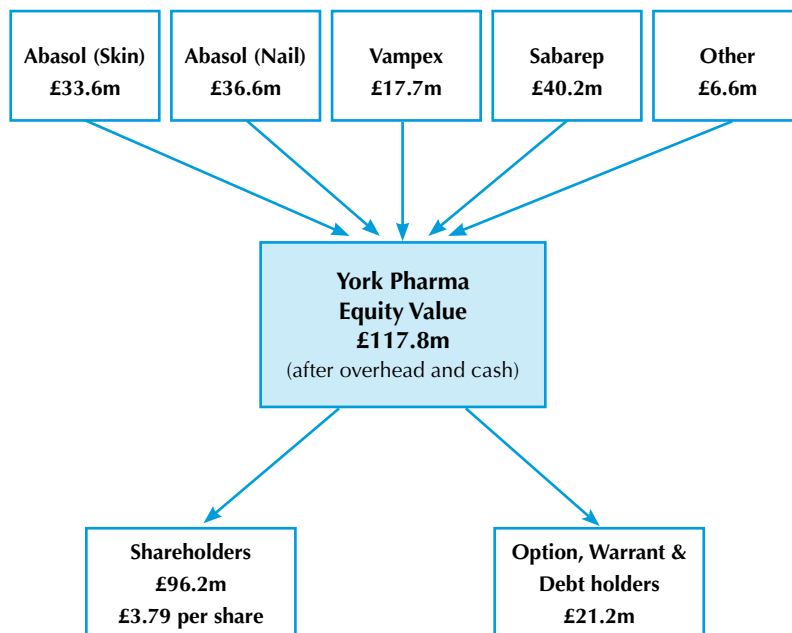
A valuation that is 4 times the current price might seem a stretch. However, Abasol skin and Sabarep, the two drugs most likely to hit the market represent roughly 50% of this value. Abasol should gain final MHRA approval in FYQ207 and Sabarep, based on GRAS status in the US, should be able, assuming that its efficacy holds up in later trials, to hit the US market in late 2008 early 2009. So why the discrepancy between current market price and our expected market value?

As outlined in the Key Risk section, we believe that there is a lingering feeling of disbelief by the general market based on the Bioglan past. But, more importantly, York has yet to overcome its first regulatory hurdle and demonstrate its ability to generate market success in the UK and Germany and snag marketing partners elsewhere. Add to this that York is perceived to be cash constrained and running out of cash in the next few quarters. While it has proven its ability to raise money as evidenced by the latest round, the question that lingers is when will they ink a significant cash deal to do away with the need to finance itself in drips and drabs? We believe that the answer to the latter question will go a long way to resolving the noted discrepancy and readjust the market capitalisation to a level more comparable to its peers and more in line with what we have calculated to be a realistic valuation.

Valuation Summary (£m)

	Core	Pessimistic
Development drugs		
Abasol		
- Skin	33.6	10.0
- Nail	36.6	23.1
Abasol Total	70.2	33.1
Vampex	17.7	17.7
Sabarep	40.2	24.8
YP004 - Melanoma	6.6	6.6
Less: overhead	27.0	27.0
Expected value of pipeline	107.8	55.2
Add: Starting cash and new funding	10.0	10.0
Total Current Value for Firm	117.8	65.2
Less: Starting Bank & Other Debt	0.4	0.4
Total Value to Equity Claims	117.4	64.8
Less: Alternative Equity Claims		
- Warrants + Options	21.2	10.8
Total Value Attributable to Equity Holders	96.2	54.0
No. Shares (m)	25.4	25.4
Value per share (£)	3.79	2.13

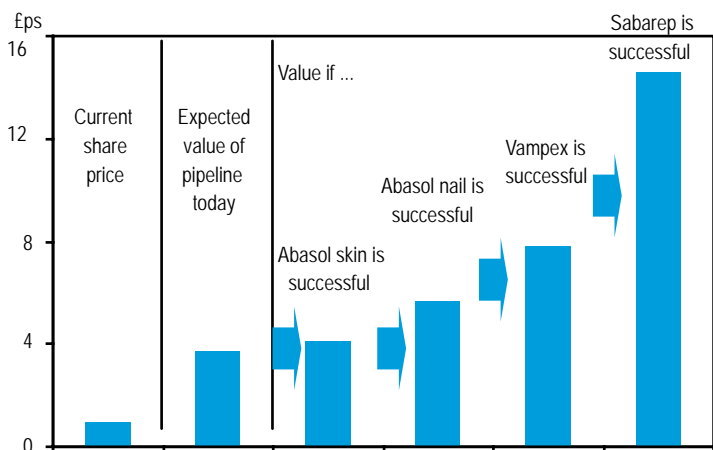
Components of York Pharma's Entity Value



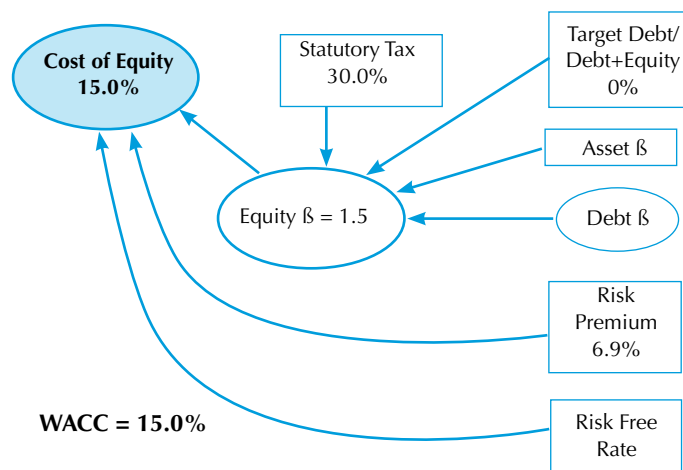
Comparable speciality pharma companies

	Symbol	Market Cap m	Shares Out. mm	Price	Rev Latest	Cash/Equiv latest	Cash/ share	Price to Cash	Market Cap to Sales	Comment/Partners/Deals
Dollar Zone										
Medicis	MRX (NYSE)	\$1,927.9	54.4	\$35.42	\$376.0	\$447.0	\$8.21	4.3	5.1	Dermatology speciality pharma
Connetics	CNCT (Nasdaq)	\$704.8	41.3	\$17.05	\$184.3	\$30.0	\$0.73	23.5	3.8	Dermatology speciality pharma
Barrier Therapeutics	BTRX (Nasdaq)	\$162.4	24.1	\$6.74	\$2.5	\$16.9	\$0.70	9.6	64.0	Derm development
Collagenex	CGPI (Nasdaq)	\$488.0	35.7	\$13.68	\$26.4	\$26.2	\$0.74	18.6	18.5	Derm spec. pharma & develop.
DUSA	DUSA (Nasdaq)	\$88.8	17.0	\$5.21	\$11.3	\$4.2	\$0.25	21.1	7.8	Photodynamic therapy
Average								15.4	19.8	
York Pharma	YRK (AIM)	\$24.1	25.4	£0.95	\$0.0	\$5.0	\$0.20	4.8	NM	
AGI Therapeutics	AGI (AIM)	\$87.8	67.4	£1.30	\$0.0	\$30.0	\$0.45	2.9	NM	Self develop/Specialty pharma
Antisoma	ASM (LSE)	\$129.0	368.7	£0.35	\$6.3	\$25.0	\$0.07	5.2	20.6	Abbott/Roche cancer D.Dev
Ark Therapeutics	AKT (LSE)	\$161.5	161.5	£1.00	\$2.4	\$6.3	\$0.04	25.7	68.7	CNS vascular drug development/outlicensing
Sinclair Pharma	SPH (AIM)	\$107.1	93.0	£1.15	\$7.0	\$10.9	\$0.12	9.8	15.4	Specialty pharma In licensing
Vernalis	VER (LSE)	\$186.9	311.5	£0.60	\$14.3	\$40.2	\$0.13	4.6	13.1	Novartis, Endo, Biogen Idec CNS drugs
CeNeS	CEN (AIM)	\$26.5	412.6	£0.06	\$0.1	\$8.5	\$0.02	3.1	530.7	CNS late stage drug development/outlicense
Average								8.6	29.4	
Other										
Basilea Pharmaceutica	BSLN (SWX)	\$1,555.0	7.4	SFr. 209.00	\$34.9	\$28.0	\$3.76	55.5	44.6	JnI/Phase III

Current EMV and value if pipeline is successful (£ps)



Weighted Cost of Capital



Key Risks

York Pharma has yet to demonstrate the successful execution of its strategy.

While Terry Sadler has a track record of building a FTSE 250 company from scratch, he was not able to translate that into a sustainable success. In the case of York Pharma, the proof will be in the achievement of milestones.

The past is not quite ancient history yet.

We are not given to analytical archaeology, but the market does remember the history of Bioglan, CEO Terry Sadler's last company. Bioglan collapsed four years ago after its leveraged structure collided with weak financial markets. This has not put off backers who clearly believe that Terry himself has got the message; he has constructed a low overhead, ungeared, focused strategy, which dazzles with simplicity and elegance. For our part, we believe that he has the experience and drive to build a successful business. Nonetheless, we would be remiss if we did not recognise that some will see the disappointments of the past as implying something of a risk.

Reliance on outside financing.

York's strategy will rely in its early stages on institutional finance. As evidenced by the recent fund raising, we accept that financing should be forthcoming with the early approval of Abasol for the topical treatment of fungal infections of the skin. Nonetheless, the ability of York to obtain such funding is pivotal to the success of its strategy.

Abasol's future is not without risks!

We do not want to pour cold water on management's passionate conviction that Abasol is set for thundering market success, but we must point out that many barriers remain. As applied to skin conditions, the recently received quasi 'approvable' letter should not pose any untoward problems in the ultimate attainment of the desired license but there remain significant risks in making the drug into a significant market presence. While the in vitro data speaks loudly of the drug's unique qualities, the company has yet to persuade the medical community of its incremental benefits by comparison to current therapies. On balance, we are on board and feel that a plausible case can be made. This said, the company has no sales and marketing track record in the antifungal market so the jury must be out on the outcome. We agree that safety is unlikely to be an issue for nail applications, but an effective formulation has yet to be selected. Thereafter the rate and duration of cure will need to be superior to incumbent treatments which, given their track record, should not be that difficult a target. Again though, York still needs to prove that this is the case.

Many development and business development barriers block the way to ultimate success.

There are still a number of formulation issues to resolve. The regulatory pathway to market is clear, but it has the potential to throw up unforeseen delays. York Pharma has done a remarkable job of de-risking the portfolio but it is hard to be completely sure that it can stick to the timelines it has set out. On the business development front, the company does not have a single deal at time of writing, so it will be required to prove to the market that it can come up with the goods. The upfront and milestone payments to be derived from these deals are a central component of the story. Without them, the company is likely to have to find a substantial amount of money to achieve its commercial objectives from other sources — possibly dilutive and, in the worst-case, not to hand.

York Pharma is a specialty pharma and development company focusing on dermatological preparations. It is based in Hitchin, UK, with the stated objective of building a sales and marketing platform in the UK and Germany and partnering or licensing out elsewhere. It plans to develop its products through to registration in most major markets and then to license them to market participants with strong regional presence. There is nothing particularly earth shattering about the business model that York Pharma has constructed. It is a sound one and in one form or another has been successfully executed by other specialty pharma and biotech houses.

The underlying strategy has two-prongs.

It involves using a late stage approvable product (e.g., Abasol for Dermatophyte (fungal) infections of the skin) to fund the construction of its sales and marketing platform for the UK and Germany and to generate some early upfront and milestone payments. This would combine with additional capital market funding to jump-start operations, while other products make their way to commercialisation. We are predicting a series of business development deals between 2007 and 2012 as the company attains licensing milestones for Abasol (skin and nails), Vampex, Sabarep (along with YP002, the skin barrier diagnostic test) and YP004 for Melanoma.

York Pharma has a pipeline of three potentially significant drugs in Phases II & III.

As seen in the accompanying table, the two indications of Abasol (skin and nail), Vampex for psoriasis and Sabarep for Atopic Eczema/Dermatitis are all poised for commercialisation over the next 2-3 years and should generate upfront and milestone payments. The products in this group are relatively safe bets as Abasol is in registration in the UK, Vampex for Psoriasis is based on a 35-year-old cytoprotective anti-ulcer drug, but in a topical formulation; and Sabarep for atopic dermatitis is a patented combination of GRAS (Generally Regarded as Safe), which generally do not require significant regulatory approvals, particularly in the US. In this light, approval of these drugs should not pose undue regulatory barriers assuming that the safety/efficacy profile for the respective indications can be demonstrated satisfactorily.

York's remaining pipeline contains some interesting sleepers.

The **Skin Barrier Diagnostic (YP002)** test being developed as an adjunct to Sabarep therapy is set to become a valuable tool for York and its licensees. It also has other applications as a prognostic tool to detect Skin Barrier Dysfunction. This is likely to find a market given the importance of this phenomenon in the development of allergies and asthma, as well as workplace related issues. **YP005 (Sphingosine-1-Phosphate)** is a naturally occurring metabolite that appears to have anti-proliferative effects that might be useful in the treatment of acne and psoriasis. It is still in early development, but a favourable safety efficacy could easily see this drug taking a 15-20% share of the £1.2 billion market for acne. Finally, **YP004** is a potentially very attractive sleeper as it has brought to light a potential mechanism for pushing the hyperproliferative melanoma cell into the desired state of differentiation. Should York be able to fully develop this concept, we would anticipate, at the very least, some significant upfront fees for the licensing of this project.

The UK and Germany Derm markets are set for a blitz from York.

The company has declared the objective of hitting these markets with a contracted out direct sales force. We see this as a prudent way of creating the base of operations and cash flow, which would put the company on a sustainable base and eventually make it an attractive merger partner or target. We estimate the costs of launching, marketing and selling Abasol for skin at roughly £16 million-18 million for both countries combined over the next 5 years. This makes such a course relatively expensive, but we recognise the longer-term strategic benefits. Once this upfront investment is made, the sales and marketing platform is ready to take on all of the other constituents in the company's pipeline for what are marginal incremental costs (which we estimate in the £3-500k). This is the crux of York Pharma's strategy and provides the leverage to earnings. We are projecting the benefits of this to emerge post 2009, which is a significant earnings inflection point.

Taking products the whole nine yards to license.

As in American Football, York is intending to take its products all the way to touchdown, through registration in Europe, the US and Japan. The costs of this programme are significant but because approvals in the UK trigger an EU-wide approval process with only marginal additional costs, York can then partner piecemeal European and selected Asian and Latin American markets for upfront cash. This should then serve to fund registrations in the US and Japan. The timings may not be as perfect as the company would wish in the early stages, so we expect the company to tap the capital markets to make up the difference. However, with the upfront cash raised from partnerships, we expect York to keep capital market fund raising to as low a level as possible.

Maximising returns from commercial partnerships and minimising dilution.

By taking its products through registration, York Pharma has its eye on upfront and milestone marketing payments. York should also be able to earn royalty rates with a minimum target in the high 20's and minimise the need to tap the capital markets to fund the development of its current plan.

Management has something to prove and the chance to do so.

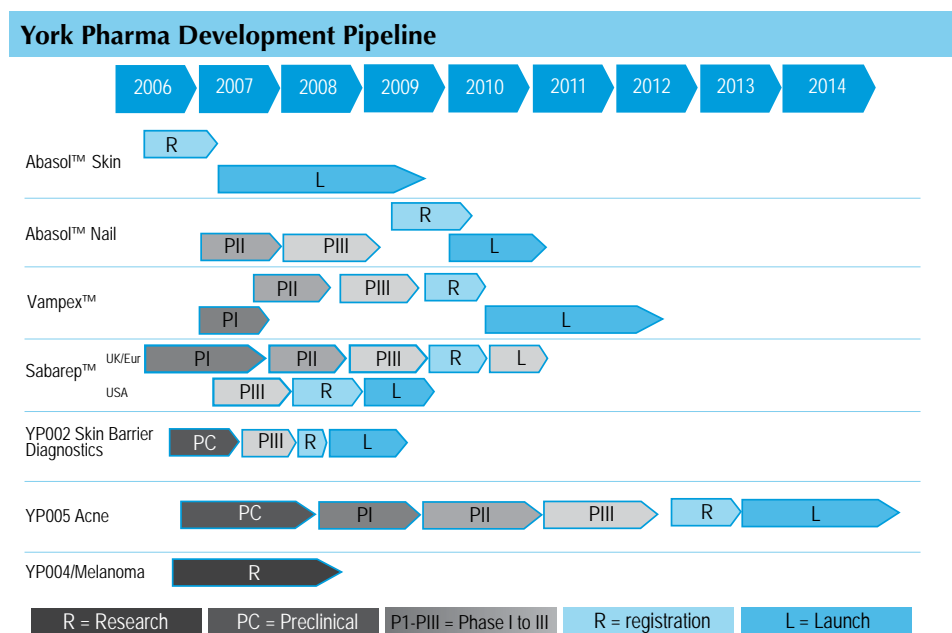
The market has demonstrated that it is willing to back Terry Sadler's ability to exploit the opportunity to hand. In effect, investors have afforded him a second chance to deliver value and so far the evidence suggests they are right. Terry has assembled a strong team and portfolio, which he has coupled with a route to market which generates financing possibilities through upfront and milestone payments. The MHRA's 'approvable letter' is a good first step; Terry now has to prove that he can get Abasol to market, roll out the approval to the EU, obtain capital market financing and snag a partner to help fund the rest of the pipeline. This paves the way for a self-sustaining specialty Derm company. We think that this is perfectly feasible. Second time successful? It all boils down to execution.

A total pipeline of close to £1.2 billion for the portfolio is on offer

We have pegged the total market potential of this pipeline at around £1.2 billion but the real value to York is more likely to be around a net £336 million if one strips out licensee sales. Adding back our projected £255 million in upfront licensing payments and we have a total value that is over £550 million by 2015. Not bad for 11 years of hard work if you can get it!

News flow should abound over the next three years.

If matters go to plan, there should be much to talk about over the next three years, from the initial approval of Abasol for skin conditions through the approvals of Vampex and Sabarep along with potentially positive development milestones for the rest. Fill this picture out with the potential for partnerships. We know of no mishaps looming in the background, but as with any pharma business, disappointment can never be ruled out.



Source: York Pharma

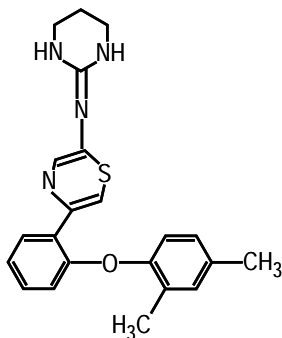
Business Dermatology 101

Dermatology is begging for safer and more effective therapies. Amongst entrepreneurial development and Speciality Pharma companies, this has spawned a mad rush to find better drugs. York Pharma should be seen as one among the plethora of novel approaches under way. We see their approach as based on some very elegant science, which we believe has a fair shot of fulfilling its promise.

York Pharma's portfolio covers a substantial portion of the £7.5 billion global dermatology market. It is currently crowded with generic products, often the only therapies available to dermatologists. These may be clinically adequate but many introduce side effects or quality of life issues. They often require rotation to minimise these adverse effects. The drive for safer and more effective medicinal products for dermatological disease is on and York appears to be smack in the middle of it with a portfolio of drugs set for launch between 2007 and 2012.

We briefly revisit the profile, development status, and prospects for each of them.

Abafungin



Source: York Pharma

Abasol™ (abafungin in a 1% Cream formulation)

Overview

Abafungin is a broad-spectrum antifungal agent that the accompanying diagram shows to be a derivative of guanidine, which is a normal by-product in protein metabolism usually found in urine. Abafungin appears to act in two different ways. On the one hand, as with many antifungal drug classes, its fungistatic activity inhibits the synthesis of ergosterol, which is a key component of the fungal cell membrane, via the competitive inhibition of SAM-dependant C24-methyltransferase. On the other hand its fungicidal activity is believed to be due to a direct interaction with another membrane component, phosphatidylserine, causing membrane disruption, leakage of cell contents and cell death.

Its broad-spectrum profile seems to be based on the above duality of action, which enables this class of compounds to display activity against a wide variety of fungi, including dermatophytes, as well as yeasts and Gram-positive bacteria.

Abafungin was licensed from its inventors after Bayer had decided not to pursue further development of the compound. It has been tested extensively in humans as a topical agent for dermatomycoses. It appears to be safe and effective for this indication and is awaiting approval from the UK authorities as a referent to a pan-European registration. The full Abasol profile, if confirmed clinically in humans, could translate into a significant market position as a first line agent of choice for a wide variety of dermatological and other infectious indications.

Mechanism of Action

Abafungin's broad spectrum of action and activity against active and non-growing (resting) organisms is a key differentiating feature of this drug and is illustrated in the accompanying graphs. As seen in these graphs (based on *in vitro* data), abafungin is highly potent against yeast by comparison with other commonly used antifungal agents, in particular terbinafine (Lamisil: Novartis), by far the market leader.

As seen at the bottom of these two graphs, abafungin is not only effective against active yeast but can also attack, disrupt and enable the killing of dormant yeast and dermatophytes largely responsible for the relapses that occur between 60% and 70% of the time.

Abafungin is also a potent agent against a broad spectrum of resting dermatophytes and compares very favourably to current therapeutics in these tests.

To date, organisms resistant to abafungin have not been seen in clinical trials. There can be no guarantees on this score, but the drug's dual mechanism of action lowers the probability that resistance will occur. One of the mechanisms relates to the disruption of a structural component of the fungal cell membrane by physical action, which is not regulated by a direct genetic mechanism, making such resistance less likely. The development of resistance to other classes of antifungal drugs, including the azole class, could be a serious setback, giving rise to the need for new therapies, particularly in the treatment of candidosis (yeast infections) in AIDS/HIV cases.

To summarise, the profile of abafungin appears to put it at a potential competitive advantage by comparison with the market leaders for the following reasons:

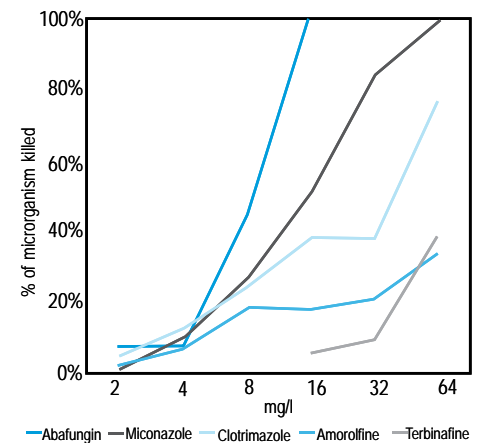
- it offers broad spectrum action against dermatophytes, other fungi, moulds, yeasts and even bacteria;
- it operates against resting cells, where it is highly effective;
- it seems to demonstrate diminished propensity to provoke resistance, owing to its dual mechanism of action.

Indications being pursued

York Pharma is pursuing two primary indications in the near term: Dermatophytosis and Onychomycosis or fungal infections of the skin and the nail respectively.

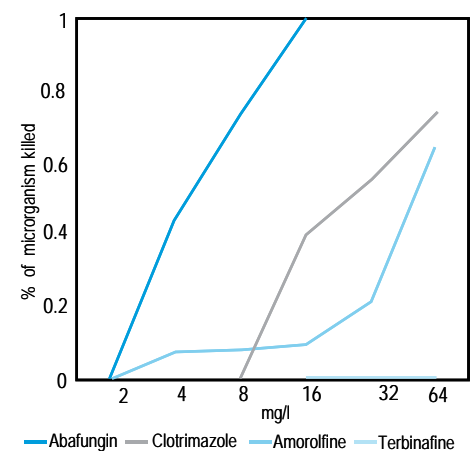
Fungicidal activity of different antimycotics

against clinical isolates of active yeasts



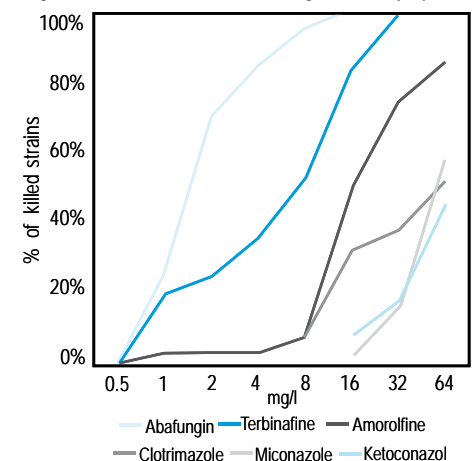
Fungicidal activity of different antifungals

against clinical isolates of resting yeasts



Fungicidal activity of different antifungals

against clinical isolates of resting dermatophytes



Source: York Pharma

Dermatomycosis

This is a family of diseases of the skin and hair. With Abasol (a 1% cream formulation of abafungin), York Pharma are pursuing an indication for superficial dermatomycoses treatable with topical creams, lotions and sprays. These diseases are denominated by a Latin binomial name, which includes the prefix *tinea*. There are a number of diseases that fall under this family including *tinea pedis* (more commonly known as athlete's foot) and *tinea capitis*, which is an infection of the scalp. The three Phase III clinical trials that have been conducted were aimed primarily at superficial dermatomycoses in general and *tinea pedis* in particular.

Onychomycosis

This term generally denotes an infection of the nail. Onychomycosis is most often caused by dermatophytes. Other pathogens may cause onychomycosis as well, such as yeasts (e.g., *Candida albicans*) and very occasionally by non-dermatophytic moulds (e.g., *Scopulariopsis brevicaulis*). Current treatments that feature are either oral or topical. Given the side effects inherent in oral agents, these tend to be reserved for more serious cases. Oral treatment would either be Lamisil (a 3 month daily course) or Sporanox (a 1 week course every month over 6 months). More common would be topical treatment and here the runaway favourite is a prescription topical lacquer solution called topical Penlac (a lacquer formulation of ciclopirox, Sanofi Aventis). The main problem with this topical treatment is its poor sustained efficacy (high relapse rates) and secondarily, the duration of treatment (12 months). A treatment course that is effective, shorter in duration, kills both active and resting cells and is effective in yeast or other mixed infection aetiologies would be a welcome addition in fighting this condition.

Other conditions

There are a number of other conditions which are targets for topical Abasol. These include vulvovaginal candidosis, candidosis of the skin and inflammatory erythema. Any non-dermatological applications are likely to be out-licensed by the company.

Clinical Status

Dermatophytosis/Tinea pedis/Athlete's Foot

Bayer conducted extensive development of Abafungin before it made a strategic decision to de-emphasise dermatology and the original inventors acquired the compound. The summary of their trials (which are an integral part of the registration package submitted to the MHRA in 2005), are depicted in the accompanying table.

In extensive Phase II clinical trials conducted by the originator (Bayer), abafungin creams displayed extensive clinical activity in a wide variety of fungal and yeast infections. To put this into perspective, for inter-digital tinea pedis (that is, infection between the toes), Abasol is 96.9% effective by comparison with Lamisil which has demonstrated a 75% efficacy; and for yeast infections, Abasol is 90-100% effective by comparison with Lamisil which is only 20% effective.

In Phase III testing in Germany and Japan, Abasol's safety and efficacy profile was comparable to that of Canesten (clotrimazole, Bayer) and equal or better to that of Mycospor (bifonazole, Bayer), two commonly used drugs for *tinea pedis* (athlete's foot). In a multicentre, head-to-head trial versus Bayer's own Canesten topical cream (1%), a 1.5% formulation of Abasol cream was equivalent overall but superior in *Candida* (yeast) triggered *tinea pedis*. While the UK application is based on a broad indication including all superficial dermatomycoses, yeast infections and moulds, the US applications are likely to be more narrowly focused on *tinea pedis* as its primary indication for registration. York Pharma submitted its registration to the MHRA at the end of July 2005.

Phase IIa & IIb Clinical studies:

	Improvement in %
Interdigital tinea pedis	96.9 %
Vesicular tinea pedis	74.5 %
Tinea corporis	93.8 %
Tinea cruris	100.0 %
Candidal intertrigo	92.1 %
Interdigital erosion	81.0 %
Chromophytosis	100.0 %

(Total of 1093 patients studied in Phase II)

Source: York Pharma

Summary of Bayer's trials of Abafungin

Phase	# of Patients	Trial objective	Results
Phase I	57	Safety Study in normal subjects 3 comparative studies skin and photo sensitivity active compound and base	Comparable for both active compound and base in both skin and photo sensitivity
Phase IIa & IIb	1093	Phase IIa: Pilot open study to evaluate efficacy and safety of 1% abafungin cream in 303 patients with superficial dermatomycoses Phase IIb: Double blind efficacy and safety study of abafungin 1% and 1.5% cream in 790 patients with superficial dermatomycoses	High degree of efficacy across various conditions (see table)
Phase III Japan	Multicenter 1626	Efficacy Trials 1) randomised double blind placebo controlled (1146) versus Mycospor 2) open study (480) abafungin solution vs cream Once Daily dose	1) Efficacy and Safety equivalent to Mycospor 2) Solution and cream efficacy are equivalent
Phase III Germany	Multicenter 121	Randomised double blind versus 1% Canesten cream	Equivalent overall but superior in <i>tinea pedis</i> due to <i>Candida</i> spp

Source: York Pharma

On October 2, York announced that it had received notification from the MHRA of the need for York to submit certain additional data which amounts to what the US FDA calls an 'approvable' letter. Having anticipated the need for this data, York has worked over the past year to prepare this data for submission so the process to achieve licensing should be reasonably assured. We would anticipate the final grant of the license in Q2 of fiscal 2007.

York are already conducting pre-marketing activities in the UK and intend to pursue a pan-European approval based on the EU's Mutual Recognition process with the UK used as a reference for approvals across Europe in 2007 and 2008. In parallel, York Pharma will seek discussions with the US FDA to determine the approval pathway with the intention of using as much of the clinical data submitted in the UK as possible. The diagram on p11 (see pipeline diagram) outlines our rough vision of how this will pan out.

Onychomycosis

Abasol's profile makes it a candidate for the treatment of nail infections whether they are of fungal, yeast and even perhaps gram-positive bacterial origins. The current leaders in this market are oral Lamisil for acute infections; and topical ciclopirox (Penlac, Sanofi Aventis) in a lacquer formulation for less serious attacks. York Pharma is working to formulate Abasol in the most effective way possible. A world-class formulation team are working on this with the intention of reaching the clinical stage soon.

Assuming that Abasol 1% Cream achieves registration for superficial dermatomycoses, the path to registration of a novel formulation for onychomycosis should be simpler, relying on pharmacy data for the new formulation, clinical evidence from studies in onychomycosis and general safety data in the original submission.

To compete effectively with treatment based on Penlac, York Pharma will have to show that it can achieve significant, sustainable cure rates with a relatively clean side effect profile. All the better if this can be achieved in a much shorter period of time than the 12 months required for Penlac (York hope that it can reduce this by 3-6 months). What is particularly encouraging for this indication is the activity against both resting and active fungal cells.

The Phase III trial should enable the company to go for registration in H209 with a chance of marketing in the UK from 2010 followed by rolling approvals in other markets. This would be an additional indication in a separate formulation for the same compound, so it may enjoy a faster route to market once the Abasol *tinea pedis* application receives its license and has demonstrated its safety in large scale market usage.

At this point we should note that if the 1% solution/lotion is shown to be effective, a substantial amount of off-label use is likely to be triggered, leading to increased revenues not falling out of formal marketing. No one condones such borderline clinical conduct, but investors need to take account of this arcane but very common aspect of pharmaceutical life!

Other Indications

Other indications are driven by the efficacy of Abasol against yeast. These are theoretical and preclinical in nature. Should Abasol pass muster with the MHRA, the only limitation to developing these additional indications would be financial. We suspect that York will wait for the MHRA decision and see whether it is able to extract a label which highlights Abasol's activity against yeast. If this occurs, it should trigger off-label use by dermatologists, which would prompt York Pharma to organise Phase III trials in these potential, new indications. *Candida* infections are quite widespread but the many applications will be best pursued with third parties with a non-dermatological focus as they involve long, extensive and expensive clinical development programmes.

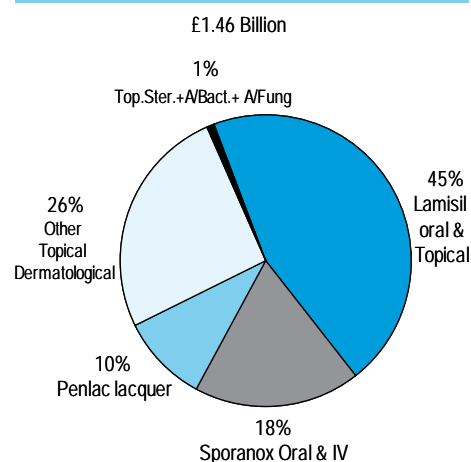
Market analysis and competitive landscape

Both topical and systemic (oral) treatment can be effective for any one superficial dermatological condition, so the markets for both need to be examined.

Based on IMS data, we estimate the total value of the 2005 antifungal market for oral and topical indications to be about £1.46 billion. Penlac (ciclopirox lacquer, Sanofi Aventis) represents about 10% of the market as a primary treatment for onychomycoses. Lamisil oral dose and cream (terbinafine, Novartis) leads the market with almost 45% of the total market and is very prominent in both the dermatomycosis (topical) and onychomycosis (topical and oral) markets. Lamisil is a highly effective treatment against fungal infections but has low activity against yeast. Both Lamisil (terbinafine, Novartis) and Sporanox (itraconazole, Janssen Pharmaceuticals/JNJ) have found significant use in onychomycosis where, even though there are severe warnings attached to oral forms of these drugs, they are applied to cases of onychomycosis where topical treatment has failed. They are reasonably effective at clearing such infections but do not have much effect on resting cells. While Sporanox is effective against *Candida albicans*, it has also been known to encounter resistant strains. Oral Lamisil treatment of onychomycoses is a daily treatment that is 3-4 months in length; its cure rate tends to range in the 30-70% range with relapse rates as high as 22%¹.

Physicians are now being warned off these oral agents. An FDA advisory note was issued in 2001 to make physicians aware of some of the serious side effects that can result from these oral therapies. The occurrence of both congestive heart failure with Sporanox and the potential for liver failure with both Sporanox and Lamisil makes these therapies less than desirable except in circumstances where there is no other option.

Antifungal Market 2005*



* both topical and oral indications

Source: 2005 IMS Data & Objective Capital estimates

¹ A. Tosti, B.M. Piraccini, C. Stinch, M.D. Colombo, *Dermatology* 1998;197:162-166

Most of the drugs developed as antifungals to date have been in the azole category (Sporanox, Diflucan, etc) or allylamines, such as Lamisil, with the limitations and side effects set out above. This suggests that the market would have an appetite for a treatment for onychomycoses of both fungal and yeast origin, with the prospect for lower resistance and little in the way of relapse, due to the effective disposal of resting and active infectious organisms. We see such a drug as a welcome addition to the market and could command a significant market share. Although some of the profile for Abasol still remains to be proven clinically, the *in vitro* data is highly indicative and serves as a powerful competitive marketing tool for York Pharma.

We set out below our projections for both the dermatomycosis and onychomycosis markets for Abasol. We believe that in onychomycosis, a more effective topical treatment over a shorter time and a better formulation could make a serious dent in the markets for both the Penlac and oral agents (Lamisil and Sporanox), and possibly help to expand the overall market. Hence our 'finger in the air' view is that the potential market for Abasol could be closer to the £150-200 million in size based on a 10-15% share of the market. Our numbers indicate peak sales at around £170 million for both indications based on sales of around £77 million for dermatomycosis and around £90-100 million for onychomycosis. It is possible that we might be a tad conservative.

In conclusion, if York Pharma were able to achieve its target profile for Abasol, there is ample rationale for it to attain a significant market position. In dermatomycosis, it should be able to achieve a significant inroad into the market by virtue of its superior activity against yeast-borne infections in *tinea pedis*/athlete's foot. A strong *in vitro*-based rationale for both a reduction in relapse rate and an apparent absence of resistance should also be strong marketing tools to make inroads into the market share of incumbents.

In onychomycosis, assuming an effective topical formulation (whether lacquer or other), the broad spectrum of activity (which appears to include Gram-positive bacteria), the activity demonstrated against resting cells and the implication that a dual mode of action might lower the prospect of resistance, could combine to present a significant advantage in comparison with Penlac. This causes us to project significant inroads into the topical market as well as a dent in the oral market.

Commercial Profile and Development

The commercial profile of Abasol is intimately linked to the ability of York Pharma to market the *in vitro* characteristics of abafungin. In the Phase III trials conducted by Bayer, the claimed superiority of Abasol versus Canesten in yeast induced *tinea pedis* is an early indication of this differentiation. We believe that York Pharma has followed the right strategy in filing this data with the MHRA to get an early foothold in the market so as to push the *in vitro* profile of the drug. Prima facie, there is no reason to believe that the MHRA would reject Abasol, as it promises non-trivial advantages. The crux will be York's message based on Abasol's scientifically proven broad spectrum in fungi and yeast along with its ability to kill resting and live cells.

It is likely that the current application will lead to an approval, in turn leading to a market introduction and a decent market share. If a *tinea pedis* yeast indication is on the label, this could help it to promote Abasol against the azoles and might be sufficient to make a dent in some portion of the market power of Lamisil even in the current absence of head-to-head data. Where a dermatologist — or even a general practitioner — suspects a yeast infection, the data points strongly to the use of Abasol over Lamisil.

In onychomycoses, the formulation work under way at present is key to making the case for Abasol. Whether it is a lacquer or some other formulation, the ease of administration, the penetration of the drug, the time to cure and the frequency of relapse, will bear upon the inclination of the medical community to substitute Abasol for Penlac.

Expected Value of Abasol™ Skin

Summary of Valuation (pre-corp tax)

Scenario (£m)	Core	Pessimistic
<i>Royalty Share</i>		
Short term forecasts	52.1	19.2
Upto Generics	0.0	0.0
Post generics growth	10.0	3.7
Decline period	4.1	1.5
EV of Royalties	66.2	24.4
Likelihood of success (PoS)	73%	69%
EMV of Royalties	48.3	16.8
Add: EMV of upfront payments	12.8	12.0
Add: EMV of milestone payments	0.0	0.0
less: EMV of dev costs	13.0	14.6
EMV of Abasol™ Skin	48.0	14.3
per share (£)	1.89	0.56

Key Market & Licence Assumptions

Indication/Market	Route to Market	Royalty Rate/Effective Margin	Approx Date	Price Impact	Impact of Generics
UK&Germany	Marketed	55%	2014	-50%	
ROE	Licensed	23%	2014	-50%	
USA	Licensed	23%	2015	-75%	
Japan	Licensed	23%	2015	-75%	
ROW	Licensed	23%	2015	-75%	

Sensitivity to change in ...

Impact of generics (+ % price decline)

-20.0% -10.0% +0.0% +10.0% +20.0%

Value (£m)	57.4	52.7	48.0	43.3	38.6
Change in Value	20%	10%	0%	-10%	-20%

Increase in royalty/margin (+%)

	-10%	-5%	0%	5%	10%
Value (£m)	37.5	42.8	48.0	53.3	58.5
Change in Value	-22%	-11%	0%	11%	22%

Components of core valuation (pre-corp tax)

Core Scenario

Expected Value of Royalties/Revenue (£ millions)					
Indication/Market	EV of cashflow	Current Stage of Dev	PoS	EMV	% of Val.
UK & Germany	30.2	Regulatory	80%	24.1	36%
ROE	10.2	Phase 3	67%	6.8	10%
USA	18.1	Phase 3	67%	12.2	18%
Japan	4.0	Phase 3	67%	2.7	4%
ROW	3.7	Phase 3	67%	2.5	4%
Total	66.2		73%	48.3	

Pessimistic view

Expected Value of Royalties/Revenue (£ millions)					
Indication/Market	EV of cashflow	Current Stage of Dev	PoS	EMV	% of Val.
UK & Germany	3.8	Regulatory	80%	3.1	13%
ROE	10.2	Phase 3	67%	6.8	28%
USA	6.6	Phase 3	67%	4.4	18%
Japan	1.9	Phase 3	67%	1.2	5%
ROW	1.9	Phase 3	67%	1.3	5%
Total	24.4		69%	16.8	

Expected Monetary Value of Abasol™ Skin
£14.3m - £48.0m
£0.56 - £1.89 per share

EMV of Upfront payments
£12.8m

EMV of Milestone Payments
£0.0m

Expected Value of Abasol™ Nail

Summary of Valuation (pre-corp tax)

Scenario (£m)	Core	Pessimistic
<i>Royalty Share</i>		
Short term forecasts	64.7	37.6
Upto Generics	21.4	11.6
Post generics growth	19.6	12.3
Decline period	4.8	3.0
EV of Royalties	110.5	64.5
Likelihood of success (PoS)	42%	42%
EMV of Royalties	46.4	27.1
Add: EMV of upfront payments	10.8	10.8
Add: EMV of milestone payments	0.0	0.0
less: EMV of dev costs	5.0	5.0
EMV of Abasol™ Nail	52.3	33.0
per share (£)	2.06	1.30

Key Market & Licence Assumptions

Indication/Market	Route to Market	Royalty Rate/Effective Margin	Approx Date	Impact of Generics	
				Price	Impact
UK&Germany	Marketed	73%	2019	-50%	
ROE	Licensed	25%	2019	-50%	
USA	Licensed	25%	2019	-75%	
Japan	Licensed	25%	2019	-75%	
ROW	Licensed	25%	2019	-75%	

Sensitivity to change in ...

Impact of generics (+ % price decline)

	-20.0%	-10.0%	+0.0%	+10.0%	+20.0%
Value (£m)	58.1	55.2	52.3	49.4	46.5
Change in Value	11%	6%	0%	-6%	-11%

Increase in royalty/margin (+%)

	-10%	-5%	0%	5%	10%
Value (£m)	38.7	45.5	52.3	59.1	65.9
Change in Value	-26%	-13%	0%	13%	26%

Components of core valuation (pre-corp tax)

Core Scenario

Expected Value of Royalties/Revenue (£ millions)

Indication/Market	EV of cashflow	Current Stage of Dev	PoS	% of	
				EMV	Val.
UK & Germany	29.7	Phase 3	42%	12.5	11%
ROE	21.4	Phase 3	42%	9.0	8%
USA	46.3	Phase 3	42%	19.4	18%
Japan	6.0	Phase 3	42%	2.5	2%
ROW	7.2	Phase 3	42%	3.0	3%
Total	110.5		42%	46.4	

Pessimistic view

Expected Value of Royalties/Revenue (£ millions)

Indication/Market	EV of cashflow	Current Stage of Dev	PoS	% of	
				EMV	Val.
UK & Germany	24.3	Phase 3	42%	10.2	16%
ROE	17.8	Phase 3	42%	7.5	12%
USA	15.4	Phase 3	42%	6.5	10%
Japan	4.0	Phase 3	42%	1.7	3%
ROW	3.0	Phase 3	42%	1.3	2%
Total	64.5		42%	27.1	

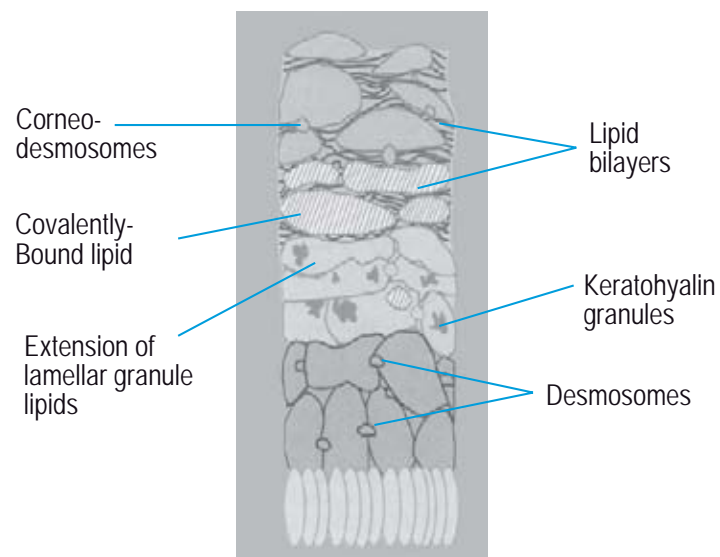
Expected Monetary Value of Abasol™ Nail
£33.0m - £52.3m
£1.30 - £2.06 per share

EMV of Upfront payments
£10.8m

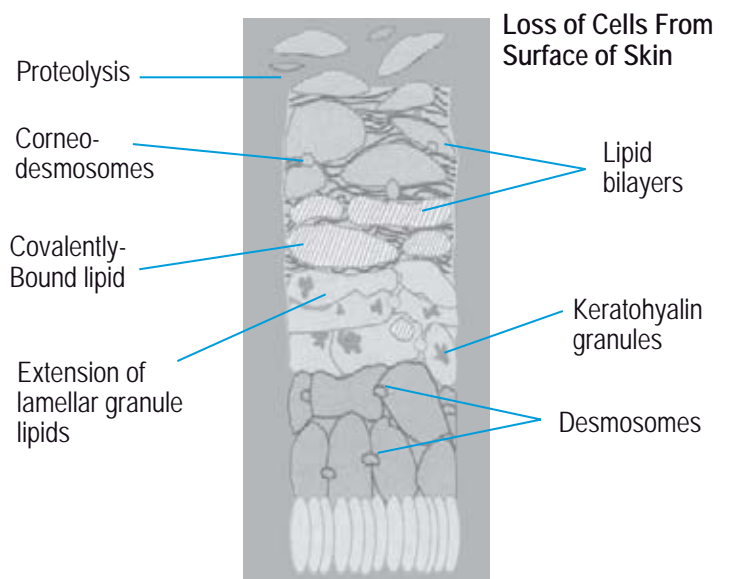
EMV of Milestone Payments
£0.0m

Skin barrier

Skin barrier:



Proteolysis of the skin barrier:



Source: York Pharma

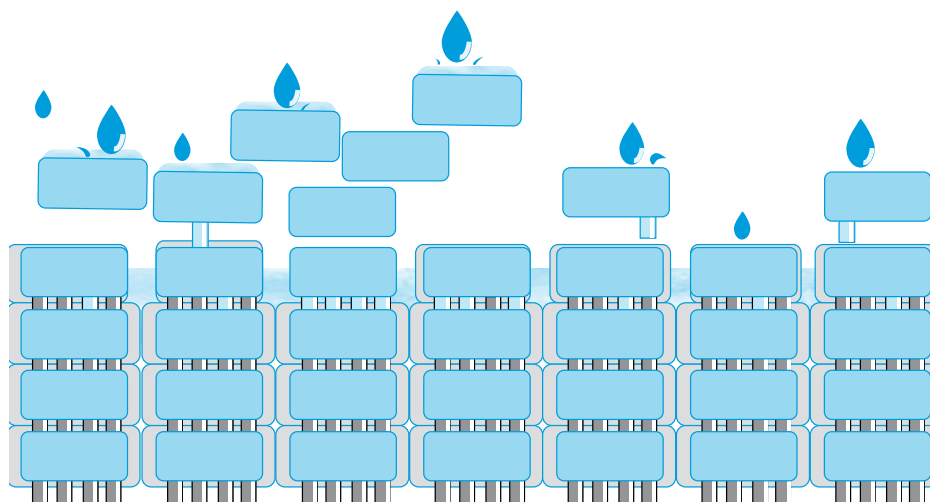
Overview

Atopic dermatitis (AD; atopic eczema) is a multi-factorial inflammatory skin disease with a strong hereditary element; both genetic and environmental factors appear to play a role in triggering the disease. The aetiology of AD is complex but does warrant some explanation to better understand the need for a product such as Sabarep. It is important to understand that the skin is a complex, dynamic structure where the balance between exfoliation (loss of skin) and renewal of skin cells is regulated via a genetically controlled mechanism. As discussed for psoriasis, normal skin is composed of different layers of cells which, through a progressive, vertically-driven transformation, take keratinocytes through stages of proliferation, differentiation, maturation and programmed cellular death, to form a complex barrier, which forms a protective shield against environmental injury.

Keratinocytes originate and migrate from the basal layer of the epidermis (or stratum basale), through terminal differentiation and, ultimately, programmed cell death and a process of keratinisation, which results in the formation of the corneal envelope. This forms a skin barrier located in the stratum corneum which consists of a series of proteins and lipids that are tightly bound together providing tensile strength. This outer layer of the skin has been depicted as a wall of bricks held together by lipid cement that acts as an effective barrier to outside fluids.

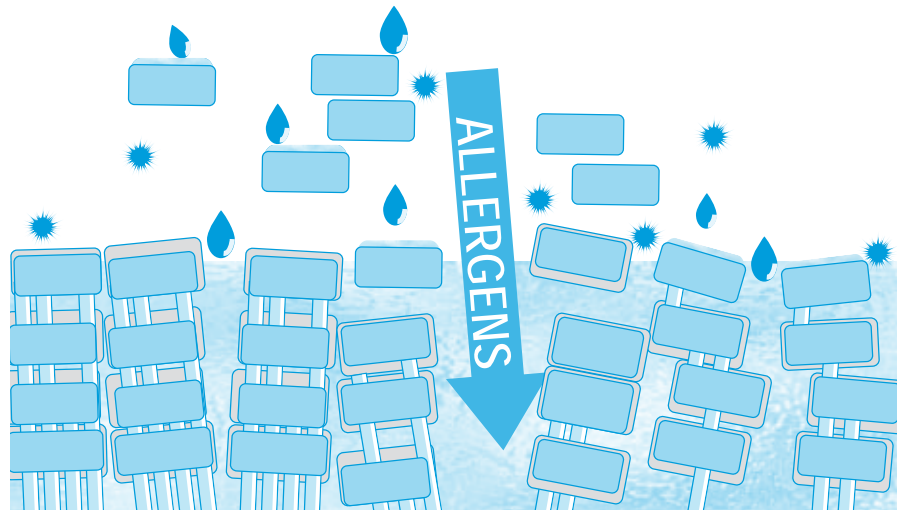
The top layer of cells eventually loosens and falls off as lower down in the epidermis the layers of the stratum corneum are progressively regenerated. The system of breaking down the surface corneal envelope leads to natural skin exfoliation (technically called desquamation), and is regulated by a system of protease enzymes and inhibitors. Any imbalance in this system can result in a disruption of the skin barrier and the entry of allergens and other irritant substances.

Protection barrier for healthy skin



Source: York Pharma

Failure of skin barrier results in allergens and moisture penetrating

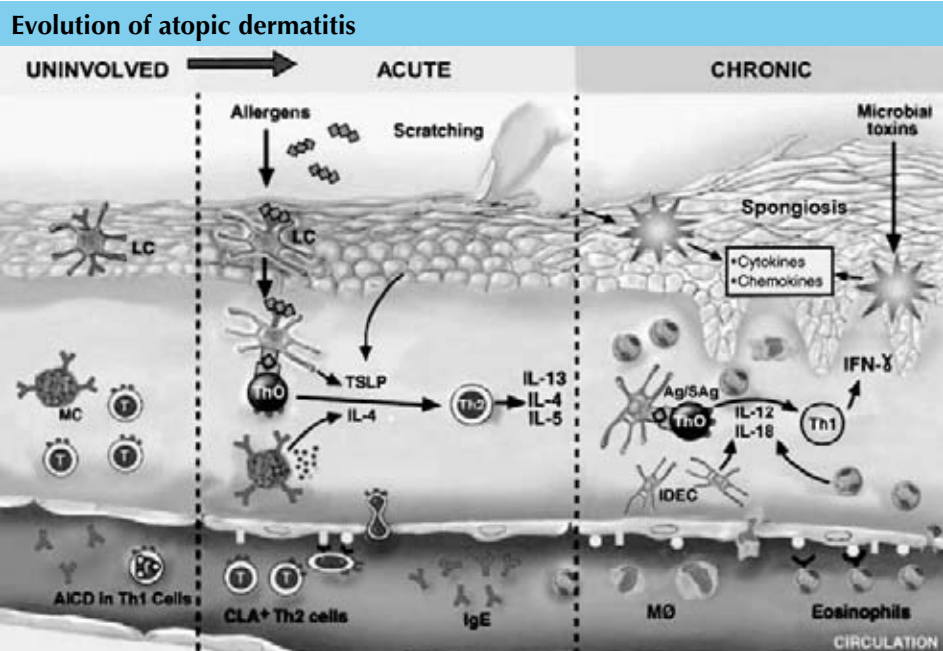


Source: York Pharma

In atopic dermatitis (AD), genetic factors are thought to create a predisposition in an individual to a progressive breakdown of the skin barrier under certain environmental conditions. This breakdown leads to increased transepidermal water loss or TEWL, which is typically accompanied by intense dry skin and inflammation. The system of proteases involved in skin exfoliation, which we describe above, is thought to be highly sensitive to pH. Raising the pH in the skin of individuals predisposed to AD has the effect of accelerating the breakdown of the protective barrier to a degree that a regenerative imbalance is created. This then enables allergens and irritants to enter triggering inflammation and an abnormal skin condition.

The use of soapy substances has the effect of increasing pH, which enhances protease activity and therefore accelerates the breakdown of the barrier. The entry of allergens triggers a cascade of inflammatory/immunological reactions and allows entry to associated bacterial or other toxins, all of which create the typical skin conditions seen in various forms of eczema/AD.

Hence, for individuals genetically predisposed to AD, inhibiting excessive protease activity through inhibition is a valid protective, prophylactic and therapeutic target. The concept of Sabarep is to combine protective emollients and moisturisers with enzyme inhibitors to achieve this protective effect.



Source: Akdis et al, *J. Allergy Clin Immunology*, 118(1), p152

Current approaches and Sabarep profile

To understand where Sabarep fits in all of this, it is important to review current therapeutic approaches. AD can occur at different times in life but its earliest and most serious occurrence is after birth in the developing infant. The breakdown of the skin's protective barrier is thought to have serious consequences for the predisposition of the child to allergies and often those individuals with allergies are prone to developing asthma as well. While the causal link between AD and asthma is controversial, the risk of developing allergies and even the possibility of such a linkage is enough to warrant significant effort to correct the problem. Hence, the detection of skin barrier dysfunction and its early treatment, are thought to be essential prophylactic measures.

Current treatments range from the use of warm water, moisturisers and emollients (in that order) in an attempt to rehydrate the skin and then seal in the hydration. To treat any inflammation or infection (mainly *Staphylococcus* gram-positive), topical glucocorticosteroids or antimicrobial treatments are used. Finally, for more persistent and serious disease, a new class of topical anti-inflammatory drugs called calcineurin inhibitors (Elidel, Novartis; Protopic, Astellas) has emerged of late.

None of these approaches are completely satisfactory. The attributes of these treatments are summarised in the accompanying table and indicate that current therapy is less than ideal offering scope for new approaches. We believe that the concept of Sabarep might just be one such approach.

The finding that a genetically determined protease inhibitor/protease system is intimately involved in the maintenance of the skin barrier's integrity has led York Pharma's researchers to the idea that a product which combines moisturising steps with a combination of emollients and protease inhibitors might help to restore and maintain the integrity of the skin barrier. Based on this concept, York Pharma has developed a mixture of compounds that can act to achieve this therapeutic goal. The attributes of this product are:

- topical cream formulation;
- novel proprietary combination;
- use of constituent substances not previously used for this purpose;
- all constituents are Generally Recognised as Safe (GRAS);
- clear and relatively simple regulatory pathway.

In using GRAS substances, York has circumvented the need for the kind of lengthy regulatory process prevalent in most pharmaceutical development programmes. GRAS substances are recognised by regulatory bodies as being safe for use without the need for general toxicology testing. However, to make a medical claim, one must still test efficacy, which is why York Pharma has plans to complete a Phase II/III clinical programme to establish the validity of the concept and demonstrate its clinical efficacy to both the regulatory authorities and the dermatological community.

Clinical status

York Pharma has recently conducted a preliminary clinical study that provided Phase II dose finding information and defined the optimum combination of constituents in the formulation. Whilst progressing the study, results became available that enabled the company to further extend its intellectual property around this product area.

At a recent analyst update, York announced the results of the trial conducted with 114 individuals in which 149 tests were performed with multiple sites for each test subject yielding 760 points of data available for evaluation. York aimed to test both of the components of Sabarep separately against Sabarep itself (an internal control) as well as Sabarep against a standard skin barrier treatment (parafin- based cream Diprobase™). Skin Barrier breakdown was triggered using 2 standard models: tape stripping of the skin and extensive soap treatment. For the component test, a measure of water loss (TEWL) and for the functional tests in the 2 models, IGA or Investigator General Assessments were carried out. The results show a statistically significant degree of restorative skin barrier capacity for Sabarep.

This data was presented to the MHRA and led to a satisfactory clinical plan being agreed with the latter. York Pharma will soon initiate a Phase IIb confirmatory clinical trial to test efficacy with the final formulation to be followed, if successful, in late 2007 by a full Phase III trial in preparation for registration around 2009.

Marketing profile and potential

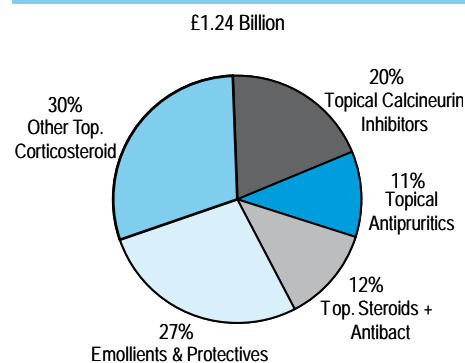
The topical AD market is a difficult one to peg precisely because certain products are used interchangeably across various indications. However, using IMS data we estimate a value for the market of around £1.24 billion growing at around 5% per annum. Since the introduction of the topical calcineurin inhibitors tacrolimus (Protopic, Astellas) and pimecrolimus (Elidel, Novartis), they have won a significant share of the market (20% in 2005). However, the black box warning from the FDA and the recommendation that these not be given to children under two, removes an important segment of the market for these drugs and leaves room for a more benign therapy. It also implies that we are likely to see a decline in the share that calcineurin inhibitors as a class have won in this market.

Emollients and protectives at 27% of the market remain the mainstay therapy along with topical steroids (42%) and antipruritics (products to treat itch) at 11%. However, these therapies have significant shortcomings in efficacy, safety or both. A novel product that provides an effective skin barrier without the side effects of current therapies would not only be welcome, but highly sought out by dermatologists. It could certainly make a serious dent in both the emollient and the calcineurin inhibitor side of the market.

The market for AD is a difficult one to estimate because it affects infants (with a prevalence of up to 20-25%), children (between 5% and 20%) and adults (around 2%). Its prevalence varies by country and by region indicating that environmental factors are in play. In infants, it is thought to have an incidence of around 20% with the highest prevalence in northern Europe and Japan with North America increasing rapidly.

From live birth data we can approximate the new market for infant atopic dermatitis treatments based on an incidence of around 20-25% of infants born in industrialised countries. With an average annual cost of around £315 per course of treatment (York Pharma and Objective Capital estimates) this leads to an estimated infant AD market in the neighbourhood of £531 million in the seven major markets. Translated into a global market of around £625 million this would represent somewhere in the region of 50% of the total eczema market worldwide.

Eczema Market 2005



Source: IMS Data

Atopic Dermatitis in Infants

	Total Population (m)	Life Births 2005 ¹ (000's)	Atopic Dermatitis ² (000's)	Annual cost ³ (£000's)
USA	295	4200	840	264,000
Japan	128	1110	222	69,708
UK	60	700	140	43,960
France	60	765	153	48,042
Germany	82	705	141	44,274
Italy	56	526	105.2	32,970
Spain	43	453	90.6	28,260
Total 7 major markets		8459	1691.8	£531,214
EU-25	460	4800	960	£336,000

¹ CDC and European Demographic Data Sheet 2006

² Assumes an incidence of 20% in the first year of life

³ Assumes an average medication cost of £314 per treatment course of 26 weeks

Source: Various sources and Objective Capital estimates

An effective skin barrier treatment would be aimed at the emollient/protective end of the market. Based on IMS estimates, this is around 27% of the total eczema market or £334 million. However, this market consists mainly of generic, partly effective, low priced products so the potential for a novel, proprietary and effective product such as Sabarep is likely to be considerably larger. Additionally, an effective product should make serious inroads into both the calcineurin inhibitor and steroid markets. In this light, we suspect that York will price Sabarep at a premium to emollients and steroids but at a slight discount to calcineurin inhibitors owing to their short-term use versus the longer-term application of a topical product such as Sabarep.

We would take the conservative view that a further 25% of market value might be available to Sabarep from premium pricing to largely generic competitors. Assuming a 2008/9 introduction, we estimate peak sales of £211 million based on a projected addressable 2014 market of close to £3.9 billion.

Finally, a third way of approaching the problem, and perhaps the most direct way, is to do a broader brush of the market based on the estimated amount used in treatment and the average cost. We have based our calculation on the average incidence of eczema in the population by region and the projected average dosage and duration of treatment. We have added in a discount factor for dosage compliance derived from the literature and have estimated a conservative average market penetration for the overall market (different from the specific product category penetrations estimated earlier). Grossing it up for global market potential yields a total market potential just under £200 million.

Estimate of Addressable Market and Peak 2014 Sales for Sabarep™

Market Segment	Est Value 2005 (£m)	Estimated Value 2014 ¹ (£m)	Growth Rate (%)	Achievable Market Penetration (%)	Expected Price Premium (%)	2014 Peak Sales (£m)
Infant AD ²	531	634	2	10	25	79
Calcineurin Inhibitors	250	390	8	15	-20	47
Emollients ³	1	197	2	20	25	49
Topical Steroids	520	621	2	5	25	40
Total	NA	NA				215

¹ 6 years after launch estimated at 2008

² Objective Capital estimate based on various sources

³ Discounted by 50% for use in infants to avoid double count

Source: Various sources and Objective Capital estimates

Bottom up view of the Atopic Dermatitis market

	Unit	US	Europe ¹	Japan
Projected Cost/100mg	£'s	25	12.5	22
Average Dosage	g	60	60	60
Average Treatment Duration	weeks	15	15	15
Cost of Treatment	£'s	384	187.5	330
Est. Disease Incidence	%	3	2	4
Total Population	m	298.44	302.44	127.46
Est. Patient Market	m	8.95	6.05	5.10
Est. Addressable Market	m	3,434	1,134	1,682
Est. Dose Compliance	%	40	40	40
Est. Market	m	1,373	454	673
Proj. Penetration	%	7	6	6
Estimated Peak Sales	m	£96	£27	£40
Total Est. Peak Sales (m)		£164		
Global Potential (m)²		£193		

¹ 5 Major Markets

² Grossed up for ROW

Source: York Pharma and Objective Capital estimates

Given the size of the total market, the consistent estimate that we have arrived at by these 2 methods (one top down and the other bottom up) project a total market penetration of a modest 5% of the overall 2014-projected market figure. We are comfortable with this and appear to be within the ballpark of what the company feels the market could be.

While we freely admit that that much of this is art (with some hand waving) rather than science, it's not a bad start. We believe that York could capture a good slug of this market with Sabarep given the right marketing partners in the US and Japan (the largest markets for eczema) and a good sales effort in the UK and Germany. To have such a large product in this end of the dermatology market is unusual (but not unheard of) but that is because none of the current treatments are that effective and there is a lot of rotation of treatments to secure better efficacy and to prevent the occurrence of side effects (such as thinning of the skin amongst others).

All in all, we are very positive about this project for the following reasons:

- the science is elegant;
- Sabarep's targeted activity has been demonstrated clinically;
- formulation work is at an advanced stage;
- the GRAS substances it contains will facilitate the regulatory process;
- it addresses a very serious yet poorly met clinical need.

Expected Value of Sabarep™

Summary of Valuation (pre-corp tax)

Scenario (£m)	Core	Pessimistic
<i>Royalty Share</i>		
Short term forecasts	122.1	61.1
Upto Generics	69.5	40.8
Post generics growth	39.5	23.2
Decline period	9.7	5.7
EV of Royalties	240.8	130.7
Likelihood of success (PoS)	20%	20%
EMV of Royalties	48.2	26.1
Add: EMV of upfront payments	11.2	11.2
Add: EMV of milestone payments	0.0	0.0
less: EMV of dev costs	1.9	1.9
EMV of Sabarep™	57.5	35.4
per share (£)	2.26	1.39

Key Market & Licence Assumptions

Indication/Market	Route to Market	Royalty Rate/Effective Margin	Approx Date	Price Impact	Impact of Generics
UK & Germany	Marketed	78%	2021	-50%	
ROE	Licenced	25%	2021	-50%	
USA	Licenced	25%	2021	-50%	
Japan	Licenced	25%	2021	-50%	
ROW	Licenced	25%	2021	-50%	

Sensitivity to change in ...

Impact of generics (+ % price decline)

	-20.0%	-10.0%	+0.0%	+10.0%	+20.0%
Value (£m)	61.4	59.4	57.5	55.5	53.6
Change in Value	7%	3%	0%	-3%	-7%

Increase in royalty/margin (+%)

	-10%	-5%	0%	5%	10%
Value (£m)	43.7	50.6	57.5	64.4	71.2
Change in Value	-24%	-12%	0%	12%	24%

Components of core valuation (pre-corp tax)

Core Scenario

Expected Value of Royalties/Revenue (£ millions)

Indication/Market	EV of cashflow	Current Stage of Dev	PoS	EMV	% of Val.
UK & Germany	68.9	Phase 2	20%	13.8	6%
ROE	12.3	Phase 2	20%	2.5	1%
USA	94.3	Phase 2	20%	18.9	8%
Japan	23.0	Phase 2	20%	4.6	2%
ROW	42.4	Phase 2	20%	8.5	4%
Total	240.8		20%	48.2	

Pessimistic view

Expected Value of Royalties/Revenue (£ millions)

Indication/Market	EV of cashflow	Current Stage of Dev	PoS	EMV	% of Val.
UK & Germany	68.9	Phase 2	20%	13.8	11%
ROE	12.3	Phase 2	20%	2.5	2%
USA	20.9	Phase 2	20%	4.2	3%
Japan	11.4	Phase 2	20%	2.3	2%
ROW	17.3	Phase 2	20%	3.5	3%
Total	130.7		20%	26.1	

Expected Monetary Value of Sabarep™
£35.4m £57.5m
£1.39 - £2.26 per share

EMV of Upfront payments
£11.2m

EMV of Milestone Payments
£0.0m

Vampex™ (carbenoxolone)

Overview

Carbenoxolone is a synthetic derivative of glycyrrhizinic acid (the active principal of liquorice root and a potent sweetener), which has been used as a cytoprotective drug for oesophageal ulceration and inflammation for over 35 years, though it has been supplanted by newer treatments. York has developed an entirely new application for this mature drug as a treatment for psoriasis. Carbenoxolone is a known inhibitor of a class of enzymes of which one happens be involved in Vitamin A metabolism. This would make carbenoxolone a 'First in Class', a proprietary indication with the potential to generate a new class of psoriasis agents. It is currently in formulation optimization and should be entering its final Phase II/III development from late 2007 with an expected launch in the 2009/10 timeframe.

Mechanism of action and disease rationale

Psoriasis is a heterogeneous disease of the skin that is induced by genetic, environmental and immunological factors. It is believed to be an inflammation-triggered T-Cell immune disorder. The aetiology of the disease is thought to be based on:

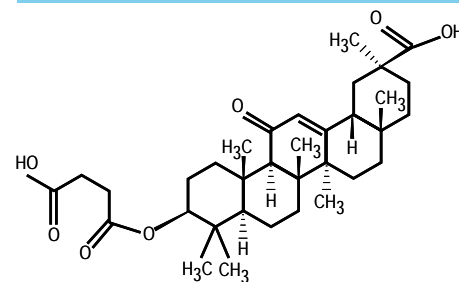
- the up-regulation of cellular hyperproliferation; and
- the down-regulation of factors that trigger apoptosis (cellular death).

The normal development of skin is one where the keratinocytes terminally differentiate to form a cornified envelope. This consists of aggregating keratin, nuclear degradation (part of cell death) and the replacement of the plasma membrane with a tough protinaceous envelope, which is crosslinked to extracellular lipids and for the skin barrier (see earlier figure under Sabarep).

In the diseased state, this process is disrupted so that the epidermal layer of the skin thickens based the hyperproliferation of these precursor cells followed by their abnormal distribution along with a concomitant reduction in apoptosis or cell death. While there are many factors that are believed to influence the pathogenesis of psoriatic plaque, an important factor in this is a cytokine called TNF- α (Tissue Necrosis Factor), which is upregulated and has become a primary target for the treatment of this disease with the advent of antibodies that aim to reduce its presence.

The role of both retinol (or vitamin A) and vitamin D3 and their respective receptors is equally important in the hyperproliferative phase of psoriasis. Retinol is synthesised from a pro-vitamin derived from carotene pigments sourced from a number of nutritional sources (including carrots, yellow fruits and dark leafy vegetables). It is a key element in the keritinsation of the skin. Vitamin D3 appears to regulate epidermal cell growth and trigger terminal cell differentiation and this has led to its use in the treatment of psoriasis. In fact, it has been shown that these two mechanisms are intimately linked through specific receptors that appear to have a direct effect on genetic activity through DNA binding and the subsequent regulation of gene transcription.

Vampex™ (carbenoxolone)



Source: York Pharma

By contrast with the potentiating effect of vitamin D3 in triggering terminal differentiation in keratinocytes, embryonic studies have shown that vitamin A deficiency triggers premature cellular differentiation and maturation². This work gave rise to the concept that triggering local Vitamin A deficiency in psoriatic plaques through the introduction of a permissive signal could push emerging proliferative keratinocytes towards terminal differentiation away from the hyperproliferative and impaired apoptotic phase typically seen in the disease.

Carbenoxolone is a known inhibitor of the enzyme retinol dehydrogenase, which converts retinol into retinal, the first stage of transformation to the biologically active form, retinoic acid. The inhibition of this reaction triggers intracellular vitamin A deficiency and carbenoxolone is therefore a member of a new class of drugs, vitamin A metabolic pathway, or VAMP inhibitors. This drug is known to inhibit VAMP, but its potential use as a topical therapeutic in the treatment of psoriasis is a York Pharma discovery for which it has sought patent protection.

Preclinical and clinical Status

Carbenoxolone has been used as a cytoprotective drug in ulcers for over 30 years. York Pharma has been able to demonstrate its antiproliferative and differentiative effects in vivo, that is, in a mouse tail model of psoriasis. The company has also conducted a Phase II efficacy and safety clinical study to determine the tolerability and clinical effects of the drug topically. In a small, single centre, double-blind, placebo-controlled trial format where the randomisation is within-subject, York were able to demonstrate that Vampex (in a 2% topical gel test formulation) is effective at improving the symptoms of psoriatic plaque. In the small sample tested, there were no adverse effects noted. A final topical formulation is currently under development and York Pharma is planning to commence full Phase II trials shortly now that its recent meeting with the MHRA has clarified the clinical path.

Drug profile, market overview and positioning

Psoriasis has a population incidence of from 1% to 5% in American and European populations. The most common form, psoriasis vulgaris or plaque psoriasis, represents around 80% of the diseased population. In mild plaque psoriasis, the areas of the body most affected are the elbows, knees and scalp whereas in the moderate from 2% to 10% of the body is affected. In the severe form where more than 10% of the body is affected, large areas of the body are affected including the legs, back and chest as well as the whole body in the worst cases.

Estimate of Psoriasis Population

Country	Prevalence (%)	Population (m)	Psoriasis Pop. (m)
US	2.6	293	7.62
Japan	1.0	127.3	1.27
France	4.7	60.4	2.84
Germany	3.8	82.4	3.13
Italy	3.1	58.1	1.80
Spain	1.4	40.3	0.58
UK	1.5	60.3	0.89
Total	2.5	721.8	18.13

Source: Datamonitor and Objective Capital estimates

² P.Kastner et al, *Development*, 124, 4749-4758

Estimated Psoriasis Patient Market

Mild to Moderate

	Total Est Pts		% Diagnosed	% Treated	% Drugs	% Topical only	Topical Only Market
	mm						
US	7.80		55%	82%	92%	77%	2.50
Japan	1.27		50%	72%	98%	64%	0.29
France	2.84		51%	84%	80%	83%	0.81
Germany	3.13		59%	77%	81%	71%	0.82
Italy	1.80		59%	81%	77%	75%	0.50
Spain	0.58		45%	88%	85%	85%	0.16
UK	0.89		60%	79%	86%	74%	0.27
Total			54%	80%	86%	76%	5.35

Source: Datamonitor, Other Sources & Objective Capital estimates

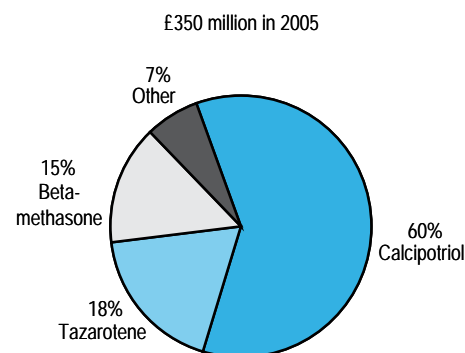
It is estimated that there are around 18 million people affected by psoriasis in the seven major world markets. Of these, some 54% are diagnosed with around 80% suffering from the mild to moderate form of the disease. Four-fifths of these are treated using only pharma therapies, as opposed to pharma+ phototherapy or phototherapy alone. In the pharma only group, around 76% are treated with topical only. This means that there are roughly 5 million patients that can be targeted for topical treatment in the mild to moderate disease category. In the severe category, an additional 1.4 million patients are treated with a combination of systemic and topical treatment.

Assuming an average cost of annual treatment is between £700 and £1400 per patient³ (all treatments included) yields a total market of around £1.6-3.2billion (\$3-6 billion). We would estimate that a topical treatment would cost somewhere in the region of £300-500 per annum (based on Dovonex cost of \$160 per 120mcg tube of 0.0005% Dovonex at 4 tubes a year). This would add up to around a £1.6-£2.5 billion potential for the topical market. At a 10% market penetration, the annual revenues attaching to Vampex would be some £160-250 million.

Another way of approaching this is given by IMS data showing that the total topical market in 2005 was around £349 million with several sources expect growth at around 10% per annum yielding a market of around £460 million in 2008, shortly before we would expect Vampex to be launched; and a market of around £822.92 million in 2014 market, the year when Vampex sales would be likely to peak. This would make Vampex about half of the total treatment market. With only 50% of patients diagnosed and only 80% of these treated, there is likely to be pent-up demand.

The market leader is calcipotriol, (Dovonex, Warner Chilcott and Leo Pharma) with 60% of the topical market. Tazoretene (Tazorac, Zorac, Allergan) is the number two product with around 30% of the market. Leo Pharmaceuticals and Warner Chilcott are about to introduce Taclonex® a composite product containing calcipotriol and the corticosteroid betamethasone; the most commonly used topical combination. All of these drugs have side effects posing quality of life issues. The main adverse effects of Dovonex are skin irritation and burning and with Tazorac, skin peeling (desquamation), skin redness (erythema), burning and dryness.

Topical Anti-Psoriasis Market



Source: IMS Data

³ M.A. de Rie, *Dermatology* 2001;202:38-43

Vampex is targeted at the mild to moderate segment of the market where the use of topical creams and ointments are practical and most common. It will also attempt to attain a profile of efficacy without the side effects displayed by the market leaders. As carbenoxolone has been on the market as an oral drug for a many years, its safety profile is well established with regulatory bodies. York Pharma will only need to show is some safety and efficacy data on a topical formulation.

We believe that if the desired profile is attained, there is no reason why Vampex would not win a significant portion of the market. We could also see Vampex expanding this market to sufferers not currently seeking treatment, in that the drugs used today are only partially effective and pose quality of life issues. Given a 2014/5 market of around £900 million and a launch date in 2009/10, we would estimate peak sales at £90-£125 million (at 10-15% market penetration) with the potential to expand that by another 20-30% for market expansion from patients who do not seek diagnosis or do not get treated. That would give us a peak estimate of £120-£160 million. Hence the range from both approaches would be somewhere around £140-£205 million as an average. The attached projections for Vampex reflect this range of estimates; we come out at the bottom end of the range with a 2015 estimate of around £150 million.

It is too early to tell whether the profile sought is achievable but the early results obtained in the small Phase II conducted by the company are encouraging.

Future Developments

The discovery of this new class of drugs opens new doors in psoriasis therapy and enables the development of analogues with an even better therapeutic profile. By the same token, the newly discovered mechanism of action leads to applications elsewhere. The development of Vampex is an example of this.

York Pharma is also conducting structure-activity studies to extend its patent protection and to seek out new compounds in this class.

Rest of pipeline

Other than the near term pipeline of Abasol, Vampex and Sabarep, York Pharma has other promising innovations in the pipeline which could add value to the overall business. These include **YP002** (a skin barrier diagnostic tool) and **YP005** (an acne treatment) both in early phases of development. As mentioned earlier, the concept of creating a vitamin A deficiency as a means to force differentiation versus hyperproliferation has “melanoma” written all over it. The YP004 - Melanoma project is being carried out with a view to outlicensing and is not seen as an integral part of York Pharma’s operations. It is nevertheless a large market and efficacious treatment would be seriously welcome and presumably rewarding. In this light, we will briefly address the market potential for this project and the potential financial value to York Pharma.

Expected Value of Vampex™

Summary of Valuation (pre-corp tax)

Scenario (£m)	Core
<i>Royalty Share</i>	
Short term forecasts	54.7
Upto Generics	34.2
Post generics growth	11.7
Decline period	2.9
EV of Royalties	103.3
Likelihood of success (PoS)	15%
EMV of Royalties	15.5
Add: EMV of upfront payments	8.2
Add: EMV of milestone payments	4.1
less: EMV of dev costs	2.5
EMV of Vampex™	25.3
per share (£)	1.00

Key Market & Licence Assumptions

Indication/Market	Route to Market	Royalty Rate/Effective Margin	Approx Date	Price Impact	Impact of Generics
UK&Germany	Marketed	77%	2021	-70%	
ROE	Licenced	25%	2021	-70%	
USA	Licenced	25%	2021	-70%	
Japan	Licenced	25%	2021	-70%	
ROW	Licenced	25%	2021	-70%	

Sensitivity to change in ...

Impact of generics (+ % price decline)

	-20.0%	-10.0%	+0.0%	+10.0%	+20.0%
Value (£m)	26.8	26.1	25.3	24.6	23.9
Change in Value	6%	3%	0%	-3%	-6%

Increase in royalty/margin (+%)

	-10%	-5%	0%	5%	10%
Value (£m)	22.2	23.8	25.3	26.9	28.5
Change in Value	-12%	-6%	0%	6%	12%

Components of core valuation (pre-corp tax)

Core Scenario

Expected Value of Royalties/Revenue (£ millions)

Indication/Market	EV of cashflow	Current Stage of Dev	PoS	EMV	% of Val.
UK & Germany	51.1	Phase 2	15%	7.7	7%
ROE	10.9	Phase 2	15%	1.6	2%
USA	22.9	Phase 2	15%	3.4	3%
Japan	9.2	Phase 2	15%	1.4	1%
ROW	9.2	Phase 2	15%	1.4	1%
Total	103.3		15%	15.5	

Expected Monetary Value of Vampex™
£25.3m
£1.00 per share

EMV of Upfront payments
£8.2m

EMV of Milestone Payments
£4.1m

YP002-skin barrier diagnostics

Overview and rationale

Most of the funding for this project has been obtained through scientific and medical grants. There is a genetic component to susceptibility to skin barrier breakdown thought to be based on the genetic dosage of proteolytic enzymes (called proteases), the activity of which is regulated by a series of inhibitors. Of necessity, we have simplified our description of this in that many other factors are involved. The genetics of this system are relatively well understood with the genes responsible for some of this activity known. This in turn opens the door to using markers of this activity to detect and predict susceptibility to breakdown of the skin's natural protective mechanism.

The importance of this should not be underestimated. Allergies and asthma have become epidemic in industrialised nations and elsewhere. While the causal link between AD and asthma is a controversial one, even the whiff of a linkage between the breakdown of skin barrier and exposure to environmental allergens and toxins with the incidence of allergy and asthma is enough to warrant resolution of the condition. The magnitude of the public health problem associated with these diseases makes the diagnosis of skin barrier dysfunction all the more relevant. This makes a tool to monitor skin barrier dysfunction a welcome addition to the dermatologist's tool-kit.

Product profile and development status

From York's standpoint, the commercial rationale is cogent. With the advent of Sabarep, a test of this nature might be used to:

- prevent exposure to sensitisers in susceptible individuals;
- detect skin barrier dysfunction leading to the use of Sabarep;
- monitor the response to therapy;
- monitor those sensitive to environmental damage in the workplace.

The test to be developed should be easy to administer (i.e., rapid and painless skin sampling), and ideally performed by the physician/nurse and then sent to a reference lab. In actual fact, York is planning to develop a point of care test for doctor's clinics. York Pharma is currently testing appropriate biomarkers, which are indicative of skin barrier malfunction. Once the clinical validation phase has been completed and appropriate patents filed, the company plans to team up with a specialist firm to create the point of care device. The timeline is a validation trial in Q108 followed by registrations with a commercial objective of an H208 approval in tandem with the US approval of Sabarep.

Market strategy and potential market

In the US alone, there were 29 million visits to dermatologists in 2003 (CDC Ambulatory Care Survey) of which 12 million were for skin rashes. Grossing that up to include the rest of the world would translate into a total of 28 million visits for the above condition. This does not account for visits to paediatricians, internal medicine specialists and family physicians for dermatological conditions, which are likely to be much higher. At £10 a test, the market would be in the £250 million-300 million range.

We believe that the ideal strategy for York Pharma is a two pronged one. The first is to promote testing as a means of triggering greater usage of Sabarep. This can be best achieved by a doctor's office test, which York Pharma might detail directly to dermatologists in conjunction with a company specialised in such tests. The tie-up with Sabarep is obvious but there are many other applications for this test.

The second involves attempting to broaden the application of the test to a variety of applications such as screening for skin sensitivity to workplace substances, screening of babies for AD susceptibility...etc.

It is too early to tell where this is going but from the information at our disposal, we offer a preliminary market estimate of £250 million-300 million out of which York and its partner might be able to garner around £150 million.

YP005-Acne

Overview and rationale

As with psoriasis and atopic dermatitis, acne is a poorly served medical condition crying out for a more effective treatment with fewer side effects. The disease is intimately linked to the onset of puberty where the production of sex hormones can cause secondary reactions. The disease itself is caused by the excessive production of an oily substance called *sebum* by the oil glands of certain skin regions of the body (primarily the face, back and chest). Although there are different forms and stages of the disease, the basic aetiology involves the obstructions of certain types of hair follicle ducts by cellular debris loosened by the overproduced sebum. This creates lesions called comedos, which become inflamed and then can be infected by bacteria. The disease mainly affects 11 to 30 year olds and in its more severe forms is a social stigma, which can trigger depression if left untreated.

York has acquired ownership of patents and 'know-how' related to the antiproliferative effects of sphingosine-1-phosphate, a metabolite of ceramide, which is a lipid component of the stratum corneum of the skin. It acts as both an intra and extracellular messenger and is implicated in promoting both cell growth and cell death. It is thought to be involved in calcium metabolism by increasing intracellular calcium concentrations, which leads to apoptosis (cell death).

The patents and associated scientific data for Sphingosine 1-phosphate and its derivatives were acquired from Dermapharm in Germany. The patent claims that the drug inhibits the proliferation of keratinocytes and promotes their differentiation. This effect is claimed not to be associated with cytotoxic mechanisms and in the event seems to have a protective effect in apoptosis (cell death) through metabolic action.

As in acne, it is sebum-triggered cellular debris that obstructs the follicular ducts leading to the comedo lesions; apoptotic protection could be a useful mechanism in inhibiting the progression of the disease. However, it is the anti-proliferative actions of sphingosine-1-phosphate that are most likely to be the determining mechanism. Also described is the usefulness of the D configuration of the molecule (versus the natural L form) as well as the attractiveness of encapsulating the molecule into a liposomal nanoparticle, to facilitate its topical delivery.

Clinical Status

This project is still in its early phases, focussing on formulation and structure activity analyses along with the generation of preclinical data. We would not anticipate a product ready for IND filing and Phase I clinicals until Q208 with a Phase 3 pivotal head-to-head trial slated to be completed by Q409. York Pharma is currently working on finalising its nanoparticulate formulation and associated GMP manufacturing with its German partner.

Market analysis and potential and product profile

Current treatments range from benzoyl peroxide gels and topical retinoids (Accutane is an example) for mild forms to oral antibiotics for more severe forms. Unfortunately, these treatments are only partially effective and tend to carry with them some significant side effects not least of which are hypercalcemia, which thins the skin, burning sensations and discomfort. In the case of tretinoin (Accutane, Roche), while a very effective and curative treatment, its side effects include arthralgia (joint pain), tendonitis and elevated triglycerides. Most worrying is that it has also been associated with birth defects among older females.

All in all, a new treatment for acne should be as effective as possible with as few side effects as possible. The metabolic effects of this substance — particularly on protein kinase C activation — give rise to potential combinations with current treatments, which might enhance the overall cure rate.

Based on IMS numbers, the 2005 market for total anti-acne preparations was in the neighbourhood of £1.2 billion (\$2.26 billion). Of this, the topical market is around £872 million or 72% of the market. The main protagonists in the topical market are benzyl peroxide, clindamycin and tretinoin (Accutane, Roche) along with a newer entrant, Differin (adapalene, Galderma), together representing 77% of the total market.

Should York be able to attain the profile for this drug that it is seeking, it should capture a significant part of the topical market. A 20% share would be in the neighbourhood of £200 million. Again, this project is at a very early stage and with no clinical evidence in humans, it is difficult to give this project much in the way of value until it has progressed further.

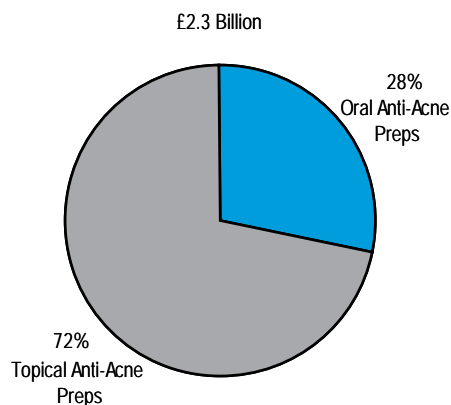
YP004-Melanoma

Overview and rationale

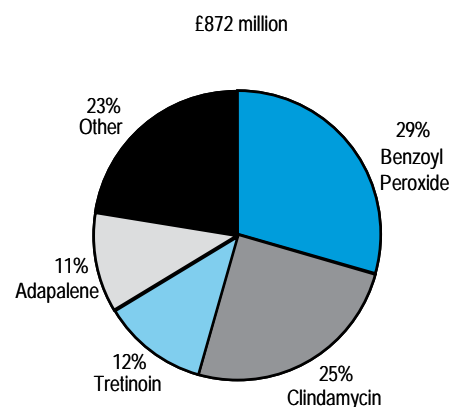
As to market metrics, we would price a course of treatment in the \$3,000 range, yielding a newly diagnosed patient market in the range of \$400 million to \$500 million. This excludes patients requiring follow-up treatment and those that relapse or have more serious disease. All in all, we think that the market is probably closer to \$1 billion. With the incidence of melanoma on the increase, it is clear that a market exists for new treatments. A lead compound has not been described in this project so it is too early to talk about valuation.

The purpose of the project is to leverage the company's scientific expertise in retinol/retinal pathways to develop a novel approach to the treatment of melanoma. Melanoma represents about 140,000 newly diagnosed patients per annum, that is 4% of total cancers worldwide, with a very high mortality rate particularly when diagnosed when the cancer is beyond the local, primary site.

Total Anti-Acne Market 2005



Topical Anti-Acne Preps 2005



Source: IMS Data & Objective Capital estimates

In the US alone, there are roughly 61,000 newly diagnosed men and women with melanoma of the skin. The overall five year survival rate is around 90%, but this masks that the 12% of patients diagnosed with regionally spread cancer, who have only a 64% survival rate and the 4% whose cancers have metastasized, who have only a 15% survival rate. It is the second most common cancer in younger patients. Where practical, surgical excision is the initial therapeutic modality of choice with or without lymph node removal. Radiotherapy of local sites is also used and currently both Interferon alpha and IL-2 adjuvant therapy are the most common treatments.

As with psoriasis, melanoma is a hyperproliferative disease of the skin where the normal differentiation pathways have been hijacked. The aetiology of the disease is complex and the causes are thought to be multi-factorial (genetics, skin pigmentation, sun damage, etc) in nature. The company has set out to see how it could create a retinol (vitamin A) deficiency and shift hyperproliferation back to normal terminal differentiation. In this case, the Retinoic Acid (active vitamin A) deficiency target mechanism involves the retinol transport system (through a protein called RBP or retinol binding protein) and a protein called RPE65, which appears to be necessary for the transformation of the native transported form of retinol (all-trans retinol) to the cis-isomer of retinal (11-cis-retinal).

Use of a monoclonal antibody against RPE65 has shown, *in vitro*, that exposure of normal human epidermal keratinocytes (NHEK) cells to this antibody appears to block RBP-retinol inhibition of cellular differentiation. In the RPE65 knockout mouse, impairment of the synthesis of a certain functional eye protein and the presence of another implies the absence of 11-cis-retinal (i.e., its impaired synthesis). All of this put together seems to point in the direction of a retinoic acid deficiency as 11-cis-retinal is an essential step to its synthesis. This implies that RPE65 along with a number of other factors (such as the elevated level of RPE65 in melanoma skin cells versus normal melanocytes) may play a role in the treatment of melanoma.

Preclinical status

More *in vitro* and *in vivo* testing needs to be done to validate the target and initial work has started on an antibody to the target. It is unlikely that this project will see the 'clinical' light of day until 2009, and this will probably be undertaken by a partner who has taken a license from York Pharma for such a drug as might emerge.

Future implications

Oncologists, rather than dermatologists, dispense melanomas and other cancer treatments. This means that the melanoma project sits ill with York Pharma's sales and marketing platform. Assuming that York is able to confirm the promise of its melanoma approach, it should be expected to license it to a player specialising in this area in return for upfront and milestone payments. Two clinical strategies then become available to such a partner: the first is to design or seek a small molecule to mimic the blocking effect of an antibody; the other would be to apply smart design to the antibody and target this as the drug. The latter has a shorter timeframe, making it more attractive to York Pharma.

Financials

Profit and Loss Statement

YE 30 Sep., £m	2004	2005	2006E	2007E	2008E	2009E
Total Revenues	0.00	0.00	0.00	3.50	10.50	15.75
Cost of Sales	0.00	0.00	0.00	0.70	2.10	3.15
Gross Profits	0.00	0.00	0.00	2.80	8.40	12.60
Licencing	0.00	0.00	0.00	0.00	0.46	3.07
Milestones & upfronts	0.00	0.00	0.00	9.00	11.00	41.00
Total Revenue	0.00	0.00	0.00	11.80	19.86	56.67
SG&A						
Depreciation		0.00	0.00	0.00	0.00	0.00
Amortisation		0.30	0.30	0.30	0.30	0.30
SM	0.00	0.00	0.44	3.57	3.71	4.61
G&A		0.55	1.86	1.90	2.30	3.50
Development costs		2.35	3.30	7.05	12.76	9.00
Total SG&A	0.42	2.80	5.89	12.82	19.07	17.41
Share-based Employee Remuneration						
Operating Profits before Non-Recurring Items	-0.42	-2.80	-5.89	-1.02	0.79	39.26
Non Recurring Items						
Earnings before Financing Costs (EBIT)	-0.42	-2.80	-5.89	-1.02	0.79	39.26
Interest Paid						
Interest Receivable	0.01	0.11				
Other finance Costs						
Change in the value of Derivative Instruments						
Pretax Profit (Loss)	-0.41	-2.69	-5.89	-1.02	0.79	39.26
Taxes(credit)	0.00	0.00	0.00	0.00	0.00	8.31
Net Income (Loss)	-0.41	-2.69	-5.89	-1.02	0.79	30.95
- Dividends						
Net retained income	-0.41	-2.69	-5.89	-1.02	0.79	30.95
Average Shares outst.	5.81	14.94	22.30	25.39	25.39	25.39
Earnings per Share (in Pence)	-7.00	-18.01	-26.43	-4.00	3.11	121.90

Source: Objective Capital

Summary Balance Sheet

YE 30 Sep., £m	2004	2005	2006E	2007E	2008E	2009E
Fixed Assets						
Intangible						
Patents & Licences	0.646	0.631				
Goodwill	0.449	3.533				
Total	1.095	4.163	3.9	3.6	3.3	3.0
Tangible Assets	0.003	0.048	0.048	0.048	0.048	0.048
Total Fixed Assets	1.098	4.211	3.915	3.619	3.323	3.027
Current Assets						
Inventories	0.000	0.000	0.000	0.875	3.500	7.438
Other Debtors and Prepayments	0.062	0.277	0.582	1.266	1.883	1.719
Cash and Cash Equivalents	0.517	7.000	1.31	2.50	0.78	28.14
Total Current Assets	0.579	7.28	1.89	4.65	6.16	37.30
Current Liabilities						
Deferred Consideration	0.400	0.200	0.200	0.200	0.200	0.200
Accounts Payable	0.054	0.192	0.404	0.878	1.306	1.192
Trade Creditors	0.020	0.059				
Other Creditors	0.009	0.031				
Accruals	0.025	0.102				
Total Current Liabilities	0.454	0.392	0.604	1.078	1.506	1.392
Net Current Assets	0.12	6.89	1.29	3.57	4.65	35.90
Total Assets- Current liabilities	1.22	11.10	5.20	7.19	7.98	38.93
Long Term Financial Liabilities	0.00	0.00	0.00	0.00	0.00	0.00
Total Long Term Liabilities	0.00	0.00	0.00	0.00	0.00	0.00
Net Assets	1.22	11.10	5.20	7.19	7.98	38.93
Shareholders Equity						
Common Stock	0.450	1.120	1.120	1.274	1.274	1.274
Share Premium Account	0.779	7.885	7.885	10.731	10.731	10.731
Share Option Reserve	0.000	0.000	0.000	0.000	0.000	0.000
Merger Reserve	0.400	5.188	5.188	5.188	5.188	5.188
Retained Earnings (Loss)	-0.406	-3.096	-8.990	-10.01	-9.216	21.738
Total	1.22297	11.10	5.20	7.19	7.98	38.93

Source: Objective Capital

Cash Flow Analysis and Cash Position

YE 30 Sep., £m	2004	2005	2006E	2007E	2008E	2009E
From Operating Activity						
Net Income (loss) from						
Continuing Operations	-0.418	-2.801	-5.894	-1.016	0.790	30.954
Depreciation	0.001	0.009	0.000	0.000	0.000	0.000
Accounts Receivable	-0.062	-0.199	-0.305	-0.684	-0.618	0.164
Accounts Payable	0.054	-0.243	0.212	0.474	0.428	-0.114
Inventory		0.000	0.000	-0.875	-2.625	-3.938
Intangible assets amortisation	0.054	0.296	0.296	0.296	0.296	0.296
Cash From Operations	-0.372	-2.938	-5.691	-1.804	-1.728	27.363
Tax Paid	0.0000	0.0000				0.00
Cash Flow from Operating Activities	-0.372	-2.938	-5.691	-1.804	-1.728	27.363
From Investing Activities						
Capex	-0.004	-0.041				
Purchase of Intangible assets	-0.269	-0.030				
Acquisition Transaction costs	0.020	-0.167				
Cash acquired on acquisition	0.000	2.025				
Payment of Deferred						
Consideration	0.000	0.000	0.000	0.000	0.000	0.000
Net Interest Received	0.012	0.111				
Net Inflow (outflow) from Investments	-0.2412	1.898	0.000	0.00	0.00	0.00
From Financing Activities						
Issue of Ordinary Shares	1.104	7.524		3.00		
Interest Paid & Similar Charges	0.000	0.000				
Other Finance Charges	0.000	0.000				
Dividend's paid	0.000	0.000	0.000	0.000	0.000	0.000
Receipt from Borrowings	0.000	0.000				
Repayment of Borrowings	0.00	0.00				
Net Receipt from borrowings	0.00	0.00				
Finance lease Payments	0.000	0.000				
Net Cash Provided for (used in) Financing Activities	1.104	7.524	0.000	3.000	0.000	0.000
Net Change in Cash	0.491	6.484	-5.691	1.196	-1.728	27.363
Cash Position and Cash per share						
Net Funds						
Beginning of Year	0.00	0.27	7.000	1.31	2.50	0.78
End of Year	0.491	7.000	1.309	2.505	0.777	28.140
Cashflow per share	£0.085	£0.469	£0.059	£0.099	£0.031	£1.108

Source: Objective Capital

Max Dyer Bartlett – Chairman

Qualified as a Chartered Accountant with Deloitte, Haskins & Sells in 1981. He then worked in investment banking in the City of London at Hoare Govett, Arbuthnot Latham and Guinness Mahon, before establishing his own financial consultancy. Mr Bartlett is a director of a number of listed and unlisted companies specialising in healthcare, instrumentation and insurance, including Cytomyx Holdings Plc, Hartest Holdings PLC, and Freeclaim IDC PLC.

Terry I. Sadler – Chief Executive Officer

Founded York Pharma in April 2003. Prior to founding York Pharma, he was Chairman & Chief Executive of Bioglan Pharma Plc, a company which he also founded in 1985, floated in 1999, and built into a FTSE 250 multi-national company. He has over 30 years experience in the pharmaceutical industry with small, medium and multi-national companies, and has created pharmaceutical operating companies in many of the world's major pharmaceutical markets. Terry Sadler was awarded the accolade of United Kingdom Master Entrepreneur 2000.

Lothar Nau – Chief Operating Officer

Joined the Group in April 2004. Lothar is a German national with sixteen years experience in the pharmaceutical industry. Most recently he was Managing Director of Riemsler Arzneimittel AG where he was responsible for the development of their dermatology and oncology business in Europe. Prior to that he was Managing Director of Bioglan Pharma GmbH, and also spent seven years in charge of the dermatology and dental care business units of Dumex GmbH, a subsidiary of the US Alpharma Group.

Ian Harvey – Finance Director

Joined the Group in March 2004. Ian qualified as a Chartered Accountant with Thomson McLintock & Co in 1973 and went on to become a Partner in BDO Stoy Hayward, where he worked for 17 years. Since leaving BDO he has chosen to hold a number of finance director positions in both private and public companies.

Michael Garrison – Commercial Director

Joined the Group in February 2005. Michael has 27 years of commercial management, drug and business development experience within the global pharmaceutical industry. He began his career in sales and marketing in the US market, working for Burroughs Wellcome for 12 years, where his commercial responsibilities included the introduction of the world's first drug for HIV (AZT/zidovudine). In 1991 he moved to the UK assuming a global marketing role within Wellcome's headquarters for the antiviral Valtrex (valaciclovir). Thereafter, he joined Gilead Sciences as Director of Global Marketing and managed their HIV portfolio before joining Phytopharm plc as Director of Business Development. His affiliation with Molecular SkinCare Ltd began in 2003 where he was CEO prior to its acquisition by York Pharma.

Norman Freedman – Non-Executive Director

Is a pharmacist who qualified in 1961 and developed a small group of pharmacies, which he sold in 1984. Norman then formed Rexodent Ltd, a company supplying the dental profession with materials, equipment and services. In 1990, Rexodent entered into a joint venture with Henry Schein Inc., the largest US and international dental distributor. Norman was also a council member of the British Dental Trade Association and the British Dental Health Foundation and has also served on a Medicines Control Agency committee.

Dr. Allan Salem – Non-Executive Director

Gained an MA., DPhil in Biochemistry and Microbiology at Wadham College, Oxford. Subsequently, he lectured in microbiology at the University of Sheffield, before joining May & Baker Limited in 1973 as a research scientist, where he rose to become a Senior Manager in the Pharmaceutical Division, before joining Ethypharm SA in 1987 as Regional Director. In 1990, he was appointed Senior Business Development Manager at Mundipharma International Limited and in 1998 joined Bioglan Pharma Plc as Pharmaceutical & Business Development Manager. Since 2002, Dr. Salem has operated as a pharmaceutical industry consultant for a number of international companies.

Sue J. Keast – Company Secretary

Joined York Pharma in April 2003. Following 14 years in domestic banking, she left to pursue a career in accountancy. In 1990, Sue joined Bioglan Pharma, and served initially as group finance director and company secretary. Latterly she was both company secretary and corporate affairs director. She has broad experience in corporate affairs and served on the government working party for Employee Share Ownership Schemes.

Dr. Simon J. Ward – Chief Scientific Officer

Graduated from The London School of Pharmacy with a Joint Honours degree in Pharmacology and Toxicology. After an appointment in industry (Smith Kline & French, Glaxo Group Research), he went on to read for a DPhil in the Department of Human Anatomy, Oxford. More recently Simon joined the University of Sheffield and became a Reader in the Division of Genomic Medicine, building a strong research laboratory with extensive collaborations. Simon was a founder of Molecular SkinCare Ltd and has maintained an active involvement in fundraising, management of research and development, product and portfolio planning and cultivation of the Group's intellectual property portfolio.

Dr. Thorsten Groeb – Group Director, Clinical & Regulatory Affairs

Is a chemist graduated from the University of Marburg, Germany. After completing his studies he joined Bioglan Pharma GmbH in February 2001 as Medical Manager and then moved to Riemser AG. He was responsible for clinical and regulatory affairs for the dermatological product range.

Dr. Karlheinz Nocker – Medical Director, Germany

Is a chemist graduated from the University of Giessen, Germany. After completing his studies, he worked for a number of pharmaceutical organisations, including Merz & Lundbeck. In 2000, he joined Bioglan Pharma GmbH as Marketing Director and then moved to Riemser AG as Marketing and Sales Director, with a portfolio of 250 different pharmaceutical products. Altogether, he has 15 years' experience in the pharmaceutical industry.

Toshio Nagae – President & Representative, Director

Joined York Pharma KK in October 2005. Toshio is a Japanese pharmacist with more than 30 year experience in the pharma industry. Toshio is keen to optimise the value of medical products, as he chaired a session "Value Optimisation of Medical Products reflecting Development & Marketing Strategies" at the 2005 Annual Meeting of DIA in Washington DC and presented valuable topics at various International Pharma Licensing Symposia in London, Venice, Tokyo, Geneva and Madrid during 2000 to 2005. His experience includes Corporate Officer responsible for Medical Marketing and Human Resources/Competencies Development at ex-Aventis Pharma, Marketing Manager at Schering-Plough and Senior Product Manager at ex-ICI Pharma. Toshio is currently a Board Member of the Pharma Licensing Association and the International Society of Pharmaco-Economics & Outcome Research in Japan.

Dr. Michael Cork – Medical Adviser

Graduated from St Andrew's University, Fyfe, Scotland with a First Class Honours degree in Medical Biology and a PhD. He went on to St John's College Cambridge for his clinical training. Michael is currently a senior academic at the University of Sheffield, holding the position of Head of Academic Dermatology and Reader in the Division of Genomic Medicine. Michael also holds active dermatology clinics at both the Royal Hallamshire Hospital and Sheffield Children's Hospital as a Senior Consultant Dermatologist.

We are pleased to bring you this report on **York Pharma**.



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Gabriel Didham, CFA
Objective Capital

Steven Zimmer, M. Sc. (Molecular Biology)
Steven has more than 25 years experience in analysis, corporate finance and as a portfolio manager in biotech and pharma including working for DLJ, CSFB and Robert Fleming in London, NY and Switzerland.

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Objective Capital Limited

2nd floor, 145 St. John St.
London EC1V 4PY
Tel: +44-(0)870-080-2965
Fax: +44-(0)870-116-0839
sales@objectivecapital.com

Internationally:
Phone: +44-20-7754 5994

US Toll-Free:
1-888-802-7215

For Marketing & Sales:
Token House
11-12 Tokenhouse Yard
London EC2R 7AS

Corporate: www.ObjectiveCapital.com
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