

## Scancell



*Scancell is developing a product platform that uniquely stimulates the immune system to treat disease. The corporate strategy is simple – spend the next two years conducting “proof of concept” studies in melanoma, run animal trials in parallel to confirm it as a platform technology, and then sell off the company and technology to the highest bidder.*

### **Executive Summary**

For the full report please visit:  
<http://www.ObjectiveCapital.co.uk/scancell.pdf>

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I certify that this report represents my own opinions.

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## Key Points

8 September 2009  
Price: 45.5p

*Scancell is developing a product platform that uniquely stimulates the immune system to treat disease. The corporate strategy is simple – spend the next two years conducting “proof of concept” studies in melanoma patients, run animal trials in parallel targeting angiogenesis to confirm it as a platform technology, and then sell off the technology to the highest bidder. To use a baseball analogy, Scancell is heading to the plate and swinging for the fences. With a differentiated technology and a focused plan, we think this Company has what it takes to circle the bases.*

- **Attractive model targeting both drug and platform**

The Holy Grail in medicine is always to develop the master key. In other words, the goal is to find the underlying cause of disease and target your therapy there. Using a proprietary DNA vaccine approach, Scancell is working towards creating such a platform technology that, if successful, will garner a premium valuation in the marketplace.

- **This is not “me too” technology**

In both viral infection and tumour models, only high avidity immune responses mediate viral clearance and tumour eradication. Previous failed attempts in the field have simply focused on generating T cell responses rather than how effective those responses are. Scancell is unique in that its preclinical data has shown the ability to generate T cell responses that work - high frequency, high avidity immune responses that actually delay tumour growth and enhance survival.

- **‘Proof of Concept’ Trial is the key that could unlock the kingdom**

The bet with this Company is relatively straight-forward – the trial hits its targeted endpoints and the Company licenses the technology to a partner or even sells the entire franchise to the highest bidder or it’s back to the drawing board.

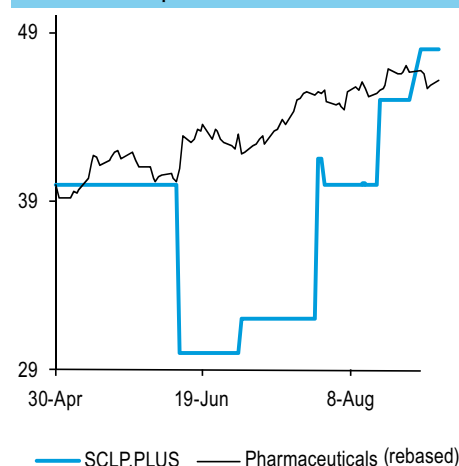
- **Valuation is conservative, with blue sky potential**

Our investment thesis is conservative, with our licensing deal estimates predicated upon Scancell as a single product Company. The goal, with early animal trials on SCIB2, is to demonstrate breadth of application. While relatively inexpensive, successful data in these trials would be worth its weight in gold.

- **A high risk, high reward proposition**

As history has shown, the path to market for therapeutic cancer vaccines is not going to be an easy one. Many bodies litter the road and the science is still very much evolving, but to the winners go the spoils. Using a conservative set of assumptions and a heavily discounted valuation methodology, we still derived a base case value for Scancell of £0.59 per share.

### Price chart (p)



### Current fair value of equity

Expected value	£5.27m
<b>Value per share</b>	<b>£0.59</b>
Optimistic scenario	£13.7m
<b>Value per share</b>	<b>£0.95</b>

### Company details

Quote	
Shares	
- PLUS	SCLP
Shares issued (m)	8.9
Fully diluted (m)	9.6
Website:	<a href="http://www.scancell.co.uk">www.scancell.co.uk</a>

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## Overview

Scancell (PLUS: SCLP) is focused on producing a successful therapeutic DNA vaccine. The technology may have potential usefulness in the treatment of numerous cancers and infectious diseases. While a range of other DNA vaccines are under development by various companies, none are yet approved.

### **The corporate focus has evolved from antibodies to DNA vaccines**

Founded in 1996, Scancell initially focused on building a portfolio of therapeutic antibodies. Ten years later, the antibodies were sold and the Company concentrated its efforts on advancing a unique approach to therapeutic vaccines it had formulated several years earlier. Scancell's ImmunoBody<sup>®</sup> technology uses DNA constructs to deliver specific antigens to the immune system, triggering an effective T cell response to attack tumours and fight off disease and infection.

### **Scancell's approach offers potential for not only a drug, but a platform technology**

While the first drug candidate is targeted at melanoma, the expectation is for this technology to represent a platform technology with the ability, by changing the expressed epitopes, to both prevent and treat a wide range of various cancers and infectious diseases. Scancell intends to drive its second development programme, SCIB2, through animal studies in an effort to validate the multifaceted functionality of the technology. SCIB2 is targeting angiogenesis and could have the versatility to attack a wide range of solid tumours. Beyond these two ImmunoBody<sup>®</sup> product candidates, Scancell is also exploring the potential of forging co-development deals with other companies to develop DNA vaccines for their proprietary targets utilizing the ImmunoBody<sup>®</sup> platform technology.

### **The bet is on the importance of high avidity T cells**

For years, a variety of cancer immunotherapies utilizing a number of different approaches have arisen that seek to stimulate an immune response. Cellular responses are common, but what is elusive is the ability to control tumour growth or the spread of infection. The scientific literature suggests that the stimulation of high avidity T cells may be the critical component in mediating viral clearance and eradicating established tumours. Scancell's lead product, SCIB1, has repeatedly shown a powerful anti-tumour effect with high avidity T cell response in animals.

### **Clear goal in place to prove the concept and then complete the hand-off**

In the case of Scancell, the exit strategy is to license the technology or sell the entire company well before a drug would ever reach the commercial markets. Successful 'proof of concept' studies have historically garnered the interest of larger biopharmaceutical companies with broad research and development programmes. Scancell expects to receive clearance to begin these studies for SCIB1 early next year, with the anticipation that the trials will take approximately two years to complete. At that point in time, or even prior, Scancell will look to negotiate a deal that could include a sizable up-front payment, milestone payments tied to development achievements, and a high single to low double-digit royalty on commercial sales. The path of selling the entire company could also be an option.

### **Strategic partnerships provide drug delivery vehicle**

The potency of DNA vaccines can be significantly enhanced by the nature of the delivery vehicle. Scancell understands the importance of an effective delivery methodology as it readies its lead product for the clinic. Over the past several months, the Company has signed deals with two separate drug delivery technology companies. The first uses electroporation technology to enhance the intracellular delivery of the DNA vaccine and will be used in the SCIB1 clinical trials. The second relies on a platform technology that enhances the immunogenicity of antigens and will be utilized in Scancell's programme targeted at infectious diseases.

### **Limited need for capital a big plus**

The Company is in good financial shape with approximately £1 million in the bank and little debt, but the cost of upcoming clinical studies will require an infusion of capital. Scancell will seek an equity raise of between £1.5 and £2 million later this year and intends to have the money in hand prior to initiating its clinical trials for SCIB1 in April of 2010. With the expectation that its clinical work on SCIB1 will require approximately two years of time and £1 million, the purpose of this capital raise is to carry the Company to its first major licensing deal or buyout.

### **The pathway may be clear, but the potholes are many**

Risk is inherent in any early stage biotech company and this one is no different. Over the next two years, the Company will need to tap the capital markets for funding, navigate the challenges of the regulatory environment, and ultimately present data convincing enough to attract a third-party suitor. Cross those hurdles successfully and the Company still must deal with the risk that the immune response is not necessarily indicative of anti-tumour response. In other words, success in its early stage clinical trials may not translate to clinical effectiveness in more definitive Phase II trials and beyond.

### **Valuation is in colour, not black-and-white**

We have attempted to quantify the magnitude of the opportunity, discounted to account for the risk involved. The anticipated up-front and milestone payments are intended to represent industry norms although, in reality, the variability between individual licensing agreements is incredibly diverse. There is also a high probability that the eventual market opportunity for this technology will expand beyond the melanoma market.

Our conservative approach is to assess the value of the SCIB1 programme in late stage patients based on the assumption that the company will licence it out at the end of its current trials. The "blue sky" for investors is obviously the potential that the company will be acquired in total at that stage – and at a substantial premium for the technology platform.

## Valuation

While Scancell may prefer to be bought outright upon completion of its early clinical trials, we have chosen to value the Company based upon a licensing partnership that includes up-front payments, milestone payments and royalties on commercial sales of SCIB1. We have chosen not to explicitly value the SCIB2 asset, but instead consider it as demonstrating the potential for a “blue sky” acquirer of the technology platform.

We have developed a timeline for expected up-front and milestone payments and included a royalty estimate in our model, in both a base case and a more optimistic set of scenarios. As common in evaluating biotech assets, we have applied significant probability-based discounts estimated from industry standard development-based probabilities of success and further discounted the expectation for cash inflows to the Company using a standard discounted cash flow approach.

In our base case we assume that if Scancell delivers efficacious results from its early clinical studies it will ultimately collect up-front and net milestone payments totalling US\$183 million and net royalties at a rate of 7% on commercial sales of product into the melanoma market. Our view is based upon a scenario in which SCIB1 has demonstrated clear proof-of-concept in melanoma patients and reflects current market partnering arrangements with similar characteristics. We have also assumed that the resulting commercial product will be in conjunction with the Ichor delivery device. In essence, we are valuing Scancell as a single product company and considering the potential for a platform technology with SCIB2 as pure blue sky.

We have focused particularly on the recent GlobelImmune and Celgene deal. Although the technology is not directly similar, GlobelImmune is working on targeted molecular immunotherapy for the treatment of cancer. Under the terms of the agreement, GlobelImmune will receive a US\$40 million upfront payment from Celgene and will be eligible to receive over US\$500 million in development and regulatory milestones, double-digit royalties and additional milestone payments based on net sales of the licensed product candidates. Our take is that GlobelImmune’s lead programme targeting pancreatic cancer might have a slightly larger clinical data package than SCIB1 at the point that Scancell expects to license it. The melanoma market that Scancell is initially targeting is slightly larger in size and the clinical need for an efficacious treatment is comparable.

In addition, GlobelImmune also has a pipeline of three additional cancer products at the preclinical stage along with three infection programmes showing proof-of-concept, whereas we expect Scancell to only have SCIB2 in the preclinical phase at the time of a deal. As a result, we are reasonably comfortable forecasting a base case scenario that delivers up-front payments and net milestones well below those received by GlobelImmune, with a net royalty rate at the low end of the range.

## Fair value summary (US\$m)

Scenario	Core	Optimistic
Development drugs		
- SCIB1	6.9	12.1
Less: overhead	2.4	2.4
<b>Expected value of pipeline</b>	<b>4.5</b>	<b>9.7</b>
Add: other assets*	1.7	1.7
Add: starting cash + new funds	2.5	2.5
Total current value for firm	8.7	13.9
Less: Bank & other debt	0.0	0.0
Total value to equity claims	8.7	13.9
Less: warrants & options	0.2	0.2
Ordinary equity holders	8.5	13.7
Value per share (US\$)	<b>0.95</b>	<b>1.53</b>
Value per share (£)	<b>0.59</b>	<b>0.95</b>

\* expected risked value of milestones due from Arana

## Summary of detailed SCIB1 valuation (US\$m)

SCIB1	Core	Optimistic
Royalty revenue*		
<b>EV of royalties</b>	<b>62.9</b>	<b>128.2</b>
<b>Likelihood of success (PoS)</b>	<b>7%</b>	<b>7%</b>
<b>EMV of royalties</b>	<b>4.2</b>	<b>8.6</b>
Add: EMV of upfront payments**	1.4	2.2
Add: EMV of milestone payments**	3.7	5.1
less: EMV of development costs**	0.5	0.5
<b>EMV***</b>	<b>8.7</b>	<b>15.3</b>
per share		
- US\$ ps	0.98	1.71
- £ ps	0.61	1.06
<b>After tax EMV</b>	<b>6.9</b>	<b>12.1</b>

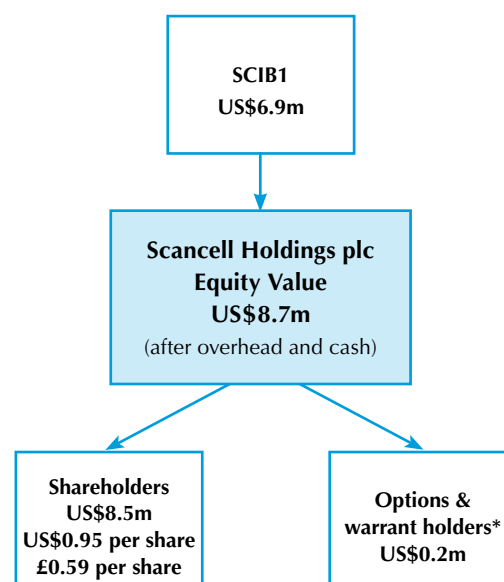
\* EV = expected value; EMV = expected monetary value (i.e., risked expected value)

\*\* net upfront, milestone and development costs have been risked based on probability of being incurred or received

\*\*\* royalty, upfront and milestone payments are based on a standalone licencing deal and assume no premium for the technology platform

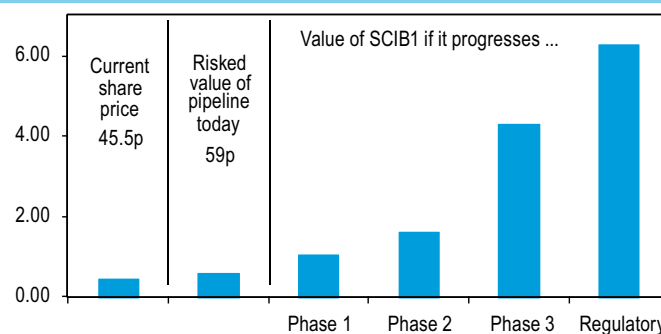
**Note:** see page 19 for revenue forecasts and page 26 for detailed SCIB1 valuation

## Components of Scancell's entity value

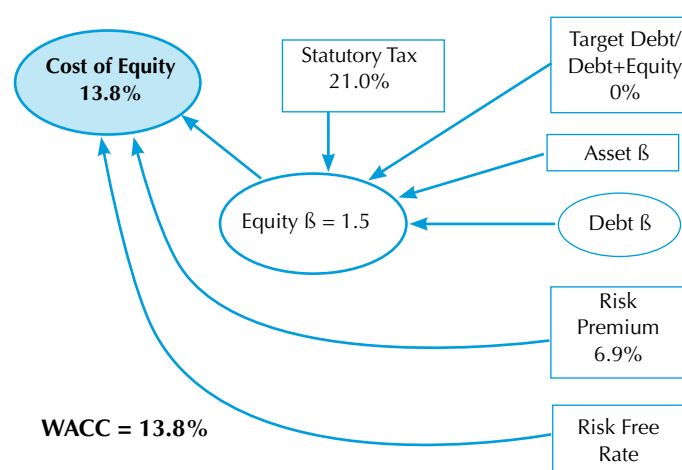


\* includes expected value of contingent option claims

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



## Weighted cost of capital



With the specifics of most licensing arrangements kept close to the vest, we realize the imperfect nature of this analysis and, therefore, have tried to remain conservative in our outlook.

Our alternative case view assumes slightly more aggressive market share capture by SCIB1, an up-front and net milestone payment package totalling US\$253 million and a net royalty of 9%. Our goal here is to portray a market that is more comfortable with the concept of a DNA vaccine at the time of licensure. Successes in the field will undoubtedly raise the profile of the development work done by Scancell and, in our estimation, drive up the price the Company can expect to receive in a partnership deal or eventual sale.

In both scenarios, we have taken the view that biosimilars will be existent in the market at the time of patent expiration for SCIB1 and that the subsequent price deterioration will amount to 25%. Our expectation is for price deterioration to occur at a more modest level than is currently seen with small molecules, in part due to the greater complexities and costs involved in developing and manufacturing the biosimilars.

We have not accounted for the potential for SCIB1, if successful, to be used in earlier stages to prevent the re-occurrence following remove of an initial melanoma tumour. While this would obviously necessitate expensive further trials, and would be dependent on any side effect profile, the market potential could be substantial.

Our analysis suggests a base case value for Scancell shares of £0.59 per share and £0.95 per share based upon a more optimistic set of assumptions. In achieving these valuations, the challenge for Scancell will be to deliver convincing clinical data on its lead drug candidate.



### **Regulatory uncertainties**

Scancell is on track to submit its Clinical Trials Application (CTA) to the UK Medicines and Healthcare Regulatory Agency (MHRA) in early January 2010. The general rule-of-thumb is for the MHRA to turn around the paperwork within 30 days, although the possibility is there for additional questions at that time. Beyond the risk involved in seeking approval to initiate clinical trials, Scancell must also contend with the eventual interpretation of the trial design and subsequent data by a future suitor or licensee.

### **Crowded field**

Therapeutic cancer vaccines are in various stages of development for at least 18 different tumour types. Melanoma, in particular, has seen the most activity, to date. While the crowded landscape brings the added risk of competition for licensing dollars and eventual commercial sales, increased activity in the field also validates the scientific merit of the approach. While perhaps not ideal for the patient, cancer therapies have a history of only providing incremental and inconsistent benefit to those afflicted with the disease and, therefore, there is the strong likelihood that multiple companies and multiple approaches will be able to share in what is now a very large, but underserved, market opportunity.

### **Need for additional capital**

Currently, Scancell has approximately £1 million in the bank. Although the monthly burn is minimal at roughly £70,000, the costs associated with the upcoming clinical trials will require the Company to secure additional funding. With an estimated cost of £1 million to complete the Phase I/IIa trials combined with the ongoing monthly burn, it is expected that Scancell will seek to raise at least £1.5 million before initiating the trials. Although its current cash holdings could carry the Company well into the first phase of its trials, the prudent course of action is to secure the funding later this year and provide the Company with enough capital to complete its Phase I/IIa trial.

As the capital markets have shown over the past year, however, no certainty can be assigned to the task of raising new funds, particularly for an early stage company with no revenue. With the need for new capital as a gating issue to the initiation of clinical studies, timing is critical and the amount of time necessary to complete financing deals of late has lengthened as macro economic conditions have suffered. Scancell has confidence that its existing shareholder base is willing to step up to the plate in this round of financing, however, and that may, in fact, accelerate the timing of a deal.

### **Clinical risk**

The science has shown efficacy in animal trials, but has yet to enter humans. In other words, the success in the laboratory now needs to be translated into the clinic. Additional challenges in the clinic, such as patient selection and adverse events, bring added risk to the equation. There is also no certainty that an immunological response in humans will be great enough to deliver a clinical benefit. Recent Phase III trial failures of cancer vaccines by Favril and Genitope drive home this point.

### **Partnering risk**

Scancell is clear in its desire to license SCIB1 after completing the Phase I/IIa trial, if not before. In a best case scenario, the studies will have shown a strong immunological response in man or, in other words, a “proof of concept.” This is a significant, value-creating milestone for early stage drug discovery companies and would likely interest multiple parties in licensing the technology or possibly even acquiring the entire Company. Of course, the devil is in the detail – in this case, in the data – and the failure to secure a satisfactory licensing deal (or several) within the next two years would place the Company in the precarious position of having to consider a sizeable capital raise to fund additional clinical studies or, worse yet, sell off its assets in a fire sale.

<b>Profit &amp; Loss</b>					
Year ending April (£000's)	2008A	2009A	2010E	2011E	2012E
Revenues					
Upfront payments	0	0	0	0	0
Milestone payments	0	0	0	0	0
Licensing/royalty revenues	0	0	0	0	0
Net revenues	0	0	0	0	0
Development costs	241	713	110	621	633
Gross profits	(241)	(713)	(110)	(621)	(633)
Administrative expenses	269	402	422	422	422
Other income	0	213	0	0	0
Depreciation	27	28	27	27	26
Profit from operations	(510)	(902)	(559)	(1,069)	(1,081)
Interest income	61	57	81	92	58
Pretax income	(449)	(845)	(478)	(977)	(1,023)
Tax	0	0	0	0	0
Tax credit	(44)	(185)	(50)	(50)	(50)
Net tax	(44)	(185)	(50)	(50)	(50)
Net income	(406)	(660)	(428)	(927)	(973)
EPS (p)	(5.6)	(7.4)	(3.2)	(6.9)	(7.3)

<b>Balance Sheet</b>					
Year ending April (£000's)	2008A	2009A	2010E	2011E	2012E
Non-current assets					
Property plant & equipment	87	82	80	79	77
Total	87	82	80	79	77
Current assets					
Debtors	51	405	250	250	250
Cash & equivalents	998	1,519	3,048	2,122	1,151
Total	1,049	1,924	3,298	2,372	1,401
Total assets	1,136	2,006	3,378	2,451	1,478
Current liabilities					
Creditors	88	167	167	167	167
Total	88	167	167	167	167
Net assets	1,047	1,839	3,212	2,284	1,311
Shareholder's equity					
Total equity	1,047	1,839	3,212	2,284	1,311

<b>Cashflow</b>					
Year ending April (£000's)	2008A	2009A	2010E	2011E	2012E
Operating profit (loss)	(510)	(902)	(559)	(1,069)	(1,081)
Depreciation charges	27	28	27	27	26
Government grants	0	-213	0	0	0
Decrease/(Increase) in debtors	12	-207	155	0	0
Increase in creditors	31	78	0	0	0
Net cash from operations	(440)	(1,216)	(377)	(1,043)	(1,055)
Cashflow from investing					
Property plant & equipment purchases	(1)	(23)	(25)	(25)	(25)
Taxation	(149)	39	50	50	50
Returns on investments and servicing of finance	61	57	81	92	58
Net cash from investing activities	(89)	73	106	117	83
Cashflow from financing activities					
Net issue of ordinary shares	21	1,665	1,800	0	0
Net cash from financing	21	1,665	1,800	0	0
Net increase (decrease) in cashflow	(507)	521	1,529	(926)	(972)
Opening cash equivalents	1,505	998	1,519	3,048	2,122
Closing cash equivalents	998	1,519	3,048	2,122	1,151

Source: *Objective Capital*

## **Appendix: Management**

### **David Evans (Non-Executive Chairman)**

As the former CFO David Evans guided Shield Diagnostics Ltd. through its IPO and then, as its CEO, through its merger with Axis Biochemical ASA to form Axis-Shield plc, a fully listed diagnostics company. In addition to being Chairman of the Company he is currently non-executive Chairman of Epistem, Immunodiagnostic Systems Holdings plc and Omega Diagnostics Group plc, all of which are AIM listed biotechnology companies.

### **Professor Lindy Durrant (CEO)**

An internationally recognised immunologist in the field of tumour therapy, Prof. Durrant has worked for 21 years in translational research, developing products for clinical trials including monoclonal antibodies for diagnostic imaging and therapy and cancer vaccines. She has a personal Chair in Cancer Immunotherapy at the Department of Clinical Oncology at the University of Nottingham and is currently running clinical trials in colorectal cancer and osteosarcoma.

### **Dr Richard Goodfellow (Commercial Director)**

Dr Richard Goodfellow has over 25 years international experience in the pharmaceutical industry, in Big Pharma and with Biotech companies. During his time at Astra, he oversaw the launch of Losec and other key products internationally. Thereafter, he held the post of Director of Licensing and New Business Development at Scotia Pharmaceuticals, where he was involved with the company's flotation on the London Stock Exchange and successfully negotiated numerous deals. Dr Goodfellow is also a founder of Paradigm Therapeutics, a Cambridge based functional genomics company and is a former Director of Enact Pharma plc.

### **Nigel Evans (Company Secretary)**

Nigel Evans has 40 years commercial and strategic responsibilities at senior levels in Rolls-Royce plc in the UK and overseas. Now an active investor in public and private companies, he oversees Scancell's corporate and financial activities. He was Executive Chairman of Scancell for seven years, until 2007, and was heavily involved with its progress during that period.

### **Michael Rippon**

Mike Rippon has over 40 years experience in the motor industry. He is now an active investor in small private companies and is one of Scancell's major private investors. He was appointed to the Board on 1 January 2004 as the Shareholder Representative.

### **Dr Matthew Frohn**

Dr Matthew Frohn graduated from Oxford Brookes University with a degree in Cell and Molecular Biology followed by a D.Phil in Biochemistry from Oxford University. He worked on research collaborations with Astra Zeneca, and a short research post with a British Biotech subsidiary before joining Oxford Technology Management in 1999, the manager of the Oxford Technology VCTs.

We are pleased to bring you this report on **Scancell**.



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Gabriel Didham, CFA  
Objective Capital

#### **Scott Davidson, CFA**

Scott has worked in the equity research industry for over ten years, focusing on the life sciences arena for the past eight years. He has previously work for Allen & Company, FAC Equities in New York. Scott is a graduate from Harvard University.

#### **Dr Alan Warrander**

Alan has over 25 years wide-ranging experience in the Pharmaceutical Industry providing advice and expert scientific opinion on Partnering, Strategic Planning and Drug Development. Alan was previously Senior Vice President, Life Sciences at Wood Mackenzie, the global consultancy firm. Prior to this he was a Director of Global Licensing with AstraZeneca and previously led a Drug Metabolism/Pharmacokinetics Unit at ICI/Zeneca Pharmaceuticals.

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