

22 October 2008

Phynova

Year End	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	PE (x)	Yield (%)
09/06	0.0	(1.6)	(13.6)	0.0	N/A	N/A
09/07	0.0	(2.9)	(14.9)	0.0	N/A	N/A
09/08e	0.0	(2.5)	(10.9)	0.0	N/A	N/A
09/09e	0.0	(4.6)	(19.0)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding goodwill amortisation and exceptional items

Investment summary: Next clinical candidate

Phynova has picked PYN6, an multi-constituent antibacterial drug candidate derived from a Chinese medicinal plant, as its next candidate for clinical studies. The decision follows two rounds of pre-clinical testing, which showed retained antibacterial activity in the intended dosage form and potential to avoid resistance. Phynova's investment case rests on it obtaining additional funds, and we do not expect a clinical study to start until more funds are in place, eg from a possible licensing deal.

Early data on PYN6

PYN6, a project for the topical prevention and treatment of bacterial infections, including meticillin-resistant *Staphylococcus aureus* (MRSA), has been chosen by Phynova as its next candidate for clinical studies. Early data indicate true bactericidal activity, rather than just inhibiting bacterial growth, and suggest that this activity is retained in gel formulation – the intended final dosage form.

Licensing deal key

Phynova has a funding requirement to continue operations beyond January 2009, and is investigating a number of fund-raising possibilities. In our view, funds would most likely come through a licensing deal to commercialise its lead project, PYN17, or a development alliance for PYN6.

Clinical studies planned

Phynova expects the first Phase I study of PYN6 to begin in 12 to 15 months, as well as planning a Phase II proof-of-concept trial with PYN17. We do not expect either study to start before the company has either raised more cash or signed up a licensing partner prepared to fund most or all late-stage development in return for milestone payments and royalties.

Valuation

We continue to believe that Phynova's current enterprise value of around £4m represents a significant opportunity, and a licensing deal with a significant pharma partner for PYN17 could prompt a share price uplift.

Price 22.5p
Market Cap £5m

Share price graph



Share details

Code PYN
Listing AIM
Sector Pharmaceuticals & Biotechnology
Shares in issue 22.6m

Price

52-week High 56.0p Low 22.5p

Balance sheet as at 31 March 2008

Debt/equity (%) N/A
NAV per share (p) 2.1
Net cash (£m) 0.5

Business

Phynova is a UK-based firm specialising in the development of prescription-only botanical drugs principally derived from the plants used in traditional Chinese medicines.

Valuation

	2007	2008e	2009e
P/E relative	N/A	N/A	N/A
P/CF	N/A	N/A	N/A
EV/sales	N/A	N/A	N/A
ROE	N/A	N/A	N/A

Revenues by geography

	UK	Europe	US	Other
0%	0%	0%	0%	0%

Analyst

Jacob Plieth 020 3077 5736
jplieth@edisoninvestmentresearch.co.uk

Company description: Developer of botanical drugs

Phynova is a UK-based firm specialising in the development of prescription-only botanical drugs – as defined by relatively recent US FDA guidance – and these are highly purified single and multiple plant fractions principally derived from Chinese medicinal plants. Such botanical agents have an existing record of extensive previous human use, along with efficacy and safety data.

The company expects these products to be treated as pharmaceuticals and will have to meet the same (or similar) standards of efficacy, safety and quality as new chemical entities. However, the existence of clinical data from the outset of each programme should mean that there is a better than average chance of success. Phynova intends to commercialise its lead pipeline products, presumably through licensing/development partners, and expand its Chinese business through the licensing in of additional Chinese botanical-derived drug candidates as well as investigating potential merger and acquisition activity.

Initial focus on PYN17

Phynova's most advanced (and potentially most lucrative) R&D project is PYN17, which is being developed for hepatitis C (HCV) symptoms, and this remains its main near-term focus. PYN17 is ready to enter a large Phase II trial, but this depends on the company securing additional cash. Funding is needed to continue operating beyond January 2009, and in the meantime we expect Phynova to run at minimal cost, conserving cash and trimming back non-essential activities, including some R&D.

Exhibit 1: Phynova's R&D pipeline

Note: *Botanic Century compound.

Product	Indication	Development stage/notes
PYN17	Liver inflammation as a result of chronic HCV infection.	Four-week, placebo-controlled Phase I/II study in 39 patients demonstrated safety and tolerability of PYN17, with levels of minor adverse events identical to that seen with placebo. Plans for a Phase II proof-of-concept study in 200 patients depend on securing additional funding.
PYN6	Antibiotic-resistant bacterial infections (including MRSA)/acne.	Licensed in under option from BCCL. Activity against major classes of antibiotic-resistant strains of bacteria (including MRSA) and against <i>Propionibacterium acnes</i> established <i>in vitro</i> . Studies show sustained anti-MRSA activity in gel formulation, and possibility to avoid resistance. Phase I trial possible in 2009.
PYN22	Obesity/fatty liver disease (non-alcoholic steatohepatitis).	A single-plant extract. <i>In vitro</i> studies in China and UK show lowering of expression of genes associated with obesity and fatty liver disease. Phase I/II trial is in preparation.
PYN9	Post-operative ileus.	In development as a rectal suppository by BCCL, which has filed an IND to begin clinical studies in China. Clinical development expected to take two years. Phynova looking at developing PYN9 in markets outside China.
PYN18	Treatment of HCV infection and dengue fever infection.	A single-plant extract. Anti-HCV activity established in industry-standard <i>in vitro</i> models. Collaborators at the Siriraj Hospital in Bangkok have confirmed activity against the dengue virus.
PYN7	Solid tumours.	Series of molecules isolated from active fractions of a plant used in China. <i>In vitro</i> studies show activity against melanoma and oesophageal and lung cancer cell lines. Phynova is collaborating with the Institute of Cancer Studies at the University of Birmingham for further preclinical development. Mechanism of action studies and lead selection possible in 2008.
BCL-5*	Type 2 (adult onset) diabetes.	Preclinical development.

Source: Edison Investment Research

Further early data support for PYN6

Phynova has announced that PYN6, its R&D project for the topical prevention and treatment of bacterial infections, including methicillin-resistant *Staphylococcus aureus* (MRSA), has been chosen as its next candidate for clinical studies (after PYN17). This followed further preclinical results, which demonstrated potential advantages over the current topical antibiotic used for routine treatment, as well as the potential for PYN6 to circumvent the build-up of drug resistance.

Nevertheless, given Phynova's funding requirement we do not expect a clinical programme to begin before additional funds are in place. The company says it expects first Phase I trials to begin within 12 to 15 months.

The latest round of preclinical screening focused on the ability of PYN6 to retain its activity in a gel formulation – its intended final dosage form – and to gain an understanding of the activity of some of the pure compounds isolated from PYN6.

Previously reported data on PYN6 used the active pharmaceutical ingredient only, and have now been backed up by preclinical studies showing that this activity is retained in a gel formulation. Phynova additionally tested several gel formulations of differing viscosity and base (different indications would require different formulation, eg nasal carriage clearance would use a thicker gel than a prophylactic for surgical wounds) and all of these showed equivalent activity at the same concentration.

Constituent components

Phynova's investigation into the activity of the constituents of PYN6 have confirmed that each acts differently, although the mechanisms of action of the individual components have not yet been elucidated.

Many traditional antibiotics are not bactericidal in nature, and rather act to inhibit the growth of bacteria – these include mupirocin, the topical antibiotic currently used routinely for treating skin infections involving MRSA (but against which MRSA is increasingly becoming resistant). Some of the components of PYN6 showed a similar type of activity. Others, however, appeared to be distinctly bactericidal, as evidenced by their MIC (minimum inhibitory concentration) and MBC (minimum bactericidal concentration) values being very similar.

Phynova further postulates that the multiple mechanism of action of PYN6 and its polymolecular nature could be important in avoiding or limiting the formation of bacterial resistance. Traditional antibiotics are typically single compounds affecting a single site, making it easier for a bacterium to become resistant to them, while a multicomponent drug that affects many different sites would require the bacterium to undergo many more mutations to develop resistance.

PYN 6 has also shown significant activity against *Propionibacterium acnes*, the organism that causes acne, and acne represents another indication for development. Phynova has filed a new patent application, and says commercial discussions are under way with several companies with an interest in infection and skin care.

Botanic Century

PYN6 is a multi-component extract from *Salvia miltiorrhiza* (Chinese sage), a plant widely used in Chinese medicine. Rights to PYN6 in Western markets were acquired by Phynova under an option from Botanic Century China Ltd, a private Chinese drug development company and contract research organisation in which Phynova holds a 45% stake.

Phynova intends to license PYN6, along with its other drug candidates, to pharmaceutical companies; it previously intended to do this after achieving clinical proof of principle, thus retaining a relatively high economic interest in projects. We expect the company to consider a range of licensing agreements, including deals at a relatively early stage of product development.

Financials

We are keeping our financial model for Phynova unchanged, and present it in Exhibit 2. We expect the company to have finished the 2008 fiscal year with around £360k in cash, and expect this to be sufficient to fund operations until the end of January 2009. We illustrate the additional funding requirement for the remainder of 2009 as an increase in long-term debt.

The key risk to Phynova's business is its funding requirement to operate beyond January 2009, especially given current market conditions and the company's share price. Other sensitivities to our assumptions include the regulatory regime for botanical pharmaceuticals, which is new and largely untested, particularly in the US; the company's ability to obtain robust intellectual property protection; the possibility of licensing development products to partners on favourable terms; a high reliance on Chinese counterparties and potential issues around enforcing contracts or obtaining remedies for breach of contract; and the fact that no institutions hold substantial shareholdings (ie above 3%) in Phynova.

Exhibit 2: Financials

	£'000s	2006	2007	2008e	2009e
Year end 30 September					
PROFIT & LOSS					
Revenue		0	0	0	0
Cost of sales		0	0	0	0
Gross profit		0	0	0	0
EBITDA		(1,661)	(2,917)	(2,484)	(4,450)
Operating profit (before GW and except.)		(1,664)	(2,924)	(2,492)	(4,460)
Goodwill amortisation		0	0	0	0
Exceptionals		0	0	0	0
Share-based payments		0	(47)	0	(40)
Operating profit		(1,664)	(2,971)	(2,492)	(4,500)
Net interest		23	84	38	(100)
Profit before tax (norm)		(1,640)	(2,899)	(2,474)	(4,590)
Profit before tax (FRS 3)		(1,640)	(2,946)	(2,474)	(4,630)
Tax		0	93	170	300
Profit after tax (norm)		(1,640)	(2,806)	(2,304)	(4,290)
Profit after tax (FRS3)		(1,640)	(2,853)	(2,304)	(4,330)
Average number of shares outstanding (m)					
		12.0	18.9	21.1	22.6
EPS - normalised (p)		(13.6)	(14.9)	(10.9)	(19.0)
EPS - FRS 3 (p)		(13.6)	(15.1)	(10.9)	(19.2)
BALANCE SHEET					
Fixed assets		8	548	582	587
Intangible assets		0	0	0	0
Tangible assets		8	16	23	28
Investment in associates		0	531	559	559
Current assets		2,232	1,845	664	629
Stocks		0	0	0	0
Debtors		254	419	300	450
Cash		1,978	1,427	364	179
Other		0	0	0	0
Current liabilities		(207)	(375)	(168)	(238)
Creditors		(207)	(375)	(168)	(238)
Short-term borrowings		0	0	0	0
Long-term liabilities		(371)	(343)	(343)	(4,343)
Long-term borrowings		0	0	0	(4,000)
Other long-term liabilities		(371)	(343)	(343)	(343)
Net assets		1,662	1,675	735	(3,365)
CASH FLOW					
Operating cash flow		(1,586)	(2,847)	(2,396)	(4,370)
Net interest		23	84	38	(100)
Tax		0	0	170	300
Capex		(8)	(16)	(15)	(15)
Acquisitions/disposals		0	(593)	0	0
Financing		3,520	2,821	1,140	0
Dividends		0	0	0	0
Other		0	0	0	0
Net cash flow		1,949	(551)	(1,063)	(4,185)
Opening net debt/(cash)		(29)	(1,978)	(1,427)	(364)
HP finance leases initiated		0	0	0	0
Other		0	0	0	0
Closing net debt/(cash)		(1,978)	(1,427)	(364)	3,821

Source: Edison Investment Research

EDISON INVESTMENT RESEARCH LIMITED

Edison is Europe's leading independent investment research company. With a team of 50 including 30 analysts supported by a department of supervisory analysts, editors and assistants, Edison writes on more than 200 companies across every sector. Working directly with corporates, investment banks and fund managers, Edison's research is read by every major institutional investor in the UK, as well as by the private client broker and international investor communities. Edison was founded in 2003 and is authorised and regulated by the Financial Services Authority.

DISCLAIMER

Copyright 2008 Edison Investment Research Limited. All rights reserved. This report has been commissioned by Phynova and prepared and issued by Edison Investment Research Limited for publication in the United Kingdom. All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report. Opinions contained in this report represent those of the research department of Edison Investment Research Limited at the time of publication. The research in this document is intended for professional advisers in the United Kingdom for use in their roles as advisers. It is not intended for retail investors. This is not a solicitation or inducement to buy, sell, subscribe, or underwrite securities or units. This document is provided for information purposes only and should not be construed as an offer or solicitation for investment. A marketing communication under FSA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research. Edison Investment Research Limited has a restrictive policy relating to personal dealing. Edison Investment Research Limited is authorised and regulated by the Financial Services Authority for the conduct of investment business. The company does not hold any positions in the securities mentioned in this report. However, its directors, officers, employees and contractors may have a position in any or related securities mentioned in this report. Edison Investment Research Limited or its affiliates may perform services or solicit business from any of the companies mentioned in this report. The value of securities mentioned in this report can fall as well as rise and are subject to large and sudden swings. In addition it may be difficult or not possible to buy, sell or obtain accurate information about the value of securities mentioned in this report. Past performance is not necessarily a guide to future performance.

Edison Investment Research

Lincoln House, 296-302 High Holborn, London, WC1V 7JH ■ tel: +44 (0)20 3077 5700 ■ fax: +44 (0)20 3077 5750 ■ www.edisoninvestmentresearch.co.uk
Registered in England, number 4794244. Edison Investment Research is authorised and regulated by the Financial Services Authority.