

epistem

Controlling life-long tissue renewal

Powering up

Epistem Holdings Plc

Interim Report and Accounts 2008



Epistem is a biotechnology company commercialising its expertise in epithelial stem cells

in the areas of oncology, gastrointestinal disease, dermatology and ageing.

Every person develops from one cell – the fertilised egg. In the early stages of development, stem cells differentiate and become committed to generating a specific tissue or organ. Adult stem cells remain capable of regenerating tissues in our organs throughout our lives.

As we get older, our body's stem cells' ability to regenerate new cellular tissue diminishes, leading to tissue ageing and disease.

Epistem is focused on understanding how cells function and are controlled, so that we can identify new drug therapies to address the major diseases of oncology, gastrointestinal disease, dermatology and ageing.

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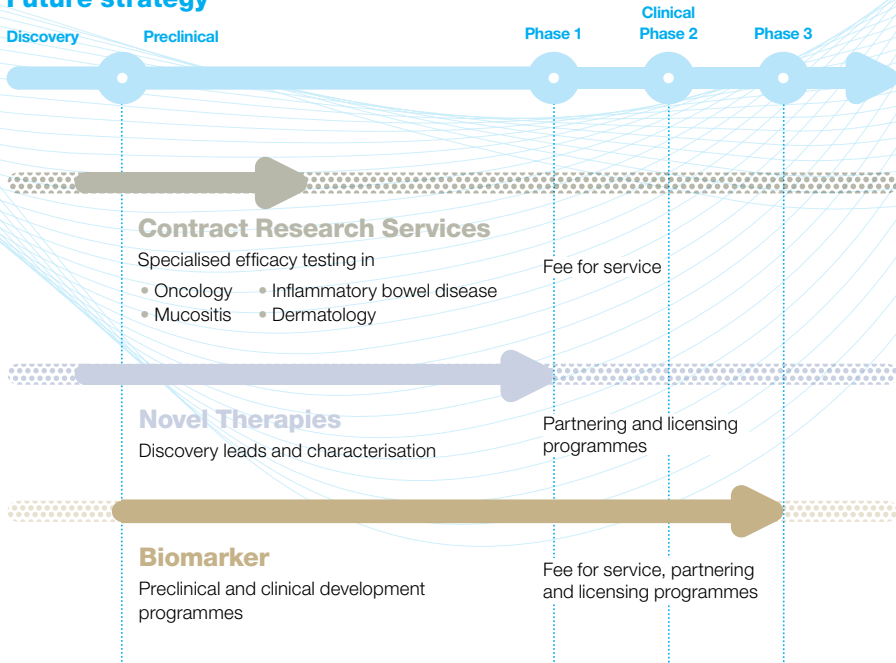
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Directors, Secretary and Advisers	IBC

Highlights

- Year on year revenue growth of 31%
- Acceleration of the Novel Therapy lead (drug) development programme
- Launch of new Biomarker division and encouraging revenue growth
- Firm demand for Contract Research Services in difficult market conditions
- Strengthening business model with significantly reduced risk profile
- Forecasting to move into profitability post the Novartis collaboration and strengthening cash reserves

A robust business model to sustain future growth

Future strategy



What We Do

Contract research services, clinical biomarkers and innovative therapeutics for drug development.

► Contract Research Services

Contract Research Services provide specialised preclinical efficacy testing primarily for drug development companies on a 'fee for service' basis. The division is growing strongly and is cash generative and profitable. Our Contract Research Services group has an established international eight year track record of providing the highest quality testing services to well over 100 companies primarily across Europe and the United States, including most major pharmaceutical companies.

We assist companies with the preclinical development of their drug therapies to treat epithelial diseases including:

- Cancers
- Mucositis (cancer supportive care)
- Inflammatory bowel disease
- UV-induced skin damage
- Wound healing
- Skin and hair disorders.

► Novel Therapies

Epistem is discovering the key regulators (proteins) of epithelial cells and developing therapeutics to control cell production, initially in the area of oncology. With over 80% of adult cancers arising from epithelial tissues, the Company believes that applying its understanding of the behaviour of stem cells and cell production will identify new targets and pathways for drug development.

The Novel Therapies division is focused on developing its own proprietary therapeutics based on its discovery of the key regulators of epithelial cell production. The team has identified over 250 potential protein regulators, which are being evaluated in the Company's preclinical efficacy models. The recent announcement of the Novartis research and development collaboration will accelerate our lead development and enable both companies to jointly explore disease opportunities in regenerative medicine.

Life-long tissue renewal explained

Epithelial stem cells

Epithelial stem cells are rare cells which represent the 'building blocks' of tissue growth and renewal. Stem cells are essential for tissue repair since they are responsible for the replacement of all cells.

Expertise

Epistem is applying its know-how and expertise to identify genes and proteins responsible for controlling cell production to develop drugs to treat cancer and other epithelial disease.

Vision

Epistem's vision is to control stem cells with its emerging protein therapeutics to prevent, treat or cure health and life-threatening disease.

► Biomarker

Epistem has developed an innovative, minimally invasive molecular biomarker test for pharmaceutical companies developing new drugs, initially in the area of oncology. The hair biomarker is designed to identify changes in gene expression that result from treatment with an oncology drug. We work closely with top-tier pharmaceutical groups to better understand the drug-induced gene expression changes in a subject during treatment.

Drug-induced genes expressed ('gene markers') are measured through the preclinical and clinical phases of drug development. This enables the measurement of the pharmacodynamic and pharmacokinetic (PD/PK) molecular characteristics of a subject in response to treatment.

This proprietary technology uses the Company's knowledge of the behaviour of epithelial stem cells and high resolution gene expression techniques to measure drug effects during development.



Chairman and Chief Executive Officer Statement



A strengthening trading position and financial outlook

across each division continues to build a solid platform for growth.

Epistem's business model continues to strengthen across each of our divisions as we begin to differentiate ourselves within the biotech sector by delivering improved trading revenues, a move towards profitability and a strengthening commercial outlook. With the recent announcement of our collaboration with Novartis, the potential of our Novel Therapies division and continuing progress in our other divisions, the Board believes that the Company offers a lower risk biotechnology business model with significant upside potential.

This Half Year report covers the six month period from the 1 July 2008 to 31 December 2008.

Please note that the first half reported results do not include any financial figures in relation to the recently announced Novartis collaboration.

Overview

The reported 2008/09 half year results maintained an important period of growth for Epistem set against an increasingly volatile external market.

Results for the first six months saw Company revenues increase by 31% to £1.4m (£1.1m: 2007/08), primarily from our 'fee for service' Contract Research Services and Biomarker divisions. The revenue increase was largely supported by growth in the newly formed Biomarker division which recorded significant revenues in its first period of reporting.

£1.4m

Sales revenues from business operations
for the first six months of the financial year.

Contract Research Services showed marginal revenue growth over the first half at £1.1m (£1.0m: 2007/08). Market sentiment was dampened by the difficult economic picture and this was reflected in caution around new business opportunities. Despite this, the Contract Research Services quality of business and sales order book remain firm.

The newly formed Biomarker division saw accelerated technical and commercial developments with revenues lifting significantly to £0.3m (£nil: 2007/08) over the period underpinned by contracts with select big pharmaceutical groups. Our biomarker scientific and technical advances were also presented as abstracts at the American Society of Clinical Oncology (ASCO) and American Association for Cancer Research (AACR) meetings.

Our Novel Therapies division progressed at pace with the continued development of our therapeutic targets and leads and the announcement earlier this month of our research and development collaboration with Novartis. The collaboration has validated our discovery approach and will allow us to integrate our discovery platform and preclinical models with a world class partner to discover new targets and accelerate our lead development and represents a major step in the development of the Company.

Despite wider market conditions, the strength of our business model has been recognised by investors with the share price well over double its AIM admission price from April 2007.

Cash reserves at 31 December 2008 remain healthy at £1.2m (£2.1m: 30 June 2008), which excludes the recently announced US\$4.0m upfront cash payment receivable from Novartis, with the prospect of improving revenues and a move into profitability following the announcement of the Novartis collaboration.

Financial Review

Sales revenues from business operations for the first six months of this financial year were £1.4m (£1.1m: 2007/08), a year on year increase of £0.3m. Revenue growth was driven by increased demand for our 'fee for service' businesses, primarily in relation to our new Biomarker services. Demand for our plucked hair biomarker rose sharply over the first half to £0.3m. Contract Research Services recorded only marginally increased revenues over the period.

Novel Therapies development costs for the first half remained consistent with last year, with manpower costs forecast to increase in the second half to meet the onset of the Novartis collaboration. The ongoing cost of the Novel Therapies collaboration will though be fully funded by Novartis. Other operational cost increases over the period were largely in relation to the commissioning of the new Biomarker division with other costs under tight control.

The loss for the period was £0.5m (£0.4m: 2007/08) which was broadly in line with last year, but depressed by the Biomarker start up costs and initial low level sales. We are well placed to see our Biomarker business move into profitability over the second half with continued revenue growth.

Chairman and Chief Executive Officer Statement (continued)

+31%

Year on year growth
in Company revenues.

The corresponding loss per share figure for the Interim period was (7p) against (6p) for the previous year.

Despite the wider economic conditions the Directors consider that the Group's cash reserves, bolstered by the Novartis collaboration up-front cash payment, places the business in a strong position, which along with our growth prospects will allow the Company to take advantage of acquisition opportunities which may present themselves in such market conditions.

Operational Review

Contract Research Services experienced steady growth over the first half with oncology services including cancer stem cells and angiogenesis receiving the strongest interest. Revenues in support of the US National Institutes of Health (NIH) showed increases from a widening in the scope of work undertaken. The early signs are that the recent change in US administration appears to have strengthened support for the likely extension of the NIH biodefence programme.

Following the commercial launch of the new hair Biomarker division at the beginning of this financial year, business opportunities have accelerated over the first half with contracts now underway with a select group of top tier pharmaceutical companies. Business contracts cover both preclinical and clinical biomarker studies with companies using the technology to better understand the drug-induced molecular expression change in treated subjects as a PD/PK (Pharmacodynamic/ Pharmacokinetic) biomarker.

Whilst still in the early stages of technical and commercial development, successful clinical results are expected to further accelerate its growth as a personalised biomarker of drug effect.

The recent announcement of our Novel Therapies collaboration with Novartis will identify new drug targets across a variety of disease areas. The collaboration combines Epistem's stem cell expertise and drug discovery programme, designed to identify the body's own key regulators of epithelial stem cells, with Novartis's insights into disease pathways & bioinformatics and drug development. The collaboration will select the best targets within these pathways for the development of new drug candidates. In addition, Epistem's preclinical models will be used to test efficacy and identify the role and mechanism of action of Novartis compounds.

Strategy

The Board believes that the next phase of Epistem's growth will see the Company transition into a profitable and cash generative company. In addition we will consider complementary acquisitions of technology and business opportunities in order to continue to deliver attractive growth. The Board believes that Epistem's business model, recently strengthened by the Novartis collaboration, differentiates Epistem within the biotech sector as a lower risk investment proposition with significant growth potential.

Cash reserves in the Company remain healthy at £1.2m, which excludes the recently announced \$4.0m upfront cash payment receivable from Novartis.

Outlook

We anticipate continued growth and increasing revenues over the second half of the current year across each of our operating divisions. This growth will include a mix of accelerated revenue growth in Biomarkers and more modest growth across our Contract Research Services. Our Novel Therapies collaboration will see the advancement in development of our lead targets and therapeutics with Novartis in order to accelerate our identification of the key stem cell regulators. The revenue growth forecast in the second half of the current year is expected to move the Company towards profitability.

With an upbeat outlook, we will also look to build on our platform strength by acquiring complementary technologies and groups as opportunities arise.

The Company is committed to maintaining its policy of employee share ownership and we will be introducing an employee share investment plan to encourage share ownership of the Company.

We believe that our heritage in stem cells, growing international status and expertise will enable us to exploit the rapidly growing stem cell and regenerative medicine industry.

The Board of Epistem remains convinced that the Group is well placed to deliver increased shareholder value in the medium term based on its current performance and the increased value opportunities now emerging.

David Evans
Chairman
10 March 2009

Matthew Walls
Chief Executive Officer

Consolidated Income Statement

For the six months ended 31 December 2008

	Six months to 31 Dec 2008 (unaudited) £'000	Six months to 31 Dec 2007 (unaudited) £'000	Year ended 30 June 2008 (audited) £'000
Revenue	1,453	1,106	2,065
Contract costs	(1,221)	(725)	(1,509)
Discovery and development costs	(389)	(526)	(1,071)
General administrative costs	(487)	(416)	(933)
Operating loss	(644)	(561)	(1,448)
Interest receivable	36	47	128
Interest payable and similar charges	(7)	(7)	(13)
Loss on ordinary activities before taxation	(615)	(521)	(1,333)
Tax credit on loss on ordinary activities	95	95	179
Loss for the financial period	(520)	(426)	(1,154)
Loss per share (pence)	(7)p	(6)p	(17)p

Consolidated Statement of Changes in Equity

For the six months ended 31 December 2008

	Share Capital £'000	Share Premium Account £'000	Share Options Reserve £'000	Reverse Acquisitions Reserve £'000	Profit and Loss Account £'000	Total £'000
At 1 July 2007	98	7,402	454	(2,484)	(2,872)	2,598
Allotment of ordinary shares	10	1,055	–	–	–	1,065
Share issue costs	–	(20)	–	–	–	(20)
Recognition of equity settled share-based payments in the period	–	–	55	–	–	55
Loss for period	–	–	–	–	(426)	(426)
At 31 December 2007	108	8,437	509	(2,484)	(3,298)	3,272
Recognition of equity settled share-based payments in the period	–	–	38	–	–	38
Loss for period	–	–	–	–	(728)	(728)
At 30 June 2008	108	8,437	547	(2,484)	(4,026)	2,582
Allotment of ordinary shares	–	9	–	–	–	9
Recognition of equity settled share-based payments in the period	–	–	45	–	–	45
Loss for period	–	–	–	–	(520)	(520)
At 31 December 2008	108	8,446	592	(2,484)	(4,546)	2,116

Consolidated Balance Sheet

As at 31 December 2008

	31 Dec 2008 (unaudited) £'000	31 Dec 2007 (unaudited) £'000	30 June 2008 (audited) £'000
Non-current assets			
Intangible assets	53	57	55
Plant and equipment	403	348	352
	456	405	407
Current assets			
Trade and other receivables	725	516	437
Tax receivables	270	255	175
Cash and cash equivalents	1,240	2,612	2,143
	2,235	3,383	2,755
Liabilities			
Current liabilities			
Trade and other payables	471	347	428
Obligations under finance leases	49	68	41
Bank overdrafts and loans	–	–	25
	520	415	494
Net current assets	1,715	2,968	2,261
Total assets less current liabilities	2,171	3,373	2,668
Non-current liabilities			
Obligations under finance leases	(55)	(101)	(86)
Net assets	2,116	3,272	2,582
Capital and reserves			
Called-up equity share capital	108	108	108
Share premium account	8,446	8,437	8,437
Share options reserve	592	509	547
Reverse acquisition reserve	(2,484)	(2,484)	(2,484)
Profit and loss account	(4,546)	(3,298)	(4,026)
Total shareholders' equity	2,116	3,272	2,582

Consolidated Statement of Cash Flows

For the six months ended 31 December 2008

	31 Dec 2008 (unaudited) £'000	31 Dec 2007 (unaudited) £'000	30 June 2008 (audited) £'000
Cash flows from operating activities			
Loss for the period	(644)	(561)	(1,448)
Depreciation, amortisation and impairment	59	50	106
Share-based payment expense	45	55	93
Operating loss before changes in working capital and provisions	(540)	(456)	(1,249)
(Increase)/decrease in trade and other receivables	(288)	(159)	(80)
(Decrease)/increase in trade and other payables	43	(48)	33
Cash generated from operations	(785)	(663)	(1,296)
Interest paid	(7)	(7)	–
Interest received	36	47	128
Tax received	–	–	165
Net cash outflow from operating activities	(756)	(623)	(1,003)
Cash flows from investing activities			
Acquisition of property, plant and equipment	(108)	(28)	(86)
Net cash outflow from investing activities	(108)	(28)	(86)
Cash flows from financing activities			
Proceeds from issue of share capital	9	1,065	1,065
Expenses of share issue	–	(20)	(20)
Repayment of borrowings	(23)	(48)	(104)
Net cash (outflow)/inflow from financing activities	(14)	997	941
Net increase/(decrease) in cash equivalents	(878)	346	(148)
Cash and cash equivalents at beginning of period	2,118	2,266	2,266
Cash and cash equivalents at end of period	1,240	2,612	2,118
Analysis of Net Funds			
Cash at bank and in hand	1,240	2,612	2,143
Bank overdrafts	–	–	(25)
Net Funds	1,240	2,612	2,118

Notes to the Interim Financial Statements

Six months ended 31 December 2008

1. Significant accounting policies

Basis of accounting

The interim financial statements have been prepared under the historical cost convention, in accordance with applicable accounting standards in particular International Financial Reporting Standards as adopted by the EU ('Adopted IFRSs').

Epistem Holdings Plc is a company incorporated in the UK.

These interim financial statements have not been audited and do not constitute statutory accounts within the meaning of section 435 of the Companies Act 2006.

The comparative figures for the financial year ended 30 June 2008 are not the statutory accounts for the financial year but are abridged from those accounts which have been reported on by the Group's auditors and delivered to the Registrar of Companies. The report of the auditors was unqualified.

These interim financial statements were approved by the Board of Directors on 10 March 2009.

The accounting policies set out below have, unless otherwise stated, been applied consistently to all periods represented in these consolidated financial statements.

Basis of consolidation

The consolidated financial statements consolidate those of the Company and its subsidiary (together referred to as the 'Group').

Subsidiaries are entities controlled by the Group. The financial statements of subsidiaries are included in the consolidated financial statements from the date that control commences until the date that control ceases. Transactions between Group companies are eliminated on consolidation.

On 16 March 2007, Epistem Holdings Plc merged with Epistem Limited, when the shareholders of Epistem Limited exchanged their shares for equivalent shares in Epistem Holdings Plc. As Epistem Holdings Plc was newly incorporated at the time of the transaction under the terms of IFRS 3 'Business Combinations', this transaction has been accounted for as a reverse acquisition, on the basis that the shareholders of Epistem Limited gained a controlling interest in the Group. The financial statements therefore represent a continuation of the financial statements of Epistem Limited.

Revenue recognition

The Company generally invoices and reports as sales 50% of the value of a new contract on signature. This policy is designed to recognise that, in negotiating contracts for new studies, the Company performs specific pre-contract work to establish the parameters of the study work. When the final report is issued to the client, the remainder of the contract is invoiced and recognised as income, at that date. In other cases where the contract does not provide for income recognition on signature, revenue is recognised as the work is invoiced.

Segment reporting

A segment is a group of assets, liabilities and operations engaged in providing products or services that are subject to risks and returns that are different from those of other parts of the business. The Group's primary format for segment reporting is based on business segments.

Research and development

Research and development expenditure is written off in the year in which it is incurred.

Share-based payments

The Group issues equity settled and cash settled share-based payments to certain employees (including directors). Equity settled share-based payments are measured at fair value at the date of grant. The fair value determined at the grant date of the equity settled share-based payments is expensed on a straight-line basis over the vesting period, together with a corresponding increase in equity, based upon the Group's estimate of the shares that will eventually vest.

Fair value is measured using the Black-Scholes pricing model. The expected life used in the model has been adjusted, based on management's best estimate, for the effects of non-transferability, exercise restrictions and behavioural considerations.

Where the terms of an equity settled transaction are modified, as a minimum an expense is recognised as if the terms had not been modified. In addition, an expense is recognised for any increase in the value of the transaction as a result of the modification, as measured at the date of modification.

Where an equity settled transaction is cancelled, it is treated as if it had vested on the date of the cancellation, and any expense not yet recognised for the transaction is recognised immediately. However, if a new transaction is substituted for the cancelled transaction, and designated as a replacement transaction on the date that it is granted, the cancelled and new transactions are treated as if they were a modification of the original transaction, as described in the previous paragraph.

Notes to the Interim Financial Statements (continued)

Six months ended 31 December 2008

2. Segment information

	Contract Research Services £'000	Bio- markers £'000	Novel Therapies £'000	Unallocated Expenses £'000	Total £'000
Six months ending 31 December 2008					
Revenue	1,123	330	–	–	1,453
Segment trading result	267	15	(364)	(458)	(540)
Less depreciation and amortisation	(18)	(11)	(23)	(7)	(59)
Less equity settled share-based payments	(13)	(8)	(2)	(22)	(45)
Operating profit/loss	236	(4)	(389)	(487)	(644)
Six months ending 31 December 2007					
Revenue	1,106	–	–	–	1,106
Segment trading result	409	–	(478)	(387)	(456)
Less depreciation and amortisation	(15)	–	(28)	(7)	(50)
Less equity settled share-based payments	(14)	–	(19)	(22)	(55)
Operating profit/loss	380	–	(525)	(416)	(561)
Twelve months ending 30 June 2008					
Revenue	2,065	–	–	–	2,065
Segment trading result	606	–	(980)	(875)	(1,249)
Less depreciation and amortisation	(32)	–	(60)	(14)	(106)
Less equity settled share-based payments	(19)	–	(31)	(43)	(93)
Operating profit/loss	555	–	(1,071)	(932)	(1,448)

Notes



Notes

Directors, Secretary and Advisers

Directors

David Evans
Matthew Walls
Christopher Potten
Catherine Booth
Gerard Brady
Roger Lloyd
Jeffrey Moore
Robert Nolan
John Rylands

Company Secretary

John Rylands

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epistem

Controlling life-long tissue renewal



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