epistem

Advancing technologies

Epistem Holdings Plc
Interim Report 2012

Highlights

- Year-on-year revenue of £3.1m (£3.1m: 2011/12)
- Announcement of supply and distribution agreement with Becton Dickinson and increased investment in diagnostics (Genedrive®)
- First half growth in the Personalised Medicine division
- Steady performance from Preclinical Services
- Continued advance and investment in our Novel Therapies drug discovery programme
- Cash placing raising £4.2m (net) contributed towards strong cash position of £7.3m

Progress

1

Progress
Preparing first Epistem products for launch.

2

Innovation
New preclinical research models in inflammation and imaging.

3

Growth
Strengthened growth in our personalised medicine division.

4

Diversity
Portfolio of license, fee-for-service, product and collaborative revenues.

About Us

Epistem is a biotechnology and personalised medicine company commercialising its expertise in epithelial stem cells and infectious disease.

Epistem develops innovative therapeutics, biomarkers and diagnostics alongside providing preclinical research services for drug development companies.

The Group's core expertise comprises a detailed understanding of the regulation of adult stem cells and novel and proprietary next generation molecular tools for use in personalised medicine.

Contents

For more information visit:
www.epistem.co.uk

What We Do

Preclinical Research Services

Personalised Medicine

Novel Therapeutics

Preclinical Services

The Preclinical Services division provides specialised preclinical efficacy services primarily for drug development companies. The division operates a 'fee for service' model and is cash-generative and profitable. Our Preclinical Services division has a well established record of providing a specialist range of testing services to major pharmaceutical and biotechnology companies globally.

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

- Cancer and cancer supportive care (mucositis);
- Inflammation and inflammatory bowel disease;
- UV-induced skin damage;
- Wound healing, skin and hair disorders.

Personalised Medicine: Biomarkers

Our Biomarker division provides highly sensitive RNA molecular measures of biological processes that improve the precision to guide drug development and disease treatment. The Group provides a broad technology offering to discover, develop and translate biomarkers for clinical drug development. We work closely with top-tier pharmaceutical groups to better understand drug-induced gene expression change in clinical subjects following treatment.

We are also using our DNA amplification technologies to identify disease markers and other gene mutations to help stratify patients for the most effective drug treatment.

Personalised Medicine: Diagnostics

Our Molecular Diagnostic division is changing the way healthcare and personalised medicine are delivered at the 'point of care'. We are also developing advanced approaches to provide molecular measures of identification outside of healthcare in 'point of need' settings.

We are now completing the development of our Genedrive® 'Point of Care' molecular diagnostic device ready for its launch into the TB market. Genedrive® can provide a 'near patient' molecular diagnosis in less than 30 minutes. Rapid, sensitive, accurate testing offers to revolutionise the field of medical diagnosis by enabling diagnostic testing to be made available at minimal cost.

Novel Therapies

The Novel Therapies division is discovering the body's own key regulators of epithelial stem cells and tissues. Based on our highly sensitive molecular techniques and core cell biology expertise, we discover and develop our own novel drug agents.

Our Novel Therapies division continues to develop our regenerative medicine and oncology leads. We are identifying the key regulators of stem cells and epithelial cell production with the primary focus to discover new drug leads across major epithelial diseases and to expand our technology and commercial discussions with collaborative partners.

Chairman and Chief Executive Officer Statement

Despite difficult economic trading conditions, Epistem continues to strengthen its core business units and advance its globally leading technologies. First half year-on-year revenues were broadly in line with the previous year at £3.1m (£3.1m: 2011/12), with a reported operating loss of £0.3m (£0.5m loss: 2011/12) reflecting a trading position which continues to largely offset our investment in our Personalised Medicine and Novel Therapies divisions.

The announcement in August 2012 of our supply and distribution agreement with Becton Dickinson and preparation for the launch of our first commercial product continues to raise the profile of our business alongside our leading biomarker, preclinical research services and drug development programmes. The $1m Becton Dickinson upfront payment is expected to be recognised in the second half of the current financial year.

This interim report covers the six-month period from 1 July 2012 to 31 December 2012.

Overview
Results for the first six months delivered revenues of £3.1m (£3.1m: 2011/12), driven by a step up in our Personalised Medicine revenues (Biomarker and Diagnostics) and a steady year-on-year Preclinical Services revenue performance which, together with the increasing investment in our diagnostics technology (Genedrive®) and our Novel Therapies drug leads, produced a reduced operating loss for the first half of £0.3m (£0.5m loss: 2011/12).

Preclinical Services
First half Preclinical Services revenues remained broadly in line with last year at £1.3m (£1.4m: 2011/12). The pharmaceutical and biotechnology industry continues to see much change and volatility across the sector with resulting caution and delay in contract closures. Despite the general market uncertainty, the division maintains a competitive niche assay offering strong business relationships, especially in relation to our Biodefence collaboration with the US National Institutes of Health (NIH).

Personalised Medicine
Biomarkers
Following the significant step up in last year's revenues, Biomarkers maintained a solid performance over the first half buoyed by our GSK biomarker collaboration and a non-recurring payment of £0.6m from the Sanofi Aventis collaboration. The Group also saw a strengthening in demand for its oncology mutations identification assays. First half Biomarker revenues were £1.3m (£1.3m 2011/12).

Diagnostics
The announcement of the supply and distribution agreement with Becton Dickinson marks the beginning of our preparation for the launch of our Genedrive® TB product. Scale up preparations, testing and market readiness for the Genedrive® unit and assay have commenced, with the unit and assays to be placed with 'Key Opinion Leaders' over the coming months.

We are completing our clinical studies in India and making final preparations for our regulatory submission to the Indian regulator to enable the sale of our Tuberculosis tests in India and the Indian sub-continent. The Indian regulatory submission is expected in May 2013. First half diagnostics revenues were £0.5m primarily relating to development payments from the US Department of Defence.

Our Novel Therapies division continues to advance its discovery and development programmes around identified novel regulators of epithelial tissue. Discussions are continuing with prospective parties around licensing and development opportunities for our novel hits/leads in both regenerative medicine and oncology. Collaborative discussions are also continuing with prospective co-development partners.

Revenue growth continues to remain key to de-risking our business model alongside the development of our leading technologies. The diversity of our business portfolio enables flexibility to help manage the differing speeds of growth, investment requirements and development timescales for each of our business divisions. We remain excited by the strength of opportunity our technology presents.

Financial Review
Sales revenues from business operations for the first six months of the current financial year were £3.1m (£3.1m: 2011/12).

Preclinical Services first half revenues remained roughly in line with last year, with the emerging growth in Personalised Medicine (Biomarkers and Diagnostics) delivering the major upside over the first half. We expect our Personalised Medicine revenues to be bolstered further with the launch of our first Genedrive® product in Tuberculosis, which should further support the revenue outlook for the Group.

Year-on-year contract costs were marginally reduced over the first half reflecting the slightly lower operational costs. We seek to carefully control the investment in our business divisions to accelerate our technology and drug development programmes, whilst balancing this against the strengthening trading performance of the Group. Overall the Company reported an operating loss of £0.3m (£0.5m: 2011/12) for the first half, which continues to reflect the targeted investment we are making across our business.

The corresponding basic loss per share figure for the first half was (2.6)p (2011/12: (4.8)p).

Following the successful cash placing of £4.2m (net) in December 2012, the first half cash reserves at the 31 December 2012 were £7.3m (£4.7m: 30 June 2012).

Operational Review
Preclinical Services continues to develop its core service offering and scientific expertise in preclinical efficacy testing to deliver an improved and extended range of new competitive models in imaging and inflammation. We anticipate a steady level of performance from this division over the second half, reflecting the cautious climate and changing industry dynamics affecting our customer base. Both our US and EU territories saw flat first half revenue performance enabling the division to deliver broadly similar year-on-year revenues. Our collaboration as part of the US NIH biodefence programme continues to strengthen.

£3.1m
Revenue

Chairman and Chief Executive Officer Statement (continued)

Personalised Medicine

Biomarker

The Biomarker division maintained its step up in last year's revenue into the first half of this financial year supported by a strengthening in the GSK fibrosis collaboration along with a 'one off' payment related to the completion of biomarker programmes under the Sanofi-Aventis biomarker collaboration. We are continuing to develop collaborations with a number of pharma partners targeting biomarkers of drug effect for key oncology pathways. The first half also saw an increase in demand for pharmacogenomic assays for the identification of oncology mutations and patient stratification markers, greatly enhanced by their prospective use with Genedrive®. We expect our collaborations to expand further over the coming year, providing biomarkers of drug effect and markers of disease progression and anticipate an ongoing strong performance from our Biomarker division over the second half.

Diagnostics

Test preparations for the launch of our first diagnostic product are underway with Becton Dickinson and Xcelris labs. Scale up of the Genedrive® unit and assays has also commenced with the first production ready units now received alongside our first production assays which are going through their final testing prior to placing in the field. Extensive testing is ongoing to test 'batch to batch' unit and assay consistency/variability and to complete our clinical work in India. The programme of testing is likely to continue over the coming months alongside the introduction of the unit and assays to 'Key Opinion Leaders' for diagnostic use and further field testing.

Whilst the launch of our TB assay remains our prime focus, other Genedrive® infectious disease assay developments are continuing around malaria, dengue, HCV and HIV (viral panels). Biosurveillance and pathogen identification work is also ongoing with the US Department of Defence.

The Novel Therapies division continues to develop and characterise its novel hits/leads and is currently in discussions with a number of groups around the next phase of development for its leads. These discussions range from funding opportunities through to co-development of our lead candidates in regenerative medicine and oncology.

Strategy

Epistem remains focused on strengthening its revenues and advancing our globally-leading technologies and scientific expertise to continue to deliver increased shareholder value. Where appropriate, we will consider the acquisition of new technologies and businesses to complement our growth strategy.

The Board believes that Epistem's growing business model differentiates us within the sector as a lower risk investment proposition with significant upside potential.

Outlook

Over the second half of the current financial year, we expect to see Preclinical Services maintain its steady revenue position which, alongside our anticipated first Genedrive® product sales in Tuberculosis and the prospect of further product and milestone payments, should rapidly advance our Personalised Medicine division. Novel Therapies discussions will continue across a group of partners, but the timing, duration and outcome of these discussions remains uncertain.

We remain committed to developing our technology, expertise and heritage in stem cells and to extending our international profile in scientific excellence across the pharmaceutical, diagnostic and regenerative medicine industries.

The Board remains confident that the Group is well placed to deliver increasing shareholder value based on its current performance and on the opportunities now emerging.

David Evans
Non-executive Chairman

Matthew Walls
Chief Executive Officer
26 March 2013

Consolidated Statement of Comprehensive Income

For the six months ended 31 December 2012

	Six months ended 31 December 2012 (unaudited) £'000	Six months ended 31 December 2011 (unaudited) £'000	Year Ended 30 June 2012 (audited) £'000
Revenue	**3,051**	3,055	5,560
Contract costs	**(2,290)**	(2,515)	(4,112)
Discovery and development costs	**(400)**	(395)	(996)
General administrative costs	**(705)**	(688)	(1,287)
Operating (loss)	**(344)**	(543)	(835)
Finance income	**15**	7	109
Finance costs	**–**	–	–
(Loss) on ordinary activities before taxation	**(329)**	(536)	(726)
Taxation on ordinary activities	**80**	145	482
Total comprehensive income for the financial period	**(249)**	**(391)**	**(244)**
(Loss) per share (pence)			
- Basic	**(2.6)p**	(4.8)p	(2.9)p
- Diluted	**(2.6)p**	(4.8)p	(2.9)p

Consolidated Statement of Changes in Equity

For the six months ended 31 December 2012

	Share capital £'000	Share premium account £'000	Employee share incentive plan reserve £'000	Share options reserve £'000	Reverse acquisitions reserve £'000	Retained earnings £'000	Total £'000
Balance at 1 July 2011	119	11,206	(88)	691	(2,484)	(3,262)	6,182
Allotment of ordinary shares	12	2,765	–	–	–	–	2,777
Share issue costs	–	(56)	–	–	–	–	(56)
Exercise of options	2	77	–	(12)	–	12	79
Purchase of own shares (SIP)	–	–	(25)	–	–	–	(25)
Recognition of equity-settled share-based payments	–	–	–	84	–	–	84
Total comprehensive income for the period	–	–	–	–	–	(391)	(391)
At 31 December 2011	133	13,992	(113)	763	(2,484)	(3,641)	8,650
Purchase of own shares (SIP)	–	–	(23)	–	–	–	(23)
Share issue costs adjustment	–	(4)	–	–	–	–	(4)
Exercise of options	–	19	–	(2)	–	(12)	5
Lapse of options	–	–	–	(1)	–	1	–
Recognition of equity-settled share-based payments	–	–	–	87	–	–	87
Total comprehensive income for the period	–	–	–	–	–	147	147
At 30 June 2012	133	14,007	(136)	847	(2,484)	(3,505)	8,862
Allotment of ordinary shares	11	4,313	–	–	–	–	4,324
Share issue costs	–	(140)	–	–	–	–	(140)
Exercise of options	1	18	–	(7)	–	7	19
Purchase of own shares (SIP)	–	–	(15)	–	–	–	(15)
Recognition of equity-settled share-based payments	–	–	–	87	–	–	87
Total comprehensive income for the year	–	–	–	–	–	(249)	(249)
At 31 December 2012	**145**	**18,198**	**(151)**	**927**	**(2,484)**	**(3,747)**	**12,888**

Consolidated Balance Sheet

As at 31 December 2012

	31 December 2012 (unaudited) £'000	31 December 2011 (unaudited) £'000	30 June 2012 (audited) £'000
Non-current assets			
Intangible assets	**2,611**	1,256	2,189
Plant and equipment	**534**	547	573
Deferred taxation	**1,082**	665	1,002
	4,227	2,468	3,764
Current assets			
Trade and other receivables	**2,956**	2,321	1,978
Tax receivables	**46**	117	41
Cash and cash equivalents	**7,332**	5,255	4,684
	10,334	7,693	6,703
Liabilities			
Current liabilities			
Deferred income	**677**	17	198
Trade and other payables	**996**	1,414	1,407
	1,673	1,431	1,605
Net current assets	**8,661**	6,262	5,098
Total assets less current liabilities	**12,888**	8,730	8,862
Non-current liabilities			
Liabilities payable 1 - 5 years	**–**	(80)	–
Net assets	**12,888**	**8,650**	**8,862**
Capital and reserves			
Called-up equity share capital	**145**	133	133
Share premium account	**18,198**	13,992	14,007
Employee share incentive plan reserve	**(151)**	(113)	(136)
Share options reserve	**927**	763	847
Reverse acquisition reserve	**(2,484)**	(2,484)	(2,484)
Retained earnings	**(3,747)**	(3,641)	(3,505)
Total shareholders' equity	**12,888**	**8,650**	**8,862**

Consolidated Statement of Cash Flows

For the six months ended 31 December 2012

	31 December 2012 (unaudited) £'000	31 December 2011 (unaudited) £'000	30 June 2012 (audited) £'000
Cash flows from operating activities			
Operating (loss) for the year	**(344)**	(543)	(835)
Depreciation, amortisation and impairment	**243**	96	193
Share-based payment expense	**87**	84	171
Operating loss before changes in working capital and provisions	**(14)**	(363)	(471)
(Increase) in trade and other receivables	**(978)**	(411)	(68)
Increase/(decrease) in deferred income	**479**	(58)	123
(Decrease) in trade and other payables	**(411)**	(33)	(40)
Net cash (outflow) from operations	**(924)**	(865)	(456)
Finance costs	**–**	–	–
Interest received	**15**	7	109
Tax received	**(5)**	–	76
	10	7	185
Net cash (outflow) from operating activities	**(914)**	(858)	(271)
Cash flows from investing activities			
Acquisition of fixed assets	**(626)**	(257)	(1,313)
Net cash outflow from investing activities	**(626)**	(257)	(1,313)
Cash flows from financing activities			
Proceeds from issue of share capital	**4,324**	2,777	2,861
Expenses of share issue	**(140)**	(56)	(60)
Exercise of share options	**19**	79	
Purchase of own shares	**(15)**	(25)	(48)
Increase/(decrease) in borrowings	**–**	(25)	(105)
Net cash inflow from financing activities	**4,188**	2,750	2,648
Net increase in cash equivalents	**2,648**	1,635	1,064
Cash and cash equivalents at beginning of year	**4,684**	3,620	3,620
Cash and cash equivalents at end of year	**7,332**	**5,255**	**4,684**
Analysis of net funds			
Cash at bank and in hand	7,332	5,255	4,684
Net funds	**7,332**	**5,255**	**4,684**

Notes to the Interim Results
to 31 December 2012

A. Business segments

	Preclinical Services £'000	Personalised Medicine £'000	Novel Therapies £'000	Unallocated £'000	Total £'000
Six months ended 31 December 2012					
Revenue	1,252	1,799	–	–	3,051
Segment trading result	348	619	(356)	(625)	(14)
Less depreciation and amortisation	(57)	(128)	(43)	(15)	(243)
Less equity-settled share-based payments)	(5)	(16)	(1)	(65)	(87)
Operating profit/(loss)	**286**	**475**	**(400)**	**(705)**	**(344)**
Six months ended 31 December 2011					
Revenue	1,403	1,652	–	–	3,055
Segment trading result	395	222	(370)	(610)	(363)
Less depreciation and amortisation	(36)	(24)	(24)	(12)	(96)
Less equity-settled share-based payments	(2)	(15)	(1)	(66)	(84)
Operating profit/(loss)	**357**	**183**	**(395)**	**(688)**	**(543)**
Twelve months ended 30 June 2011					
Revenue	2,895	2,665	–	–	5,560
Segment trading result	856	503	(700)	(1,130)	(471)
Less depreciation and amortisation	(68)	(48)	(52)	(25)	(193)
Less equity-settled share-based payments	(6)	(31)	(2)	(132)	(171)
Operating profit/(loss)	**782**	**424**	**(754)**	**(1,287)**	**(835)**

B. Earnings per share

Basis of Calculation

The basic earnings per share is calculated by dividing the earnings attributable to ordinary shareholders for the year by the weighted average number of ordinary shares in issue during the year.

The weighted average number of shares in issue during the period was 9,565,772 (2011: 8,095,560).

Notes to the Interim Financial Statements

Six months ended 31 December 2012

1. General information

The interim financial statements have been prepared in accordance with International Financial Reporting Standards ('IFRS') as adopted by the European Union and therefore comply with Article 4 of the EU IAS Regulation, International Financial Reporting Interpretations Committee ('IFRIC') interpretations and with those parts of the Companies Act 2006 applicable to companies reporting under IFRS.

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 2012 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 25 March 2013.

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

2. Significant accounting policies

Basis of consolidation

The consolidated financial statements consolidate those of the Company and its subsidiaries (together referred to as the 'Group'). They are presented in pounds sterling and all values are rounded to the nearest one thousand pounds (£k) except where otherwise indicated.

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

a. Contract revenue

Contract revenue is recognised by reference to the stage of completion of the transaction at the end of the reporting period.

b. Collaboration and licensing revenue

Contractually agreed upfront payments and similar non-refundable payments in respect of collaboration or licence agreements which are not directly related to on-going research activity are recorded as deferred income and recognised as revenue over the anticipated duration of the agreement. Where the anticipated duration of the agreement is modified, the period over which revenue is recognised is also modified.

Non-refundable milestone and other payments that are linked to the achievement of significant and substantive technological or regulatory hurdles in the research and development process are recognised as revenue upon the achievement of the specified milestone.

Income which is related to on-going research activity is recognised as the research activity is undertaken, in accordance with the contract.

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 expenditure is written off as it is incurred. Development expenditure is written off as it incurred up to the point of technical and commercial validation. Thereafter, costs are carried forward as intangible assets, subject to having met the following criteria – technical feasibility, intention and ability to sell the product or model and the availability of resources to complete the development. All intangible assets are subject to impairment review and amortisation in each financial reporting period. In assessing value in use, the estimated future cash flows are discounted to their net present values using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to that asset.

Intangible assets
Intangible assets are stated at cost less accumulated amortisation and any accumulated impairment losses. Amortisation is calculated so as to write off the cost of an intangible asset, less its estimated residual value, over the useful economic life of that asset.

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

Notes

Notes

Directors, Secretary and Advisers

Directors
David Evans
Matthew Walls
Catherine Booth
Roger Lloyd
Jeffrey Moore
Robert Nolan
John Rylands

Company Secretary
John Rylands

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