



## Highlights

- Year-on-year revenue growth to £3.1m
- Significant first half growth in the Personalised Medicine division
- Strengthening biomarkers collaboration with Sanofi-Aventis and recent announcement of new biomarker collaboration with GSK
- Increased investment in diagnostics (Genedrive™) and recent announcement of tuberculosis sales and marketing ‘channel partner’
- Continued advance and investment in our Novel Therapies drug discovery programme
- Cash placing raising £2.8m net contributed towards strong cash position of £5.3m

## Progress

Division	Field	Area of Income	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Market			
Contract Research Services	Inflammatory bowel disease, dermatology, oncology, mucositis	Fee for service									
Novel Therapies	Discovery hits/leads and early stage development	Partnering and licensing									
Personalised Medicine	Preclinical, clinical and market programmes	Fee for service, partnering, licensing, product sales									
			<b>RNA Amp™</b>				<b>Genedrive™</b>				
			Gene target identification and validation								Gene marker monitoring
							PD/PK marker	Clinical effect marker	Patient stratification	Treatment effect marker	
			Identify gene targets	Establish gene set	HNV and initial clinical translation	Confirm gene set against drug induced response				Identify patient responders/non-responders (pattern recognition)	Therapeutic biomarker (health monitoring)
											Screening biomarker for predisposition to drug/class of drug

## About Us

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Epistem is a biotechnology and personalised medicine company commercialising its expertise in stem cells in the areas of epithelial tissue and diagnosis of infectious diseases.

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

The Group's technical expertise comprises a detailed understanding of core **cell biology** and the regulation of adult stem cells located in epithelial tissue including the gastrointestinal tract, skin, hair follicles, breast and prostate and **molecular biology** utilising novel and proprietary next generation molecular tools (DNA and RNA amplification) for use in personalised medicine.

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## What We Do: Contract Research Services, Personalised Medicine and Novel Therapeutics

### Contract Research Services



The Contract Research 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 Contract Research 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
- Cancer supportive care (Mucositis)
- Inflammatory bowel disease
- UV-induced skin damage
- Wound healing
- Skin and hair disorders

# 101%

of prior year revenues

### Personalised Medicine Biomarkers



Our Biomarker division provides highly sensitive molecular measure 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.

Our biomarker 'onco-pathway' libraries assist in identifying biomarkers that are expressed as a result of treatment with oncology drugs. We work closely with top-tier pharmaceutical groups to better understand drug-induced gene expression change in clinical subjects following treatment.

# 431%

of prior year revenues

## 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 at 'point of need' settings.

We are now completing the development of our Genedrive™ point of care molecular diagnostic device. Genedrive™ is targeting providing a 'near patient' molecular diagnosis in less than 30 minutes. Rapid, sensitive, accurate testing offers to revolutionise the field of medical diagnosis by enabling viral, pathogen and gene mutation diagnosis to be made available at minimal cost.

# In Clinical Trials

## 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.

# In Development

## Chairman and Chief Executive Officer Statement



Set against a climate of difficult and uncertain macro economic conditions, Epistem has continued to make solid progress in the development of its core business and the diversification of its technologies. First half year-on-year revenues increased to £3.1m, with a reported operating loss of £0.5m reflecting the ongoing development and investment in our Personalised Medicine and Novel Therapies divisions.

The recent announcement of our Tuberculosis sales and marketing agreement with Xcelris Labs of India and a new biomarker collaboration with GSK, continue to build and diversify our commercial strengths whilst at the same time we have been advancing our leading diagnostic and drug development programmes.

This interim report covers the six-month period from the 1 July 2011 to 31 December 2011.

### Overview

Results for the first six months showed year-on-year revenue marginally increased to £3.1m (£3.0m: 2010/11), largely driven by a step up in our Personalised Medicine revenues (Biomarker and Diagnostics), which together with the increasing investment in our diagnostics technology (Genedrive™) and continuing development of our Novel Therapies drug leads gave rise to an operating loss for the first half of £0.5m (£0.1m profit: 2010/11).

### Contract Research Services

Contract Research Services revenues remained steady over the first half at £1.4m (£1.4m: 2010/11). Structural changes across the pharmaceutical and biotechnology industry have created increased volatility within the sector and some corresponding contract delays. Despite the general market uncertainty, the division holds a strong competitive position and business relationships with our customers, including the US NIH, continue to strengthen.



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### Personalised Medicine

**Biomarker** – The biomarker division picked up momentum over the first half, helped by the Sanofi-Aventis biomarker collaboration announced in March 2011 and our growing relationship in support of their oncology preclinical-clinical translational medicine programme. The recently signed 3-year lung fibrosis collaboration with GSK will further bolster our biomarker position. Biomarker revenues stepped up significantly over the first half to £1.3m (£0.4m: 2010/11).

**Diagnostics** – The announcement of the Xcelris Labs tuberculosis collaboration earlier this month marks the first major collaboration for our proprietary Genedrive™ technology. Genedrive™ is now being tested across a range of disease areas and we expect our Tuberculosis assay to move towards the regulatory approval process over the coming months. First half diagnostics revenues were £0.3m largely relating to development and technology evaluation revenues.

### Novel Therapies

Our Novel Therapies discovery and development programme continues to advance around identified novel regulators of epithelial tissue. Discussions continue with prospective parties around licensing opportunities for our novel hits/leads in both regenerative medicine and oncology. Collaborative discussions are expected to continue over the coming months.

Revenue growth remains key to de-risking our business model alongside the development of our leading technologies. The diversity of our business portfolio provides some flexibility to help manage the differing speeds of growth, investment and development for each of our business divisions and we remain excited by the prospects of our core technologies.

### Financial Review

Sales revenues from business operations for the six months of the current financial year were £3.1m (£3.0m: 2010/11), a year-on-year increase of £0.1m.

Contract Research Services first half revenues remained broadly in line with last year, with the growth in Personalised Medicine (Biomarkers and Diagnostics) showing the greatest divisional increase over the first half. Personalised Medicine revenue growth offset the year-on-year absence of Novel Therapies revenues related to the Novartis funded drug discovery programme. The Diagnostics revenues which are starting to emerge should help further support the revenue outlook for the group. Demand over the period for our core scientific expertise and technology remained firm.

Contract costs increased in the first half, largely reflecting the increased business growth in Personalised Medicine. Measured and careful investment in our business divisions continues to accelerate our technology developments and maintain our drug development programmes. Overall the Company reported an operating loss of £0.5m (£0.1m: 2010/11) for the first half, which reflects the increased but targeted investment we are currently making across our business.

The corresponding basic earnings/(loss) per share figure for the first half was (4.8)p (2010/11: 0.9p).

Following a successful cash placing of £2.7m (net) in November 2011, the first half cash reserves at the 31 December 2011 were £5.3m (£3.6m: 30 June 2011).

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# Chairman and Chief Executive Officer Statement

(continued)

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## Operational Review

Contract Research Services continues to develop and strengthen its core biology and scientific expertise to deliver improved drug efficacy models to the highest level of quality and service. Following last year's step up in revenue growth and margins, we anticipate a reduced level of growth from this division over this financial year partly reflecting the structural changes affecting a number of our core customers. Overall, a steady first half revenue performance across the US and Europe allowed this division to deliver broadly similar year-on-year revenues. Our collaboration as part of the US NIH biodefence program continues to strengthen.

## Personalised Medicine Biomarker

Divisional growth improved significantly over the first half supported by the Sanofi-Aventis oncology biomarker programme. During the first year of the Sanofi-Aventis collaboration, we have built a close working relationship with the French and US teams to support the development and delivery of targeted biomarkers of drug effect for key oncology pathways. We have also recently announced a new biomarker collaboration with GSK in lung fibrosis. The GSK collaboration is expected to expand further over the coming years to provide both biomarkers of drug effect and markers of disease progression. We anticipate a solid performance from our biomarker division into the second half.

## Diagnostics

The announcement of the Xcelris Labs tuberculosis collaboration marks the first major contract and 'channel partner' for the newly created Diagnostic group using our next generation Genedrive™ device and ID™ assay technology. Genedrive™ is a molecular diagnostic device for near patient 'Point of Care' testing targeting a wide range of infectious diseases and biological mutations. Its simple sample preparation, low cost and rapid diagnosis (~30mins) across a broad spectrum of diseases is expected to change the way 'Point of Care' diagnostics tests are delivered. Genedrive™ is now undergoing testing across a range of infectious diseases, oncology mutations and biosurveillance applications with selected channel partners and the Company will make further announcements in due course.

The Novel Therapies division has made good progress in the development of its novel hits/leads over the first half. Discussions are ongoing with selected groups around the 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 technology 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 Contract Research Services maintain its steady revenue position alongside the advancement of 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 advancing our 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  
14 March 2012

## Matthew Walls

Chief Executive Officer

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# Consolidated Statement of Comprehensive Income

For the six months ended 31 December 2011

	Six months ended 31 Dec 2011 (unaudited) £000	Six months ended 31 Dec 2010 (unaudited) £000	Year ended 30 June 2011 (audited) £000
<b>Revenue</b>	<b>3,055</b>	2,978	5,752
Contract costs	(2,515)	(1,467)	(3,072)
Discovery and development costs	(395)	(646)	(979)
General administrative costs	(688)	(772)	(1,316)
<b>Operating (loss)/profit</b>	<b>(543)</b>	93	385
Finance income	7	11	18
Finance costs	-	(2)	(46)
<b>(Loss)/profit on ordinary activities before taxation</b>	<b>(536)</b>	102	357
Taxation on ordinary activities	145	(29)	28
<b>Total comprehensive income for the financial period</b>	<b>(391)</b>	<b>73</b>	<b>385</b>
<b>(Loss)/earnings per share (pence)</b>			
- Basic	(4.8)p	0.9p	4.9p
- Diluted	(4.8)p	0.8p	4.3p

## Consolidated Statement of Changes in Equity

For the six months ended 31 December 2011

	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 2010	119	11,206	(43)	633	(2,484)	(3,647)	5,784
Allotment of ordinary shares	-	-	-	-	-	-	-
Share issue costs	-	-	-	-	-	-	-
Purchase of own shares (SIP)	-	-	(23)	-	-	-	(23)
Exercise of options	-	-	-	-	-	-	-
Recognition of equity-settled share-based payments	-	-	-	6	-	-	6
Total comprehensive income for the period	-	-	-	-	-	73	73
At 31 December 2010	119	11,206	(66)	639	(2,484)	(3,574)	5,840
Purchase of own shares (SIP)	-	-	(22)	-	-	-	(22)
Recognition of equity-settled share-based payments	-	-	-	52	-	-	52
Total comprehensive income for the period	-	-	-	-	-	312	312
At 30 June 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 year	-	-	-	-	-	(391)	(391)
At 31 December 2011	133	13,992	(113)	763	(2,484)	(3,641)	8,650

# Consolidated Balance Sheet

As at 31 December 2011

	31 December 2011 (unaudited) £000	31 December 2010 (unaudited) £000	30 June 2011 (audited) £000
<b>Non-current assets</b>			
Intangible assets	1,256	388	1,075
Plant and equipment	547	584	567
Deferred taxation	665	505	520
	<b>2,468</b>	<b>1,477</b>	<b>2,162</b>
<b>Current assets</b>			
Trade and other receivables	2,321	1,199	1,910
Tax receivables	117	75	117
Cash and cash equivalents	5,255	4,320	3,620
	<b>7,693</b>	<b>5,594</b>	<b>5,647</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Deferred income	17	230	75
Trade and other payables	1,414	987	1,447
Obligations under finance leases	–	14	–
	<b>1,431</b>	<b>1,231</b>	<b>1,522</b>
<b>Net current assets</b>	<b>6,262</b>	<b>4,363</b>	<b>4,125</b>
Total assets less current liabilities	<b>8,730</b>	<b>5,840</b>	<b>6,287</b>
<b>Non-current liabilities</b>			
Liabilities payable 1 - 5 years	(80)	–	(105)
<b>Net assets</b>	<b>8,650</b>	<b>5,840</b>	<b>6,182</b>
<b>Capital and reserves</b>			
Called-up equity share capital	133	119	119
Share premium account	13,992	11,206	11,206
Employee share incentive plan reserve	(113)	(66)	(88)
Share options reserve	763	639	691
Reverse acquisition reserve	(2,484)	(2,484)	(2,484)
Retained earnings	(3,641)	(3,574)	(3,262)
<b>Total shareholders' equity</b>	<b>8,650</b>	<b>5,840</b>	<b>6,182</b>

# Consolidated Statement of Cash Flows

For the six months ended 31 December 2011

	31 December 2011 (unaudited) £000	31 December 2010 (unaudited) £000	30 June 2011 (audited) £000
<b>Cash flows from operating activities</b>			
Operating (loss)/profit for the year	(543)	93	385
Depreciation, amortisation and impairment	96	99	194
Share based payment expense	84	6	58
Operating (loss)/profit before changes in working capital and provisions	(363)	198	637
(Increase) in trade and other receivables	(411)	(188)	(899)
(Decrease) in deferred income	(58)	(744)	(899)
(Decrease)/Increase in trade and other payables	(33)	(27)	433
Net cash (outflow) from operations	(865)	(761)	(728)
Finance costs	-	-	(46)
Interest received	7	11	18
Tax received	-	75	75
	7	86	47
Net cash (outflow) from operating activities	(858)	(675)	(681)
<b>Cash flows from investing activities</b>			
Acquisition of fixed assets	(257)	(328)	(1,093)
Net cash outflow from investing activities	(257)	(328)	(1,093)
<b>Cash flows from financing activities</b>			
Proceeds from issue of share capital	2,777	-	-
Expenses of share issue	(56)	-	-
Exercise of share options	79	-	-
Purchase of own shares	(25)	(23)	(45)
Increase/(decrease) in borrowings	(25)	(25)	68
Net cash inflow/(outflow) from financing activities	2,750	(48)	23
Net increase/(decrease) in cash equivalents	1,635	(1,051)	(1,751)
Cash and cash equivalents at beginning of year	3,620	5,371	5,371
<b>Cash and cash equivalents at end of year</b>	<b>5,255</b>	<b>4,320</b>	<b>3,620</b>
<b>Analysis of net funds</b>			
Cash at bank and in hand	5,255	4,320	3,620
<b>Net funds</b>	<b>5,255</b>	<b>4,320</b>	<b>3,620</b>

## Notes to the Preliminary Results

to 31 December 2011

### A. Business segments

	Contract Research Services £000	Personalised Medicine £000	Novel Therapies £000	Unallocated £000	Total £000
<b>Six months ended 31 December 2011</b>					
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)
<b>Operating profit/(loss)</b>	<b>357</b>	<b>183</b>	<b>(395)</b>	<b>(688)</b>	<b>(543)</b>
<b>Six months ended 31 December 2010</b>					
Revenue	1,386	383	1,209	–	2,978
Segment trading result	424	(68)	601	(759)	198
Less depreciation and amortisation	(26)	(24)	(36)	(13)	(99)
Less equity-settled share-based payments	–	(4)	(2)	–	(6)
<b>Operating profit/(loss)</b>	<b>398</b>	<b>(96)</b>	<b>563</b>	<b>(772)</b>	<b>93</b>
<b>Twelve months ended 30 June 2011</b>					
Revenue	3,002	1,130	1,620	–	5,752
Segment trading result	1,029	148	716	(1,256)	637
Less depreciation and amortisation	(55)	(38)	(74)	(27)	(194)
Less equity-settled share-based payments	(7)	(17)	(1)	(33)	(58)
<b>Operating profit/(loss)</b>	<b>967</b>	<b>93</b>	<b>641</b>	<b>(1,316)</b>	<b>385</b>

### 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 8,095,560 (2010: 7,933,983).

# Notes to the Interim Financial Statements

Six months ended 31 December 2011

## 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 2011 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 13 March 2012.

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 & 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 is incurred up to the point of technical and commercial validation. Thereafter, costs are carried forward as intangible assets and subject to impairment review and amortisation.

### **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  
Christopher Potten  
Catherine Booth  
Roger Lloyd  
Jeffrey Moore  
Robert Nolan  
John Rylands

### Company Secretary

John Rylands

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