



## Ark Therapeutics Group plc

### *Interim Results for the First Half of 2009*

#### HIGHLIGHTS

<b>Cerepro<sup>®</sup></b>	<ul style="list-style-type: none"> <li>• Cerepro<sup>®</sup> MAA filing cleared validation and review commenced at EMEA</li> <li>• Named Patient Supply approval for Cerepro<sup>®</sup> in France and Finland</li> <li>• First update of results of Cerepro<sup>®</sup> Phase III trial showed strengthened results</li> </ul>
<b>Trinam<sup>®</sup></b>	<ul style="list-style-type: none"> <li>• Trinam<sup>®</sup> awarded Fast Track status by FDA</li> <li>• First patient enrolled into US Phase III Study for Trinam<sup>®</sup></li> </ul>
<b>Vitor<sup>™</sup></b>	<ul style="list-style-type: none"> <li>• Pilot Phase III trial continues with first readout expected later this year</li> </ul>
<b>Pre-clinical</b>	<ul style="list-style-type: none"> <li>• Three further gene-based programmes approaching Phase I clinical development</li> </ul>
<b>Woundcare</b>	<ul style="list-style-type: none"> <li>• Sales in the six months to 30 June 2009 showed 61% increase over first six months of 2008</li> <li>• International medical device sales collaboration on Kerraboot<sup>®</sup> signed with AOTI Ltd</li> </ul>
<b>Manufacturing</b>	<ul style="list-style-type: none"> <li>• Major advance in commercial-scale adenoviral gene-based medicine production using suspension process in single use systems</li> </ul>
<b>Corporate/ Commercial</b>	<ul style="list-style-type: none"> <li>• VEGF-C and -D gene and technologies for lymphatic disease licensed to Oy Lx Therapies Ltd in Finland</li> <li>• Multiple gene regulation technology patent filed</li> <li>• Prestigious European R&amp;D prize won by Ark founder</li> <li>• Dennis Turner, Chairman since September 1999, retired on 30 June 2009; Andrew Christie appointed Chairman from 1 July 2009</li> <li>• Cash, cash equivalents and money market investments of £28.6m at 30 June 2009 (£50.5m at 30 June 2008)</li> </ul>
<b>Post-period events</b>	<ul style="list-style-type: none"> <li>• Commencement of contract manufacture for Oy Lx Therapies Ltd VEGF-C gene medicine programme</li> <li>• Kerraglove<sup>®</sup> woundcare device for burns on the hand launched</li> <li>• Commencement of Phase I/IIa refractory angina trial with AIV Institute</li> </ul>

## INTERIM MANAGEMENT REPORT

### Chairman and Chief Executive's review

In the first half of 2009 Ark has moved forward significantly with its pioneering DNA-based medicine programmes achieving manufacturing, development and regulatory progress with its lead and late stage pre-clinical products. Many of the achievements we have announced represent significant "world firsts" in biomedicine.

We started the year with the announcement that the EMEA had commenced formal review of the Marketing Approval Application (MAA) for Cerepro<sup>®</sup> (for brain tumours) and, in April, we reported strengthened efficacy results from the first annual update of Cerepro<sup>®</sup>'s Phase III trial. Trinam<sup>®</sup> (for haemodialysis access) commenced enrolment of its US Phase III study and was also awarded Fast Track status by the FDA. We also made real progress in our pre-clinical second generation gene-based programmes. Our UK woundcare business has continued to show strong sales growth in the period maintaining the trend reported in 2008. We believe the convincing health economic benefits of Ark's woundcare products are significant factors in the rise in formulary inclusions and increased sales in the UK. Later in the period we announced an international deal with AOTI for Kerraboot<sup>®</sup> supply to use in combination with their TWO<sub>2</sub> oxygen device for leg ulcers. Other commercial activities in the period included the out-licensing of the lymphangiogenic rights to VEGF-C and VEGF-D to Oy LX Therapies Ltd in return for an "evergreen" equity stake and royalty on future sales. Immediately post period we commenced production for Oy Lx Therapies Ltd, securing our first contract manufacturing agreement. Our facilities in Finland are now routinely operating at Biosafety 2 standards making both research and clinical grade gene medicines and we continue to make significant improvements in commercial gene vector production technologies.

### Pipeline Review

**Cerepro<sup>®</sup>** - Cerepro<sup>®</sup> is our gene-based therapy for the treatment of glioblastoma (brain cancer). We completed the Phase III development for Cerepro<sup>®</sup> and submitted the revised MAA to the EMEA in late 2008. We started 2009 by announcing that the EMEA had commenced formal review of the MAA. In February we announced that the first Named Patient supply had been approved in France and shortly after we reported that the Phase III trial results had been updated in accordance with the regulations for gene therapy. In the update, the efficacy data had strengthened significantly in Cerepro<sup>®</sup>'s favour as more patients had reached the trial end point (death or re-intervention). In May we reported that a second country, Finland, had started Named Patient supply. Immediately post period we met with the EMEA rapporteurs as part of the ongoing MAA review process and we have recently finalised the submission of various updated and additional analyses and technical information requested by the EMEA. The EMEA is expected to make a decision as to whether Cerepro<sup>®</sup> receives marketing approval by the end of 2009.

**Trinam<sup>®</sup>** - Trinam<sup>®</sup> is our novel gene-based medicine being developed in the USA under Special Protocol Assessment (SPA) for the treatment of haemodialysis access. Trinam<sup>®</sup> uses the same successfully established adenovirus technology as Cerepro<sup>®</sup>. Late in 2008 we completed technical work to qualify a suitable finished product potency assay in response to a request from the FDA allowing us to file the updated Investigative New Drug (IND) application at the start of 2009. No further issues have been raised by the FDA and we completed set-up of the first US study centre towards the middle of the period. In May, Trinam<sup>®</sup> was awarded Fast Track status by the FDA. In the same month the first patient was recruited into the study and we are focusing our efforts on driving recruitment locally in the USA.

**Vitor<sup>™</sup>** – Vitor<sup>™</sup> is a small molecule under development for the treatment of cachexia, a form of severe weight loss that occurs in terminal cancer. The product has shown encouraging results in non-small lung and colon cancer and is currently in the Phase III development stage. Recruitment of the Phase III pilot study has been ongoing in the first half of the year. Recruitment has however been slower than we would have liked, confirming our decision to pilot the new Phase III trial design for logistics prior to commencing full Phase III development. We will, however, run an interim report on the study later this year. This will enable us to decide on the design and viability of this programme, as well as the most appropriate commercial route to execute it.

### Pre-clinical

As we reported last year, the success and "approvable status" (as evidenced during the first EMEA review of Cerepro<sup>®</sup> in 2007) of our adenoviral delivery technology, together with the associated range of validated product release assays and environmental standards, have constituted a major breakthrough for the gene-based medicine sector. This success has catalysed our decision to prioritise and move further gene-based programmes based on this successful technology into clinical development.

In the period we completed the pre-clinical “proof-of-principle” testing and toxicology for EG011, a programme to treat refractory angina and for EG016 in peripheral vascular disease. Following an IND application to the Finnish National Agency for Medicines, post period, approval has been received to start a Phase I/IIa trial in collaboration with the AIV Institute in Finland. Additionally, we have progressed the pre-clinical work on EG013 a programme in foetal growth restriction in accordance with the outcome of our meeting last year with the Gene Therapy Working Party (GTWP) at the EMEA. Most recently, post period, we have taken formal Scientific Advice from the MHRA expert committee in this area, allowing us to finalise the toxicology requirements and the Phase I/IIa trial design. Toxicology has now commenced and we anticipate entering a Phase I/IIa trial in conjunction with University College Hospital, London, in mid 2010.

Of key significance to the existing and future progress with all three of the above programmes is use of the highly promising shortform of VEGF-D gene to which we obtained the full rights in angiogenesis and lymphangiogenesis (now out-licensed), free of royalties, through the acquisition of Lymphatix Oy in early 2008. Ark completed manufacturing of shortform VEGF-D to full cGMP standards during the first half of this year in our Kuopio facility, giving us certified clinical grade material for all the toxicology and clinical trials. This considerably leverages our ability to develop rapidly and cost effectively our second generation of gene-based medicines without the significant technology and regulatory risks associated with the pioneering work for our first lead products.

We have also made progress with our VEGF related neuropilin 1 (“NP-1”) receptor antagonist programme. NP-1 is a key target for the treatment of cancer and eye disease. During the period our chemists mapped the structure of the NP-1 receptor pocket and developed rapid screening assays to enable small ‘designer’ molecules to be synthesised and rapidly tested for activity. We now have two lead molecules showing potency at single nanomolar levels.

## **Woundcare**

In 2009 the sales growth momentum we reported in 2008 continued with sales for the first half increasing to £665k reflecting a 61% period on period growth. All Ark woundcare products have demonstrated good health economic justification for their use and we have been particularly pleased with the level of local and regional UK formulary adoptions across the product range. Flaminal<sup>®</sup> and Kerraped<sup>®</sup> have shown continued good growth this year and KerraMax<sup>®</sup>, which appeared to be well received by nurses when launched in October 2008, has performed well, in line with the initial market response. In June we announced a collaboration with AOTI who will sell Kerraboot<sup>®</sup> as part of a treatment regimen with their TWO<sub>2</sub> oxygen device for leg ulcers. This starts to open up use of Kerraboot<sup>®</sup> in main European and US markets.

The sales trend post period has continued to strengthen with July showing the first positive cash contribution from the woundcare products. Finally, in line with our goals, we announced the launch of Kerraglove<sup>®</sup>, a semi-breathable plastic mitten-shaped device for the management of hand burns. In trials so far, this has produced good healing with less pain when changed and less macerating than existing containment dressings. At present we are focused on driving the sales of the current product range, but we will continue to screen and secure or develop further products that are a good strategic fit for our salesforce.

## **Patent Portfolio Update**

As of the end of this reporting period, Ark has 50 patents granted and 93 applications pending and we remain successful at overcoming the various objections and oppositions that occur in the prosecution process. In February we announced a breakthrough technology patent covering a construct (shRNA) that can both down and up regulate gene function. This has the ability to supersede existing RNAi silencing technology which has limitations with specificity and delivery. When taken as a whole with our targeted insertional gene technology IP, Ark scientists are assembling a strong array of future genomic medicine tools capable of working at the chromosomal gene level.

We have had discussions with a number of companies regarding our stroke patent in Europe and have commenced the next stage in realising its commercial potential with litigation. In the US we have resolved all outstanding office actions with the Patent Office, clearing all prior art raised so far by the examiner. We now await communication as to when the US stroke patent might be granted triggering further milestone receipts from our out- licence with Boehringer Ingelheim.

## **Manufacturing**

Throughout the first half of 2009 we continued to operate successfully our existing approved cGMP facilities (GMP 1 and GMP 2) in Kuopio, Finland to the requisite Biosafety level 2 standards, making further commercial supply batches of Cerepro<sup>®</sup> and toxicology and clinical grade batches of VEGF-D. Synchronisation of reagent procurement, manufacturing and commercial invoicing systems continues in preparation for Cerepro<sup>®</sup> launch.

Validation of our new GMP 3 facility has proceeded according to plan and completion to full cGMP standard is expected towards the end of 2009. GMP 3 is already being used for manufacturing development work and in June we announced a material breakthrough in our commercial scale manufacturing technology process, giving considerably higher yields of adenovirus based gene medicine products. When validation is completed, GMP 3 will be fully set up for the advanced disposable single use systems (SUS) at both research and commercial scale, giving Ark considerable scope and flexibility to use this facility for its own products as well as to undertake contract manufacturing for other companies in the DNA based medicine sector. The first of these was announced on 1 July with Oy Lx Therapies Ltd in Helsinki.

## **Corporate Activities**

Following the acquisition of Lymphatix Oy in early 2008, we undertook a review of the immediate exploitation options for the VEGF-C and VEGF-D gene families within the licensed uses. In early 2009 we granted a licence to Oy Lx Therapies Ltd in Helsinki to exploit the lymphangiogenesis opportunities for VEGF-C and VEGF-D. This is an area of significant unmet medical need and Oy Lx Therapies Ltd has the specialist clinical knowledge and development expertise to exploit the disease area. Ark has secured an "evergreen" equity stake in Oy Lx Therapies Ltd and royalties on future sales of any developed products using the licensed genes.

## **Financial review**

Revenues of £0.665m were recorded in the six months ended 30 June 2009 (six months ended 30 June 2008: £0.412m), the increase of 61% in the period reflecting the successful launch of KerraMax<sup>®</sup> in the second half of 2008 and the strong growth in Flaminal<sup>®</sup> and Kerraped<sup>®</sup> sales.

Expenditure on research and development for the period totalled £8.0m (six months ended 30 June 2008: £8.2m), the small period on period reduction due to much reduced expenditure on the Cerepro<sup>®</sup> Phase III trial, offset by increasing expenditure on the Trinam<sup>®</sup> Phase III study and by increased depreciation on commissioning of our biologics manufacturing facility.

Selling, marketing and distribution costs for the period were £0.8m (six months ended 30 June 2008: £0.7m).

Administrative expenses for the period totalled £3.2m (six months ended 30 June 2008: £3.6m). The lower spending in the period was principally as a result of headcount reductions and a continuing focus on management of costs.

Other expenses for the period totalled £2.2m (six months ended 30 June 2008: other income of £0.7m). Unrealised exchange losses on translation of inter-company loans amounted to £1.6m and fair value adjustments on US and Euro denominated cash balances and USD forward exchange contracts totalled £0.6m for the six months ended 30 June 2009 reflecting the strengthening of Sterling over the same period (six months ended 30 June 2008: unrealised exchange gains amounted to £0.5m and fair value adjustments on Euro denominated cash balances of £0.2m).

In the six months ended 30 June 2009, the Group earned interest of £0.5m on its cash deposits (six months ended 30 June 2008: £1.6m), the decrease reflecting lower interest rates and cash balances.

Total net assets (defined as total assets less total liabilities) have decreased from £61.3m at 30 June 2008 to £42.7m at 30 June 2009, principally due to the decrease in cash and cash equivalents and money market investments (£28.6m at 30 June 2009 versus £50.5m at 30 June 2008). Property, plant and equipment at 30 June 2009 of £12.5m (30 June 2008: £9.8m) reflected the investment in the Group's expanded biologics manufacturing facility in Finland.

Net cash outflow from operating activities for the period was £12.0m (six months ended 30 June 2008: £11.2m).

## **Risks and uncertainties**

There are a number of potential risks and uncertainties that could have a material impact on the Group's performance over the remaining six months of the financial year and could cause actual results to differ materially from expected and historical results. The risks which were identified and outlined in the Annual Report and Accounts 2008 in the Directors' Report on page 24, which does not form part of this interim statement, and which include clinical and regulatory risk, competition and intellectual property risk, and economic, financial and counterparty risk, have not changed and therefore remain relevant for the remaining six months of 2009.

## Summary and Outlook

In the first half of 2009 Ark has continued to make real progress in pioneering its advanced gene-based medicines on both regulatory and development fronts. We expect to report the outcome of the EMEA's review of the Cerepro<sup>®</sup> MAA late in the year and to update the market on out-licensing deals in non-core markets and our own plans to exploit Cerepro<sup>®</sup> in the main European markets. During the second half of 2009 we expect the Phase I/IIa study in peripheral vascular disease to commence enrolment in Finland using shortform VEGF-D and we will commence final toxicity work for EG013 prior to starting the Phase I/IIa trial in the UK in 2010. We also expect to give interim results for the Vitor<sup>™</sup> Phase III pilot trial and look forward to being able to report further progress towards sustainable profitability in our woundcare business.

We ended the period with £28.6m of cash reserves, after finalising the capital expenditure on our new manufacturing facilities. We have continued to give a strong focus to matching cash utilisation in 2009 to progress, as well as to generating income from our woundcare business and from manufacturing contracts for gene-based medicines. In addition we have a number of potentially cash generative discussions ongoing regarding our IP and exploitation of Cerepro<sup>®</sup> in non-core territories. We will continue to maintain this focus on cash utilisation and on progressing our many opportunities for cash generation across the business.

On behalf of the Board we would like to thank Mr Dennis Turner for his guidance and very significant contribution to building the Company over the last 10 years and to welcome Mr Andrew Christie who took over as Chairman as of 1 July 2009.

In summary, our progress towards the EMEA's decision on Cerepro<sup>®</sup> and potential launch of the first gene-based medicine remains "on track". We have further strengthened our portfolio based on "approvable" adenovirus technology, made real progress towards sustainable profitability of our woundcare products and signed the first contract manufacturing agreement. Ark is well placed to evolve as an independent advanced biomedicines provider and we look forward to building success off the many "firsts" which the Company has already achieved.

Andrew Christie, Chairman

Nigel Parker, Chief Executive Officer

26 August 2009

**Condensed consolidated income statement  
For the six months ended 30 June 2009 (unaudited)**

	Note	Six months ended 30 June 2009 £'000	Six months ended 30 June 2008 £'000	Year ended 31 December 2008 £'000
<b>Revenue</b>		<b>665</b>	412	929
Cost of sales		(361)	(235)	(479)
<b>Gross profit</b>		<b>304</b>	177	450
Research and development expenses		(7,951)	(8,188)	(16,461)
Selling, marketing and distribution costs		(844)	(736)	(1,667)
Other administrative expenses		(2,787)	(2,948)	(5,275)
Share-based compensation		(422)	(682)	(980)
Administrative expenses		(3,209)	(3,630)	(6,255)
Other (expenses)/income		(2,202)	678	3,472
<b>Operating loss</b>		<b>(13,902)</b>	(11,699)	(20,461)
Investment income		490	1,631	2,896
Finance costs		(17)	(17)	(35)
<b>Loss on ordinary activities before taxation</b>		<b>(13,429)</b>	(10,085)	(17,600)
Taxation		788	919	1,715
<b>Loss on ordinary activities after taxation, being retained loss for the period</b>		<b>(12,641)</b>	(9,166)	(15,885)
Loss per share (basic and diluted)	4	<b>6 pence</b>	4 pence	8 pence

**Condensed consolidated statement of comprehensive income  
For the six months ended 30 June 2009 (unaudited)**

	Six months ended 30 June 2009 £'000	Six months ended 30 June 2008 £'000	Year ended 31 December 2008 £'000
Loss on ordinary activities after taxation, being retained loss for the period	(12,641)	(9,166)	(15,885)
Exchange differences on translating foreign operations recognised directly in equity	(136)	99	329
<b>Total comprehensive income for the period</b>	<b>(12,777)</b>	(9,067)	(15,556)

All results relate wholly to continuing activities. All results are attributable to equity holders of the parent.

**Condensed consolidated balance sheet  
As at 30 June 2009 (unaudited)**

	<b>30 June 2009 £'000</b>	30 June 2008 £'000	31 December 2008 £'000
<b>Non-current assets</b>			
Goodwill	2,455	2,328	2,622
Other intangible assets	1,166	1,187	1,812
Property, plant and equipment	12,495	9,759	15,120
	<b>16,116</b>	13,274	19,554
<b>Current assets</b>			
Inventories	488	503	479
Derivative financial instruments	181	123	610
Trade and other receivables	1,270	2,246	2,098
Research and development tax credits receivable	2,513	2,696	1,713
Current tax receivable	19	-	50
Money market investments	24,637	42,500	33,509
Cash and cash equivalents	4,009	7,987	7,137
	<b>33,117</b>	56,055	45,596
<b>TOTAL ASSETS</b>	<b>49,233</b>	69,329	65,150
<b>Non-current liabilities</b>			
Deferred income	1,663	1,180	1,892
Obligations under finance leases	51	70	62
Loans	493	469	578
	<b>2,207</b>	1,719	2,532
<b>Current liabilities</b>			
Trade and other payables	4,001	6,217	7,109
Deferred income	202	-	321
Obligations under finance leases	29	34	32
Loans	51	73	58
	<b>4,283</b>	6,324	7,520
<b>TOTAL LIABILITIES</b>	<b>6,490</b>	8,043	10,052
<b>Equity</b>			
Share capital	2,071	2,051	2,052
Share premium	118,630	117,897	117,899
Merger reserve	38,510	38,510	38,510
Foreign currency translation reserve	194	75	313
Share-based compensation	4,422	3,727	4,017
Reserve for own shares	(2,024)	(1,274)	(1,274)
Retained loss	(119,060)	(99,700)	(106,419)
<b>TOTAL EQUITY</b>	<b>42,743</b>	61,286	55,098
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>49,233</b>	69,329	65,150

**Condensed consolidated statement of changes in equity  
(unaudited)**

	Share capital	Share premium	Merger reserve	Foreign currency translation reserve	Share-based compensation	Reserve for own shares	Retained loss	Total
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
<b>Balance as at 31 December 2007</b>	2,019	116,571	36,989	(31)	3,052	-	(90,534)	68,066
Total comprehensive income for the period	-	-	-	106	(7)	-	(9,166)	(9,067)
Share-based compensation	-	-	-	-	682	-	-	682
Equity share options issued	1	67	-	-	-	-	-	68
Issue of share capital	31	1,261	1,521	-	-	-	-	2,813
Share issue expenses	-	(2)	-	-	-	-	-	(2)
Purchase of own shares by Family Benefit Trust	-	-	-	-	-	(1,274)	-	(1,274)
<b>Balance as at 30 June 2008</b>	2,051	117,897	38,510	75	3,727	(1,274)	(99,700)	61,286
Total comprehensive income for the period	-	-	-	238	(8)	-	(6,719)	(6,489)
Share-based compensation	-	-	-	-	298	-	-	298
Equity share options issued	1	2	-	-	-	-	-	3
<b>Balance as at 31 December 2008</b>	2,052	117,899	38,510	313	4,017	(1,274)	(106,419)	55,098
Total comprehensive income for the period	-	-	-	(119)	(17)	-	(12,641)	(12,777)
Share-based compensation	-	-	-	-	422	-	-	422
Issue of share capital	18	732	-	-	-	-	-	750
Share issue expenses	-	-	-	-	-	-	-	-
Equity share options issued	1	(1)	-	-	-	-	-	-
Purchase of own shares by Family Benefit Trust	-	-	-	-	-	(750)	-	(750)
<b>Balance as at 30 June 2009</b>	2,071	118,630	38,510	194	4,422	(2,024)	(119,060)	42,743

**Condensed consolidated cash flow statement**  
**For the six months ended 30 June 2009 (unaudited)**

	Note	Six months ended 30 June 2009 £'000	Six months ended 30 June 2008 £'000	Year ended 31 December 2008 £'000
<b>Net cash outflow from operating activities</b>	5	(12,001)	(11,177)	(20,447)
<b>Investing activities</b>				
Acquisition of Lymphatix Oy net of cash acquired		-	34	34
Interest received		1,322	1,601	2,663
Proceeds from money market investments		8,872	3,500	12,491
Purchases of property, plant and equipment		(1,290)	(5,943)	(7,944)
Purchases of intangible assets		-	(56)	(957)
<b>Net cash generated from/(used in) investing activities</b>		8,904	(864)	6,287
<b>Financing activities</b>				
Proceeds from borrowings		40	47	58
Repayment of borrowings		(66)	(87)	(166)
Proceeds on issue of shares		-	66	69
Finance costs		(13)	(13)	(17)
Grants received		10	1,060	2,171
<b>Net cash (used in)/generated from financing activities</b>		(29)	1,073	2,115
Net decrease in cash and cash equivalents		(3,126)	(10,968)	(12,045)
Cash and cash equivalents at beginning of period		7,137	19,067	19,067
Effect of exchange rate changes		(2)	(112)	115
<b>Cash and cash equivalents at end of period</b>		4,009	7,987	7,137

## Notes to the financial information

### 1 General information

This interim financial information was authorised for issue on 26 August 2009. The information contained within in respect of the year ended 31 December 2008 does not constitute statutory accounts within the meaning of Section 240 of the Companies Act 1985. A copy of the statutory accounts for the year ended 31 December 2008 has been delivered to the Registrar of Companies. The Auditors' report on those accounts was not qualified, did not draw attention to any matters by way of emphasis and did not contain statements under Section 237(2) or (3) of the Companies Act 1985.

A copy of the interim results for the six months ended 30 June 2009 can be found on the company's website at [www.arktherapeutics.com](http://www.arktherapeutics.com).

### 2 Basis of preparation

The annual financial statements of Ark Therapeutics Groups plc are prepared in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union. The condensed set of financial statements included in this half-yearly report has been prepared in accordance with International Accounting Standard 34 'Interim Financial Reporting', as adopted by the European Union.

In determining the appropriate basis of preparation of the financial statements, the Directors are required to consider whether the Group can continue in operational existence for the foreseeable future, being a period of not less than twelve months from the date of the approval of the half-year financial information. During the six months ended 30 June 2009, there was a continuing focus on the management of costs within the Group. As at 30 June 2009, the Group had cash and cash equivalents of £28.6 million, and the Group had net assets of £49 million. Management prepares detailed cash flow forecasts which are reviewed by the Board on a regular basis. The forecasts include assumptions regarding future income and expenditure together with various scenarios which reflect opportunities, risks and appropriate mitigating actions. Whilst there are inherent uncertainties regarding the cash flows associated with product development and commercialisation, the Directors are satisfied that there is sufficient discretion and control as to the timing and quantum of cash outflows to ensure that the Group is able to meet its liabilities as they fall due for the foreseeable future. Therefore, having made relevant enquiries, including consideration of the Group's current cash resources and the cash flow forecasts, the Board has a reasonable expectation that, at the time of approving the half-yearly financial information, the Group has adequate resources to continue in operational existence for the foreseeable future. Accordingly, the Board continues to adopt the going concern basis in preparing the financial information.

The same accounting policies, presentation and methods of computation have been followed in the condensed set of financial statements as applied in the Group's latest annual audited financial statements for the year ended 31 December 2008, except as described below. Seasonal changes to the Group's operations are not material.

#### Changes in accounting policy

In the current financial year, the Group has adopted IFRS 8 "Operating Segments" and International Accounting Standard 1 "Presentation of Financial Statements" (revised 2007).

IFRS 8 requires operating segments to be identified on the basis of, inter alia, internal reports about the components of the Group that are regularly reviewed by the chief operating decision maker to allocate resources to the segments and to assess their performance. The chief operating decision maker has been identified as both the Chief Executive Officer and the Chief Financial Officer combined. The previous standard, IAS 14 "Segment reporting", required the Group to identify both business and geographical segments based on a risks and rewards approach. The segmental information required by IAS 34 which is included in note 3 below is presented in accordance with IFRS 8. The comparatives have been restated accordingly.

IAS 1 (revised) requires the presentation of comprehensive income as a separate component, either within the income statement or within the statement of changes in equity. As a result, the statement of changes in equity has been reformatted to show a separate subtotal representing comprehensive income.

### 3 Business and geographical segments

In accordance with IFRS 8, the Group is required to define its operating segments based on, inter alia, the internal reports presented to its chief operating decision maker in order to allocate resources and assess performance. These reports focus on the Group's only business activity, being the discovery, development and commercialisation of products in areas of specialist medicine, with particular focus on vascular disease and cancer, and therefore no segmental information has been shown.

All revenue from external customers for the current and prior periods relates to the sales of woundcare products to customers in the United Kingdom. An analysis of the Group's geographical non-current assets is shown below:

	<b>30 June 2009 £'000</b>	30 June 2008 £'000	31 December 2008 £'000
UK	<b>12,502</b>	10,151	13,460
Finland	<b>14,258</b>	11,380	17,184
Inter-segment eliminations (being inter-company loans)	<b>(10,644)</b>	(8,257)	(11,090)
	<b>16,116</b>	13,274	19,554

Non-current assets comprise goodwill, property, plant and equipment, other intangible assets and inter-company loans and are attributed to the location where they are situated.

#### 4 Loss per share

International Accounting Standards require presentation of diluted earnings per share when a company could be called upon to issue shares that would decrease net profit or increase net loss per share. Since the Group is loss making, there is no such dilutive impact.

The calculation of basic and diluted loss per ordinary share is based on the loss of £12,641,000 for the six months ended 30 June 2009 (six months ended 30 June 2008 - £9,166,000; year ended 31 December 2008 - £15,885,000) and on 207,025,649 ordinary shares (June 2008 - 204,963,744; December 2008 - 205,077,342) being the weighted average number of ordinary shares in issue.

#### 5 Reconciliation of operating loss to net cash outflow from operating activities

	<b>Six months ended 30 June 2009 £'000</b>	Six months ended 30 June 2008 £'000	Year ended 31 December 2008 £'000
Operating loss	<b>(13,902)</b>	(11,699)	(20,461)
Depreciation and amortisation	<b>1,350</b>	755	1,518
Change in fair value of cash flow hedge	<b>429</b>	-	(610)
Deferred income	<b>(78)</b>	(27)	(95)
Share-based compensation	<b>422</b>	682	980
Unrealised exchange loss/(gain)	<b>1,586</b>	-	(2,450)
Operating cash flows before movements in working capital	<b>(10,193)</b>	(10,289)	(21,118)
(Increase)/decrease in receivables	<b>(29)</b>	(143)	331
Increase in inventories	<b>(9)</b>	(122)	(98)
Decrease in payables	<b>(1,783)</b>	(921)	(1,595)
Cash used by operations	<b>(12,014)</b>	(11,475)	(22,480)
Research and development tax credit received	-	298	2,058
Income taxes refunded/(paid)	<b>13</b>	-	(25)
<b>Net cash outflow from operating activities</b>	<b>(12,001)</b>	(11,177)	(20,447)

#### 6 Non-cash investing and financing activities

On 5 January 2009 the Ark Therapeutics Group plc Family Benefit Trust (the "FBT") subscribed for 1,910,000 ordinary shares in the Company at a cost of £750,000. The Company financed the share purchase by way of a contribution, totalling £469,000, and the remainder by way of a loan.

#### 7 Related party transactions

Transactions between the Company and its subsidiaries, which are related parties, have been eliminated on consolidation and are not disclosed in this note.

The following transactions with Company Directors took place during the year at arm's length:

	<b>Six months ended 30 June 2009 £'000</b>	Six months ended 30 June 2008 £'000	Year ended 31 December 2008 £'000
<b>Consultancy fees earned in period</b>			
S Ylä-Herttuala	<b>38</b>	38	75
<b>Consultancy fees owed as at period end</b>			
S Ylä-Herttuala	<b>38</b>	38	75

The remuneration of key management personnel in the period was in line with the amounts disclosed in the annual report for the year ended 31 December 2008.

## Statement of Directors' responsibilities

We confirm to the best of our knowledge:

- (a) the condensed set of financial statements has been prepared in accordance with IAS 34 "Interim Financial Reporting";
- (b) the interim management report includes a fair review of the information required by DTR 4.2.7R (indication of important events during the first six months and description of principal risks and uncertainties for the remaining six months of the year); and
- (c) the interim management report includes a fair review of the information required by DTR 4.2.8R (disclosure of related parties' transactions and changes therein).

The Directors of Ark Therapeutics Group plc are listed in the Ark Therapeutics Group plc annual report for the year ended 31 December 2008, with the exception of the following two changes during the period: with effect from 30 June 2009 Dennis Turner resigned from the Board and Andrew Christie was appointed Non-Executive Chairman with effect from 1 July 2009. A list of current Directors is maintained on the Company's website: [www.arktherapeutics.com](http://www.arktherapeutics.com).

By order of the Board

Martyn Williams  
Chief Financial Officer

26 August 2009

## **Independent review report to Ark Therapeutics Group plc**

We have been engaged by the Company to review the condensed set of financial statements in the half-yearly financial report for the six months ended 30 June 2009 which comprises the condensed consolidated income statement, the condensed consolidated statement of comprehensive income, the condensed consolidated balance sheet, the condensed consolidated statement of changes in equity, the condensed consolidated cash flow statement and related notes 1 to 7. We have read the other information contained in the half-yearly financial report and considered whether it contains any apparent misstatements or material inconsistencies with the information in the condensed set of financial statements.

This report is made solely to the Company in accordance with International Standard on Review Engagements (UK and Ireland) 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" issued by the Auditing Practices Board. Our work has been undertaken so that we might state to the Company those matters we are required to state to them in an independent review report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company, for our review work, for this report, or for the conclusions we have formed.

### **Directors' responsibilities**

The half-yearly financial report is the responsibility of, and has been approved by, the Directors. The Directors are responsible for preparing the half-yearly financial report in accordance with the Disclosure and Transparency Rules of the United Kingdom's Financial Services Authority.

As disclosed in note 2, the annual financial statements of the Group are prepared in accordance with IFRSs as adopted by the European Union. The condensed set of financial statements included in this half-yearly financial report has been prepared in accordance with International Accounting Standard 34, "Interim Financial Reporting," as adopted by the European Union.

### **Our responsibility**

Our responsibility is to express to the Company a conclusion on the condensed set of financial statements in the half-yearly financial report based on our review.

### **Scope of Review**

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" issued by the Auditing Practices Board for use in the United Kingdom. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK and Ireland) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

### **Conclusion**

Based on our review, nothing has come to our attention that causes us to believe that the condensed set of financial statements in the half-yearly financial report for the six months ended 30 June 2009 is not prepared, in all material respects, in accordance with International Accounting Standard 34 as adopted by the European Union and the Disclosure and Transparency Rules of the United Kingdom's Financial Services Authority.

### **Deloitte LLP**

Chartered Accountants and Statutory Auditors  
Cambridge, UK

26 August 2009

Notes: A review does not provide assurance on the maintenance and integrity of the website, including controls used to achieve this, and in particular on whether any changes may have occurred to the financial information since first published. These matters are the responsibility of the Directors but no control procedures can provide absolute assurance in this area.

Legislation in the United Kingdom governing the preparation and dissemination of financial information differs from legislation in other jurisdictions.