



Ark Therapeutics Group plc
Interim report 2006

From Science to Patients



From science to patients

Ark Therapeutics is a specialist healthcare group focused on vascular disease and cancer, two of the largest therapeutic markets in the world.

Ark has one marketed product and an exciting late-stage portfolio addressing significant areas of unmet clinical need. The pipeline is supported by a number of advanced pre-clinical candidates which have already shown encouraging *in vivo* therapeutic proof-of-principle results.



Market focused product portfolio

Product	Description	Phase I	Phase II	Phase III	Marketed
Kerraboot®	Wound management				
Cerepro™	Gene-based medicine				
Vitor™	Small molecule				
Trinam®	Gene-based medicine				

Stage complete Stage entered

Highlights

PERIOD HIGHLIGHTS

- Cerepro™ MAA filing progressing with EMEA
- Phase III study shows Vitor™ significantly slows progression of cachexia in two cancer types
- Unique DNA-based targeting system, Scavidin®, halts tumour progression in two cancer models
- Kerraboot® patent granted in the US
- Six international marketing/distribution deals signed for Kerraboot®
- Flaminal® in-licensed to strengthen UK devices business and Drug Tariff price secured
- Placing and open offer completed raising £25.5m (post expenses)
- Cash, cash equivalents and money market investments of £49.4m at 30 June 2006 (£40.5m at 30 June 2005, £34.3m at 31 December 2005)

POST PERIOD EVENTS

- Vitor™ US patent granted
- Trinam® Phase II recruitment completed; preliminary results very positive



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Indication

Comment

Foot and leg ulcers

Launched in the UK. US approved. International marketing commenced.

Operable malignant glioma

MAA filed in Europe. Orphan Drug Status (FDA/EMEA).

Cancer-related cachexia

Effect in man confirmed. Fast track designation (FDA).

Haemodialysis access

Orphan Drug Status (FDA/EMEA).

Chairman and Chief Executive's review

Building on progress

We are pleased to report that the first half of 2006 has seen Ark continue to build on the key milestone achievements reported in late 2005, a number of which represented 'world firsts' for the industry. Strong interest in Ark from both existing and new investors, allowed us successfully to conclude a very well-supported fundraising in May. It was particularly encouraging to see the large number of existing shareholders who exercised their pre-emption rights. Consequently, our balance sheet has been significantly strengthened and we closed the period with just under £50m of cash reserves.

Overall, our progress in this increasingly challenging healthcare environment has strengthened our business significantly.

Pipeline review

Cerepro™

Early in the year we received the first questions from the EMEA in relation to our filing for marketing approval of Cerepro™ in malignant glioma. Cerepro™ is the first gene medicine ever to undergo formal review for a marketing approval (ex-China), so this review is particularly important as it clarifies the overall regulatory requirements for European approval of this new and exciting class of medicines. The Company's resources have been prioritised to complete necessary work and respond to the EMEA's first questions. Some notable achievements have been made in the period, without which we would not be able to file our response. Our cGMP facility in Finland has

manufactured the essential 'conformity' batches to commercial supply specifications. Ark's headquarters has satisfactorily completed a full good clinical practice ("GCP") system inspection under the new EU pharmaceutical regulations. The Phase II Cerepro™ study, which forms the main clinical evidence in the submission, has also been subject to a GCP inspection as part of the review process and the report noted that the results give an accurate description of the trial and source data, and that the endpoint data are reliable from a GCP perspective.

Our financial and strategic plans for Cerepro™, as presented at the time of the recent fundraising, remain unchanged. It is, however, clear that we have made good progress with the marketing application in the period.

Recruitment into the Phase III/IV study has proceeded according to schedule and to date external concerns that patients would be reluctant to participate in a gene medicine trial have proved unfounded. Over a third of patients have now been recruited into the trial. Surgeons are finding the product acceptable to administer and adverse events reported to the Company to date are consistent with those of the earlier studies and give no cause for concern.

Overall, Cerepro™ has progressed well during the first half of this year and the product remains on track to become what would be the first gene-based medicine in the world (ex-China) to be made commercially available.

Trinam®

In the US-based Phase II study in kidney dialysis patients who have undergone vascular access graft surgery, enrolment of the high-dose patients and the standard care controls is complete. The very promising efficacy results already reported with the low-dose treatment have strengthened further in the period, with the average graft survival period of low dose patients increasing to 17.8 months, compared with the 4.5 month average they had previously experienced. All five high dose Trinam® patients with successfully implanted grafts remain open and the average patency period has already reached 8 months, with three approaching 12 months. We are therefore optimistic for the success of the high dose group. Three out of four of the standard care controls have already blocked (average patency 3.3 months). No systemic distribution of the product has been found at the high dose and we have previously reported this for the low dose.

Under US regulations, patients in gene therapy trials are monitored for life. The data to date from this study indicates that Trinam® has an acceptable safety profile and a clinical effectiveness well beyond the Company's expectations. The Company plans an end of Phase II meeting with the FDA towards the end of the year in preparation for the Phase III study. Approval for a study has already been received from the US Recombinant Advisory Committee.

We are delighted with Trinam®'s progress and the efficacy results to date confirm our original enthusiasm for the product's potential.

Vitor™

At the start of the year we reported full results of the first Phase III clinical study of Vitor™ in cancer cachexia, the first human study of the agent in this disease. Treatment with Vitor™ significantly ($p = 0.028$) slowed the rate of cachexia in two of the cancers studied (small cell lung and colon cancer). In the smaller group of pancreatic cancer patients, who exhibit a more aggressive form of cachexia, the rate of weight loss slowed with Vitor™ treatment and, whilst the magnitude of effect approached that observed in the other two cancers, the effect on this third cancer was not statistically significant. The study reports are now finalised and, with this proof-of-principle data, we are in a good position for discussions with regulators later this year, for finalising the architecture of a final Phase III study to commence in 2007.

EG005

EG005 is an oral therapy for the treatment of the fat metabolism disorder lipodystrophy, in HIV-positive patients. The product is in early clinical development to assess its effect on a range of end points relevant to this poorly understood disease. Last year we reported results for a three-month experimental Phase II study in 50 patients which showed interesting data in the product's favour in four markers of the condition. The one-year voluntary extension

of that study has now completed and we expect to report the initial results in the near future, at which point we will make a decision regarding the product's ongoing development.

Devices

Kerraboot®

Following our decision to increase the absorbency of Kerraboot®, we are pleased to report that the first half of 2006 has shown a steady growth in UK sales, with prescriptions written by doctors and nurses in the period being 38% higher than in the same period last year. We continue to receive consistent positive reports of the efficacy of the product, particularly in diabetic foot ulcers. Whilst we still have a lot to achieve in growing UK sales, the period on period growth has occurred at a time when the UK market has been very difficult. In particular the influence of regional (primary care trust) formularies in determining prescribing has never been greater and we are encouraged by the fact that, in the period, the number of formulary inclusions has risen to 17, from two at November 2005. Immediately post period, we introduced the white version of Kerraboot®, for patients who prefer their ulcers not to be visible. The early market signs are that this will be a beneficial addition to the sales portfolio.

On the international front, we have successfully concluded six distribution deals, including one for the important Chinese market. The first international orders have recently been received from two licensees (Turkey and Australia/New Zealand).

Elsewhere, we are expecting regulatory and pricing approvals to be achieved by the majority of licensees during the second half of this year.

Clinical trials of Kerraboot® in China and Norway at national leg ulcer centres have produced the same good clinical results as those seen in the UK, and have confirmed the cost benefit for the product in those markets.

Whilst the healthcare sales environment in the UK will undoubtedly remain tough for the foreseeable future, the cost benefit ratio of Kerraboot® should be a favourable catalyst in developing sales of the product.

Flaminal®

We were delighted to announce both the successful in-licensing and NHS price reimbursement for Flaminal®, a novel enzyme-based topical anti-infective product for wounds where healing is slowed by high levels of bacteria in the wound bed. This will be sold by our existing sales force. The UK market for this product class is circa £30m and has grown over 50% in the last two years. With Flaminal® offering a healing rate benefit of up to three times those published for existing products, and notably being highly active against methicillin-resistant *Staphylococcus aureus* ("MRSA"), we believe the sales potential of Flaminal® in the UK is significant. We will announce the launch date shortly.

We have identified further interesting in-licensing targets in the woundcare devices area which will help us to build a stand-alone devices business in line with our corporate objectives.

Pre-clinical and research

Scavidin[®], our novel gene-based drug-targeting system, demonstrated control of tumour growth with both the chemotherapy paclitaxel and the radiotherapy yttrium in two pre-clinical cancer models. This was achieved at dose levels up to ten times less than those currently given. This represents a very significant benefit in the use of these agents where effectiveness is limited by side effects at existing doses. Additionally, our Neuropilin 1 small molecule antagonist programme has identified two interesting leads (one small peptide and one small molecule) which have shown in *in vitro* models to inhibit the growth and spread of cancer cells. Depending on regulatory agency advice, we hope to take at least one of these two programmes into human studies in the next 18 months. At the research level, our targeted integrating vector clip technology remains extremely exciting and considerable progress is also being made with the anti-angiogenic VEGF receptor antagonists which we believe may have high utility in degenerative diseases in the eye. For these earlier stage projects, our scientists continue to operate under our highly cost effective academic/industry co-operation model.

Manufacturing and new facility

Manufacturing of Cerepro[™] commenced early in 2006 in our cGMP production facility in Kuopio. The manufacturing of virus-based gene medicines to commercial specifications is one of the most complex manufacturing processes in the industry. So far, we have completed six successful

production runs conforming to the batch release criteria, confirming our ability to supply finished product for commercial use. We have successfully performed a further series of specific production line process validations to comply with EMEA requirements.

Construction of our new Kuopio manufacturing facility has progressed well during the period and we are now in the process of finalising the design of the internal layout and production equipment installations.

Financial review

The unaudited financial statements for the six months ended 30 June 2006 are prepared in accordance with the Group's accounting policies based on International Financial Reporting Standards ("IFRS") as adopted by the European Union.

Net cash outflow from operating activities for the period was £10.5m (six months ended 30 June 2005: £7.5m). Following receipt of £25.5m net proceeds of the placing and open offer in the period, cash, cash equivalents and money market investments were £49.4m at 30 June 2006 (£40.5m at 30 June 2005).

Revenues of £0.15m were recorded in the first six months of 2006 (six months ended 30 June 2005: £1.3m, which included the first £1.2m of initial milestone receipts due under the licensing agreement with Boehringer Ingelheim). The Kerraboot[®] revenues of £0.15m compare to £0.12m for the prior period. Prescriptions written for

Kerraboot® in the UK rose 38% in the six months ended 30 June 2006, compared with the six months ended 30 June 2005.

Research and development expenditure in the first six months of 2006 was £6.2m (six months ended 30 June 2005: £5.7m), reflecting the continued investment in the cGMP manufacturing facility in Finland as the Company scales up for Phase III and commercial production, and progress with the Cerepro™ and Trinam® later stage studies.

Sales and marketing expenses for the period were £0.8m (six months ended 30 June 2005: £0.7m) and related exclusively to the UK sales and marketing activities for Kerraboot®.

Administrative expenses for the period were £3.2m (six months ended 30 June 2005: £3.0m), with the rise being mainly due to an increase in the share-based compensation charge in the period.

In the six months ended 30 June 2006 the Group earned interest on its cash deposits of £0.8m (six months ended 30 June 2005: £1.0m), reflecting the lower cash balance prior to the fundraising.

Summary and outlook

The first half of this year has been one of the most demanding periods in the history of the Company as management has successfully executed a secondary fundraising, the development and manufacturing groups have progressed the MAA filing of Cerepro™ and progress

continues to be made in our other clinical and pre-clinical programmes.

We look forward to building on the achievements of the first six months and reporting on developments with the Cerepro™ MAA filing and the Phase III/IV study for that product, as well as on regulatory next-steps for Vitor™ and Trinam® and on our progress in our commercialisation activities.



Dennis Turner
Chairman



Nigel Parker
Chief Executive Officer

30 August 2006

Consolidated income statement

for the six months ended 30 June 2006 (unaudited)

	Note	Six months ended 30 June 2006 £'s	Six months ended 30 June 2005 £'s	Year ended 31 December 2005 £'s
Revenue		148,362	1,270,021	2,346,928
Cost of sales		(61,152)	(44,200)	(101,800)
Gross profit		87,210	1,225,821	2,245,128
Research and development expenses		(6,181,369)	(5,733,109)	(13,941,303)
Selling, marketing and distribution costs		(835,906)	(650,285)	(1,273,122)
Other administrative expenses		(2,749,402)	(2,713,254)	(5,181,539)
Share-based compensation		(476,643)	(249,182)	(504,600)
Administrative expenses		(3,226,045)	(2,962,436)	(5,686,139)
Other income		16,702	16,679	33,507
Operating loss		(10,139,408)	(8,103,330)	(18,621,929)
Investment income		753,232	1,026,099	1,893,382
Finance costs		(12,298)	(11,009)	(46,521)
Loss on ordinary activities before taxation		(9,398,474)	(7,088,240)	(16,775,068)
Taxation		700,000	618,631	1,640,253
Loss on ordinary activities after taxation, being retained loss for the period		(8,698,474)	(6,469,609)	(15,134,815)
Loss per share	2	(0.06)	(0.05)	(0.12)

All results relate wholly to continuing activities.

Consolidated balance sheet

as at 30 June 2006 (unaudited)

	30 June 2006 £'s	30 June 2005 £'s	31 December 2005 £'s
Non-current assets			
Goodwill	1,306,091	1,306,091	1,306,091
Other intangible assets	267,942	62,310	74,787
Property, plant and equipment	1,436,867	1,192,905	1,327,322
	3,010,900	2,561,306	2,708,200
Current assets			
Inventories	138,180	327,599	251,366
Trade and other receivables	3,683,654	3,293,963	2,802,837
Money market investments	45,180,305	20,000,000	28,000,000
Cash and cash equivalents	4,252,873	20,507,642	6,290,227
	53,255,012	44,129,204	37,344,430
TOTAL ASSETS	56,265,912	46,690,510	40,052,630
Current liabilities			
Trade and other payables	4,112,256	3,615,783	5,167,537
Loans	46,429	22,485	46,301
	4,158,685	3,638,268	5,213,838
Non-current liabilities			
Loans	411,167	465,704	433,185
	411,167	465,704	433,185
TOTAL LIABILITIES	4,569,852	4,103,972	5,647,023
Equity			
Share capital	1,593,726	1,271,609	1,274,931
Share premium	75,225,858	49,806,146	50,032,370
Merger reserve	36,988,989	36,988,989	36,988,989
Foreign currency translation reserve	(21,027)	(20,339)	(21,028)
Share-based compensation	1,446,507	714,446	969,864
Retained loss	(63,537,993)	(46,174,313)	(54,839,519)
Shareholders' funds	51,696,060	42,586,538	34,405,607
TOTAL LIABILITIES AND EQUITY	56,265,912	46,690,510	40,052,630

Consolidated statement of changes in equity

for the six months ended 30 June 2006 (unaudited)

	Share capital	Share premium	Merger reserve	Foreign currency translation reserve	Share-based compensation	Retained loss	Total
	£'s	£'s	£'s	£'s	£'s	£'s	£'s
Balance as at							
31 December 2004	1,263,337	49,430,703	36,988,989	(23,194)	465,264	(39,704,704)	48,420,395
Exchange differences							
on translating foreign operations recognised directly in equity	-	-	-	2,166	-	-	2,166
Share-based compensation	-	-	-	-	504,600	-	504,600
Loss for the year	-	-	-	-	-	(15,134,815)	(15,134,815)
Equity shares issued	6,644	431,349	-	-	-	-	437,993
Bonus issue	4,950	(4,950)	-	-	-	-	-
Adjustment of share issue expenses	-	175,268	-	-	-	-	175,268
Balance as at							
31 December 2005	1,274,931	50,032,370	36,988,989	(21,028)	969,864	(54,839,519)	34,405,607
Exchange differences							
on translating foreign operations recognised directly in equity	-	-	-	1	-	-	1
Share-based compensation	-	-	-	-	476,643	-	476,643
Loss for the period	-	-	-	-	-	(8,698,474)	(8,698,474)
Issue of share capital	318,745	26,774,592	-	-	-	-	27,093,337
Equity share options issued	50	3,751	-	-	-	-	3,801
Share issue expenses	-	(1,584,855)	-	-	-	-	(1,584,855)
Balance as at							
30 June 2006	1,593,726	75,225,858	36,988,989	(21,027)	1,446,507	(63,537,993)	51,696,060

Consolidated cash flow statement

for the six months ended 30 June 2006 (unaudited)

		Six months ended 30 June 2006 £'s	Six months ended 30 June 2005 £'s	Year ended 31 December 2005 £'s
	Note			
Net cash outflow from operating activities	3	(10,450,414)	(7,483,600)	(14,064,778)
Investing activities	4	(17,074,770)	(19,440,679)	(27,455,521)
Financing activities	4	25,490,393	204,613	552,075
Decrease in cash and cash equivalents		(2,034,791)	(26,719,666)	(40,968,224)
Cash and cash equivalents at beginning of period		6,290,227	47,256,285	47,256,285
Effect of exchange rate changes		(2,563)	(28,977)	2,166
Cash and cash equivalents at end of period		4,252,873	20,507,642	6,290,227

Notes to the financial information

1 BASIS OF PREPARATION - IFRS BASIS

The results for the six months to 30 June 2006 have been prepared on the basis of the accounting policies set out in Ark Therapeutics Group plc's 2005 Annual Report and Accounts. The results for the six months to 30 June 2006 and 2005 are unaudited but have been reviewed by the auditor, Deloitte & Touche LLP. The interim accounts do not constitute statutory accounts as defined in section 240 of the Companies Act 1985. The results for the full year 2005 have been taken from the Group's 2005 Annual Report and Accounts. The auditor has reported on the 2005 accounts and the report was unqualified and did not contain a statement under section 237(2) or (3) of the Companies Act 1985. The Group's 2005 Report and Accounts have been filed with the Registrar of Companies.

Copies of the interim results for the six months ended 30 June 2006 are being sent to all shareholders. A copy can also be found on the Company's website at www.arktherapeutics.com.

2 LOSS PER SHARE

IAS requires 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. For a loss making company with outstanding share options, net loss per share would only be increased by the exercise of out-of-money options. Since it seems inappropriate to assume that option holders would exercise out-of-money options, no adjustment has been made to diluted loss per share for out-of-money share options.

The calculation of basic and diluted loss per ordinary share is based on the loss of £8,698,474 for the six months ended 30 June 2006 (six months ended 30 June 2005: £6,469,609; year ended 31 December 2005: £15,134,815) and on 133,836,891 ordinary shares (June 2005: 126,463,186; December 2005: 127,168,920) being the weighted average number of ordinary shares in issue.

Notes to the financial information (continued)

3 RECONCILIATION OF OPERATING LOSS TO NET CASH OUTFLOW FROM OPERATING ACTIVITIES

	Six months ended 30 June 2006 £'s	Six months ended 30 June 2005 £'s	Year ended 31 December 2005 £'s
Operating loss	(10,139,408)	(8,103,330)	(18,621,929)
Depreciation and amortisation	516,799	194,527	447,343
(Increase)/decrease in accounts receivable	(193,804)	(609,873)	3,873
Decrease in inventories	113,186	3,410	79,644
(Decrease)/increase in accounts payable	(1,188,008)	44,206	1,568,205
Share-based compensation	476,643	249,182	504,600
Net cash outflow from operations	(10,414,592)	(8,221,878)	(16,018,264)
Research and development tax credit (overpaid)/received	(35,822)	738,278	1,953,486
Net cash outflow from operating activities	(10,450,414)	(7,483,600)	(14,064,778)

4 ANALYSIS OF CASH FLOWS FOR HEADINGS NETTED IN THE CASH FLOW STATEMENT

	Six months ended 30 June 2006 £'s	Six months ended 30 June 2005 £'s	Year ended 31 December 2005 £'s
Investing activities			
Interest received	802,041	948,093	1,350,011
Finance costs	(10,696)	-	(17,050)
Purchases of money market investments	(17,180,305)	(20,000,000)	(28,000,000)
Purchases of property, plant and equipment	(369,045)	(370,599)	(745,554)
Purchases of other intangible assets	(316,765)	(18,173)	(44,927)
Proceeds on sale of property, plant and equipment	-	-	1,999
Net cash outflow from investing activities	(17,074,770)	(19,440,679)	(27,455,521)
Financing			
Issue of shares	25,512,283	227,098	613,261
Repayment of loans	(21,890)	(22,485)	(61,186)
Net cash inflow from financing	25,490,393	204,613	552,075

Independent review report to Ark Therapeutics Group plc

Introduction

We have been instructed by the Company to review the financial information for the six months ended 30 June 2006 which comprises the income statement, the balance sheet, the statement of changes in equity, the cash flow statement and related notes 1 to 4. We have read the other information contained in the interim report and considered whether it contains any apparent misstatements or material inconsistencies with the financial information.

This report is made solely to the Company in accordance with Bulletin 1999/4 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 interim report, including the financial information contained therein, is the responsibility of, and has been approved by, the Directors. The Directors are responsible for preparing the interim report in accordance with the Listing Rules of the Financial Services Authority which require that the accounting policies and presentation applied to the interim figures are consistent with those applied in preparing the preceding annual accounts except where any changes, and the reasons for them, are disclosed.

Review work performed

We conducted our review in accordance with the guidance contained in Bulletin 1999/4 issued by the Auditing Practices Board for use in the United Kingdom. A review consists principally of making enquiries of Group management and applying analytical procedures to the financial information and underlying financial data and, based thereon, assessing whether the accounting policies and presentation have been consistently applied unless otherwise disclosed. A review excludes audit procedures such as tests of controls and verification of assets, liabilities and transactions. It is substantially less in scope than an audit performed in accordance with International Standards on Auditing (UK and Ireland) and therefore provides a lower level of assurance than an audit. Accordingly, we do not express an audit opinion on the financial information.

Review conclusion

On the basis of our review we are not aware of any material modifications that should be made to the financial information as presented for the six months ended 30 June 2006.

Deloitte & Touche LLP

Chartered Accountants
Cambridge, UK

30 August 2006

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.



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