

Oxford BioMedica Interim Report 2009

Reducing risk, maximising value



“Our new collaboration with sanofi-aventis enables us to advance the development of four LentiVector®-based products to treat ocular diseases. This was a key step in our strategy to reduce risk and maximise the value of our assets.”

Professor Alan Kingsman
Chairman

Development	Commercial
Enhanced potential	Increased income
<ul style="list-style-type: none"> • TroVax®: Follow-up analysis of TRIST study in renal cancer confirms clinical activity • TroVax®: Received FDA support and guidance on development in metastatic cancer • ProSavin®: Encouraging efficacy maintained for one year in Phase I/II trial • Ocular programmes: Initiated joint development plan for four LentiVector®-based products 	<ul style="list-style-type: none"> • Partnered with sanofi-aventis to develop novel therapies for ocular diseases <ul style="list-style-type: none"> – Upfront payment of US\$26 million – Committed funding of up to further US\$24 million over three years • Regained rights to TroVax® from sanofi-aventis • Commenced new TroVax® partnering initiative for further development

Financial ¹
Strengthened cash
<ul style="list-style-type: none"> • Net loss² of £0.5 million (H1 2008: £1.1 million) • Revenue² of £13.9 million (H1 2008: £13.4 million) • Net cash generated³ of £12.7 million (H1 2008 cash burn³ £11.8 million) • Net cash⁴ at 30 June of £34.8 million (30 June 2008: £27.0 million) • Current resources are sufficient to fund operations into first half of 2012

¹ Unaudited financial results for six months ended 30 June 2009

² Including exceptional items

³ Net cash generated by/used in operating activities plus sales and purchases of non-current assets

⁴ Cash, cash equivalents and current financial assets

Business Review

Overview

The year to date has seen some major events for Oxford BioMedica, which have significantly strengthened our financial resources and enhanced the potential of our core LentiVector® and 5T4 antigen technologies. Our new collaboration with sanofi-aventis enables us to advance the development of four LentiVector-based products to treat ocular diseases. This was a key step in our strategy to reduce risk and maximise the value of our assets. We made good progress towards our other partnering objectives, particularly for ProSavin®, which continues to impress in its first clinical trial. We have also implemented a new initiative to re-partner TroVax®, having regained worldwide rights. With support from the US Food and Drug Administration (FDA) for further development of TroVax and the encouraging findings from our latest analysis of the TRIST study, TroVax remains an important clinical asset. Our net cash position of £34.8 million at the end of the first half of 2009 is sufficient to support our operations into 2012 and provides a strong platform from which to deliver our strategic goals.

Operational review

TROVAX®: cancer

The reprioritisation of sanofi-aventis's portfolio in April 2009 resulted in our regaining the worldwide rights to TroVax. As part of the agreement, we received an immediate payment of US\$16.5 million from sanofi-aventis, which included an amount for reimbursement of certain previously committed development costs.

Despite not achieving its primary endpoint, the follow-up analysis of the TRIST study in metastatic renal cancer has yielded valuable insights into the efficacy of TroVax. In July 2009, we received the final comments from the FDA's review of the data, in which the agency acknowledged all of the points raised by our analysis and provided a clear path for further development of TroVax in multiple cancer settings. Following this outcome, we implemented a broad initiative to secure new partners for the development and commercialisation of TroVax.

Analysis of patients' survival in the TRIST study, as at 13 March 2009, showed a statistically significant advantage

to TroVax compared to placebo in sub-sets of patients, although the advantage was not significant in the overall population. Our analysis also identified haematological parameters that appear to predict whether patients are likely to respond to and benefit from TroVax treatment. These markers could be used to select patients for future studies, thus increasing the likelihood of a successful trial. For most of the common cancer types against which TroVax could be effective, abnormal haematology is less evident than in renal cancer. Hence, such selection would not dramatically reduce the size of suitable patient populations and would have only a modest impact on the market opportunity for TroVax.

In its comments on the TRIST data, the FDA agreed that confounding issues, including an imbalance of patients' baseline prognostic factors, may have contributed to the outcome of the TRIST study. Furthermore, the FDA accepted that there was no specific adverse event signal related to TroVax. The most frequent TroVax-related side effect was low-grade transient irritation at the injection site.

The FDA noted that the survival advantage for TroVax compared to placebo in patients receiving concomitant interleukin-2 was encouraging. Furthermore, the FDA agreed that, scientifically, it is reasonable to postulate that patients with a better haematological profile might respond more favourably to treatment with a cancer vaccine such as TroVax.

The FDA supported our proposal to pursue clinical development of TroVax in multiple types of metastatic cancer, notably colorectal, ovarian, hormone-refractory prostate and triple-negative breast cancer. The agency agreed that these were appropriate indications for TroVax, prior to further trials in renal cancer or in the adjuvant setting. Abnormal levels of haematological factors, which may have adversely affected the immune response in the TRIST study, are less evident in the proposed cancer indications than in metastatic renal cancer. The FDA invited submissions of adaptive Phase II/III trial designs in metastatic colorectal cancer and will work with Oxford BioMedica and our collaborators to prepare suitable protocols for submission and review. In addition, the FDA agreed to consider further development of TroVax in adjuvant indications, particularly adjuvant colorectal cancer, pending further clinical data in the metastatic setting.

Business Review

Operational review

TROVAX®: cancer continued

Earlier in the year, we presented updated results from the completed Phase I/II and II trials of TroVax in metastatic colorectal cancer and metastatic renal cancer at the Annual Meeting of the American Society of Clinical Oncology (ASCO). The updated cross-trial analyses confirmed the anti-cancer activity of the 5T4-specific immune response induced by TroVax. Furthermore, in the colorectal cancer trials, enhanced patient survival was detected after as few as two vaccinations of TroVax.

Our findings from the follow-up analysis of the TRIST study are consistent with the results from these previous trials, demonstrating that TroVax is both immunologically active and that there is a correlation between the strength of the 5T4-specific antibody response and improved survival. Detailed results from the TRIST study will be presented at the joint 15th Congress of the European CanCer Organisation (ECCO) and 34th Congress of the European Society for Medical Oncology (ESMO) in Berlin, Germany on 22 September 2009.

We are finalising clinical protocols for further trials, while advancing discussions with prospective commercial partners. We are also working with clinical trial networks and clinicians who may conduct independent studies of TroVax. We look forward to reporting the detailed TRIST results later in the year and, with new partners, commencing new clinical trials of TroVax in due course.

Separately, in January 2009, Bavarian Nordic re-filed its complaint against Oxford BioMedica in the USA, alleging infringement of US patents relating to Modified Vaccinia Ankara, the vector system used in TroVax. We maintain that the re-filed complaint is without merit and that it merely re-states previous claims of the original complaint, which was dismissed by the Court in January 2009. We continue to oppose this action.

PROSAVIN®: Parkinson's disease

Recent data from the Phase I/II trial of ProSavin in patients with mid-stage Parkinson's disease (PD) who are experiencing reduced benefit on L-DOPA 'equivalent' therapy have strengthened our confidence in the product's potential. Earlier in the year, the cohort of three patients at the second dose level completed their treatment. ProSavin has been safe and well tolerated in all patients, with no serious adverse events and no evidence of immunotoxicity. All patients have reduced or maintained their PD medication relative to baseline, during a period when they would have been expected to increase the dose required.

We reported in July 2009 that patients treated at the first dose level maintained their improvement in motor function for one year, with an average improvement of 29%. Analogous investigator assessments of patients in the second (two-fold higher dose) cohort have shown similar benefit at three months. All patients have experienced a better quality of life. The average increase in quality of life for patients in the first cohort was 42% at one year, based on a standard measure of clinical benefit that is recorded by the patient.

The study's independent Data Monitoring Committee reviewed the data in July 2009, as required by the study protocol, and supported the Company's proposal to proceed to a third dose level that is five-fold higher than the dose administered to the first cohort. We aim to evaluate a new delivery technology for the administration of the third dose level of ProSavin. The new technique reduces the surgical time, facilitates higher dosing and has the potential to provide better reproducibility as the number of study centres expands. This could reduce the overall clinical development timeline for the programme and increase the market opportunity.

We are finalising a protocol amendment for submission to the French Health Products Safety Agency (AFSSAPS) to incorporate the enhanced procedure in the trial. To accelerate the completion of the trial, we are also considering other amendments to the trial and have identified additional centres that could participate.

In parallel with the ongoing trial, we are designing protocols for the next stage of development, which we plan to present to both the FDA and European Medicines Agency (EMA). Manufacturing development is

underway to optimise the production process of ProSavin for larger studies and commercial supply. We have designed stable producer cell lines that should enable significant increases in scale. Discussions with prospective partners are also progressing and our objective is to complete the Phase I/II study and advance into larger studies with a partner as soon as possible.

Ocular programmes

In collaboration with sanofi-aventis, we are advancing four preclinical LentiVector-based product candidates into clinical trials for the treatment of ocular diseases. This collaboration is a significant milestone for the Company and it is the first product-based commercial deal to exploit the potential of our LentiVector technology. The decision to partner these products at the preclinical stage was part of our strategic realignment earlier in the year to conserve capital resources and to reduce our investment in early-stage programmes.

Through our new partnership with sanofi-aventis, signed in April 2009, we received an upfront payment of US\$26 million and retained development responsibility through Phase I/II proof-of-concept studies, with committed funding of up to a further US\$24 million over three years. If sanofi-aventis exercises its worldwide option to licence the products, we are entitled to receive further undisclosed license fees, milestone payments and royalties on product sales, the terms of which are consistent with other deals of this size and scope.

The four products covered by the agreement are: RetinoStat® for wet age-related macular degeneration, StarGen™ for Stargardt disease, UshStat™ for Usher syndrome 1B and EncorStat™ for corneal graft rejection. Age-related macular degeneration (AMD) is a major cause of blindness, affecting an estimated 25 to 30 million people in the Western world and the wet form accounts for 90% of all severe vision loss from the disease. RetinoStat is designed to require less frequent injections into the eye than current therapies for wet AMD. The three other products are targeting retinal or corneal disorders for which there are currently no effective treatments. Hence, we are addressing important unmet needs for patients and families affected by these debilitating ocular diseases. The joint development plan aims to advance all four product candidates into Phase I/II trials within three years, with RetinoStat and StarGen expected to enter clinical trials before the end of 2010.

Other activities

Following our strategic realignment in the second half of 2008, we curtailed clinical activities for Hi-8® MEL and MetXia® and focused our preclinical and research efforts on key product candidates. We continue to pursue partnership and alternative strategies to maximise the value of our development programmes and to leverage our extensive intellectual property portfolio. In the first half of 2009, we advanced discussions with a number of potential licensees.

Business Review

Financial review

The post-tax loss of £0.5 million for the first half of 2009 (H1 2008: £1.1 million) is net of an exceptional profit of £5.2 million that relates to termination of the TroVax collaboration and the close-out of current phase III TroVax development. The pre-exceptional net loss was £5.7 million.

On termination of the TroVax collaboration in April 2009, the Company accelerated the recognition of £5.5 million of deferred revenue, and recognised a termination fee of £4.4 million as exceptional revenue. Related costs, net of reimbursement of certain items by sanofi-aventis, were £1.6 million. Further exceptional items were a £2.6 million provision for costs to close out the TRIST clinical trial, and £0.5 million to write off prepaid costs of the planned QUASAR clinical trial in adjuvant colorectal cancer.

Non-exceptional revenue in the first half of 2009 was £4.0 million (H1 2008: £13.4 million), of which £1.1 million (H1 2008: nil) related to the new ocular collaboration with sanofi-aventis and £2.8 million (H1 2008: £13.3 million) related to the TroVax collaboration. Deferred income at 30 June 2009 was £15.8 million (30 June 2008: £13.1 million).

Non-exceptional operating costs (research and development costs plus administrative expenses) were £10.7 million, a reduction of £4.6 million (30%) over the first half of 2008. £4.4 million of the reduction in costs was attributable to lower expenditure on the TRIST study in the first half of 2009.

Net interest receivable in the first half of 2009 was £0.4 million (H1 2008: £1.0 million). This reflects a dramatic reduction in interest rates. The net tax credit in the period was £0.8 million (H1 2008: £0.9 million).

Overall cash, cash equivalents and available for sale investments increased by £12.9 million during the first six months of the year, giving a balance of £34.8 million at 30 June 2009. These increased resources, together with the ongoing support from sanofi-aventis for the expanded ocular programmes, have extended the estimated cash window, based on current activity levels, out into the first half of 2012.

Principal risks and uncertainties

The principal risks and uncertainties facing the Company remain those set out on page 42 of the 2008 Annual Report & Accounts, a copy of which is available on our website www.oxfordbiomedica.co.uk. The risks and uncertainties relate to intellectual property and patent protection, development risk, regulatory review risk, collaboration and third party risk, pharmaceutical pricing risk, competition risk, financial risk, staff risk and risks specific to gene therapy. Our principal risks and uncertainties remain the same for the second half of 2009. In the near term the Company's exposure to foreign exchange risk may be slightly increased, as it had US\$13.5 million (£8.2 million) of its cash and cash equivalents in US dollars at 30 June 2009. The Company has dollar-denominated commitments or spending plans in excess of US\$12 million over the next 12 months, which provide a natural hedge against most of this.

Current market conditions have affected the valuations of companies in Oxford BioMedica's sector and stage of development, and have restricted some companies' ability to raise capital. These factors do not have an immediate impact on Oxford BioMedica, as we have a strong balance sheet with sufficient working capital to fund operations into the first half of 2012. A prolonged downturn in the equity market could impact the Company's future activities to the extent that they may depend on additional financing.

Outlook

Our new collaboration with sanofi-aventis is the first step towards establishing a more sustainable business. We aim to build on the progress achieved during the first half of the year and to leverage the full potential of our IP and development portfolio through further partnerships and collaborations. We are also exploring opportunities to accelerate profitability through value-enhancing corporate activity that provides additional drivers of growth. With our enhanced cash position, we are well positioned in this challenging financial environment and we remain committed to our goal of creating a high-value, profitable biopharmaceutical company.

Consolidated Statement of Comprehensive Income

for the six months ended 30 June 2009

	6 months ended 30 June 2009 (unaudited)			6 months ended 30 June 2008 (unaudited) £000	12 months ended 31 December 2008 (audited)			
	Notes	Pre- exceptional £000	Exceptional items (note 5) £000		Total £000	Pre- exceptional £000	Exceptional items (note 5) £000	Total £000
Revenue		4,035	9,889	13,924	13,403	18,394	–	18,394
Cost of sales		(275)	(715)	(990)	(1,124)	(1,295)	–	(1,295)
Research and development costs		(7,784)	(3,807)	(11,591)	(12,921)	(22,482)	(4,561)	(27,043)
Administrative expenses		(2,928)	(169)	(3,097)	(2,345)	(3,840)	–	(3,840)
Other operating income: grants receivable		78	–	78	18	113	–	113
Operating (loss)/profit		(6,874)	5,198	(1,676)	(2,969)	(9,110)	(4,561)	(13,671)
Finance income		401	–	401	977	1,662	–	1,662
Finance costs		(29)	–	(29)	(16)	(24)	–	(24)
(Loss)/profit before tax		(6,502)	5,198	(1,304)	(2,008)	(7,472)	(4,561)	(12,033)
Taxation		778	–	778	875	1,992	–	1,992
(Loss)/profit for the period		(5,724)	5,198	(526)	(1,133)	(5,480)	(4,561)	(10,041)
Other comprehensive income								
Currency translation differences		15	–	15	3	(67)	–	(67)
Total recognised (expense)/income for the period		(5,709)	5,198	(511)	(1,130)	(5,547)	(4,561)	(10,108)
Basic and diluted (loss)/profit per ordinary share	6	(1.1p)	1.0p	(0.1p)	(0.2p)	(1.0p)	(0.9p)	(1.9p)

The notes on pages 9 to 19 form part of this financial information

Consolidated Statement of Financial Position

As at 30 June 2009

	Notes	30 June 2009 (unaudited) £000	30 June 2008 (unaudited) £000	31 December 2008 (audited) £000
Assets				
Non-current assets				
Intangible assets	7	11,119	15,597	11,119
Property, plant and equipment		688	697	688
		11,807	16,294	11,807
Current assets				
Trade and other receivables	8	4,078	9,400	7,305
Current tax assets		2,937	3,423	2,119
Financial assets: Available for sale investments	9	17,250	21,856	13,750
Cash and cash equivalents	9	17,589	5,134	8,141
		41,854	39,813	31,315
Liabilities				
Current liabilities				
Trade and other payables	10	11,279	10,356	10,558
Deferred income	11	5,634	9,750	4,486
Current tax payable		–	3	–
Provisions	12	2,575	59	88
		19,488	20,168	15,132
Net current assets		22,366	19,645	16,183
Non-current liabilities				
Other non-current liabilities		74	96	131
Deferred income	11	10,169	3,392	3,957
Provisions	12	571	557	631
		10,814	4,045	4,719
Net assets		23,359	31,894	23,271
Shareholders' equity				
Ordinary shares		5,395	5,373	5,373
Share premium		109,881	109,686	109,686
Merger reserve		14,310	14,310	14,310
Translation reserve		(677)	(622)	(692)
Retained losses		(105,550)	(96,853)	(105,406)
Total equity		23,359	31,894	23,271

The notes on pages 9 to 19 form part of this financial information

Consolidated Statement of Cash Flows

for the six months ended 30 June 2009

	Notes	Six months ended 30 June 2009 (unaudited) £000	Six months ended 30 June 2008 (unaudited) £000	Year ended 31 December 2008 (audited) £000
Cash flows from operating activities				
Cash generated by/(used in) operations	13	12,327	(12,638)	(20,610)
Net interest received		612	1,557	2,162
Tax credit received		–	102	2,551
Overseas tax paid		(36)	(38)	(74)
Net cash generated by/(used in) operating activities		12,903	(11,017)	(15,971)
Cash flows from investing activities				
Proceeds from sale of property, plant and equipment		1	1	10
Purchases of property, plant and equipment		(159)	(75)	(162)
Purchases of intangible assets		–	(679)	(766)
Net (purchase)/maturity of available for sale investments		(3,500)	5,329	13,435
Net cash (used in)/generated by investing activities		(3,658)	4,576	12,517
Cash flows from financing activities				
Net proceeds from issue of ordinary share capital		217	611	611
Net cash generated by financing activities		217	611	611
Net increase/(decrease) in cash and cash equivalents				
Cash and cash equivalents at 1 January		8,141	10,962	10,962
Effects of exchange rate changes		(14)	2	22
Cash and cash equivalents at period end	9	17,589	5,134	8,141

The notes on pages 9 to 19 form part of this financial information

Statement of Changes in Shareholders' Equity

As at 30 June 2009

Group	Share capital £000	Share premium £000	Merger reserve £000	Translation reserve £000	Losses £000	Total £000
At 1 January 2008	5,347	109,101	14,310	(625)	(96,201)	31,932
Six months ended 30 June 2008:						
Exchange adjustments	-	-	-	3	-	3
Loss for the period	-	-	-	-	(1,133)	(1,133)
Total recognised expense for the period	-	-	-	3	(1,133)	(1,130)
Share options						
Proceeds from shares issued	2	50	-	-	-	52
Value of employee services	-	-	-	-	481	481
Issue of shares excluding share options	24	545	-	-	-	569
Costs of share issues	-	(10)	-	-	-	(10)
At 30 June 2008 (unaudited)	5,373	109,686	14,310	(622)	(96,853)	31,894
Six months ended 31 December 2008:						
Exchange adjustments	-	-	-	(70)	-	(70)
Loss for the period	-	-	-	-	(8,908)	(8,908)
Total recognised expense for the period	-	-	-	(70)	(8,908)	(8,978)
Share options						
Value of employee services	-	-	-	-	355	355
At 31 December 2008 (audited)	5,373	109,686	14,310	(692)	(105,406)	23,271
Six months ended 30 June 2009:						
Exchange adjustments	-	-	-	15	-	15
Loss for the period	-	-	-	-	(526)	(526)
Total recognised expense for the period	-	-	-	15	(526)	(511)
Share options						
Proceeds from shares issued	-	4	-	-	-	4
Value of employee services	-	-	-	-	382	382
Issue of shares excluding share options	22	150	-	-	-	172
Net repayment of costs of share issues	-	41	-	-	-	41
At 30 June 2009 (unaudited)	5,395	109,881	14,310	(677)	(105,550)	23,359

The notes on pages 9 to 19 form part of this financial information

Notes to the Financial Information

for the six months ended 30 June 2009

1 GENERAL INFORMATION AND BASIS OF PREPARATION

The Company is a public limited company incorporated and domiciled in the UK. The address of its registered office is Medawar Centre, Oxford Science Park, Oxford, OX4 4GA.

The Company has its primary listing on the London Stock Exchange.

This condensed consolidated interim financial information was approved for issue on 26 August 2009.

This condensed consolidated interim financial information does not constitute statutory accounts within the meaning of Section 434 of the Companies Act 2006. Statutory accounts for the year ended 31 December 2008 were approved by the Board of Directors on 11 March 2009 and delivered to the Registrar of Companies. The report of the Auditors on the 2008 accounts was unqualified, did not contain an emphasis of matter paragraph and did not contain any statement under section 498 of the Companies Act 2006.

This condensed consolidated interim financial information has not been audited.

The condensed consolidated interim financial information for the six months ended 30 June 2009 has been prepared in accordance with the Disclosure and Transparency Rules of the Financial Services Authority and with IAS 34 'Interim financial reporting' as adopted by the European Union. The condensed consolidated interim financial information should be read in conjunction with the annual financial statements for the year ended 31 December 2008, which have been prepared in accordance with IFRSs as adopted by the European Union.

2 STATEMENT OF DIRECTORS' RESPONSIBILITIES

The Directors confirm that this condensed consolidated interim financial information has been prepared in accordance with IAS 34 as adopted by the European Union and that the interim management report includes a fair review of the information required by DTR 4.2.7 and DTR 4.2.8, namely:

- An indication of important events that have occurred during the first six months and their impact on the condensed set of financial statements, and a description of the principal risks and uncertainties for the remaining six months of the financial year; and
- Material related party transactions in the first six months and any material change in related-party transactions described in the last annual report.

The Directors of Oxford BioMedica plc are listed in the Oxford BioMedica plc annual report for 31 December 2008. A list of current Directors is maintained on the Company's website: www.oxfordbiomedica.co.uk.

By order of the Board



John Dawson
Chief Executive Officer
26 August 2009

Notes to the Financial Information

3 ACCOUNTING POLICIES

Except as described below, the accounting policies applied are consistent with those of the annual financial statements for the year ended 31 December 2008, as described in those annual financial statements.

Taxes on income in the interim periods are accrued using the tax rate that would be applicable to expected total annual earnings.

The following new standards, amendments to standards or interpretations are mandatory for the first time for the financial year beginning 1 January 2009 and have been applied by the Group:

- IAS 1 (revised), 'Presentation of financial statements'. The revised standard prohibits the presentation of items of income and expenses (that is 'non-owner changes in equity') in the statement of changes in equity, requiring 'non-owner changes in equity' to be presented separately from owner changes in equity. All 'non-owner changes in equity' are required to be shown in a performance statement. Entities can choose whether to present one performance statement (the statement of comprehensive income) or two statements (the income statement and statement of comprehensive income). The Group has elected to present a single statement of comprehensive income. The interim financial statements have been prepared under the revised disclosure requirements.
- IFRS 8, 'Operating segments'. IFRS 8 replaces IAS 14, 'Segment reporting'. It requires a 'management approach' under which segment information is presented on the same basis as that used for internal reporting purposes. Management considers that there is only one reportable segment: biotechnology research and development. Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker has been identified as the Senior Management Group that makes strategic decisions. Assets, liabilities and overheads are allocated to this one segment.
- IFRS 2 (amendment), 'Share-based payment'. IFRS 2 (amendment) deals with vesting conditions and cancellations. The amendment does not have a material impact on the Group's financial statements.
- IAS 32 (amendment), 'Financial instruments: Presentation'. The amendment does not have a material impact on the Group's financial statements.
- IAS 39 (amendment), 'Financial instruments: Recognition and measurement'. The amendment does not have an impact on the Group's financial statements.

The following new standards, amendments to standards or interpretations are mandatory for the first time for the financial year beginning 1 January 2009, but are not currently relevant for the Group:

- IAS 23 (amendment), 'Borrowing costs'.
- IFRIC 13, 'Customer loyalty programmes'.
- IFRIC 15, 'Agreements for the construction of real estate'.
- IFRIC 16, 'Hedges of a net investment in a foreign operation'.

3 ACCOUNTING POLICIES (CONTINUED)

The following new standards, amendments to standards and interpretations have been issued, but are not effective for the financial year beginning 1 January 2009 and have not been early adopted:

- IFRS 3 (revised), 'Business combinations' and consequential amendments to IAS 27, 'Consolidated and separate financial statements', IAS 28, 'Investments in associates' and IAS 31, 'Interests in joint ventures', effective prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after 1 July 2009. Management is assessing the impact of the new requirements regarding acquisition accounting, consolidation and associates on the Group. The Group does not have any joint ventures. The revised standard continues to apply the acquisition method to business combinations, with some significant changes.
- IFRIC 17, 'Distributions of non-cash assets to owners', effective for annual periods beginning on or after 1 July 2009. This is not currently applicable to the Group, as it has not made any non-cash distributions.
- IFRIC 18, 'Transfers of assets from customers', effective for transfer of assets received on or after 1 July 2009. This is not relevant to the Group, as it has not received any assets from customers.

Use of estimates and assumptions

The preparation of financial statements in conformity with generally accepted accounting principles requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates and judgements are continually made and are based on historic experience and other factors, including expectations of future events that are believed to be reasonable in the circumstances.

Critical accounting estimates and assumptions

In the six months ended 30 June 2009 the Group received an initial payment of US\$26.0 million (£16.6 million) from the sanofi-aventis ocular gene therapy collaboration. This is recognised as revenue on a straight-line basis over 36 months from May 2009 to April 2012, the expected duration of the current phase of the collaboration. £924,000 has been recognised as revenue in the six months ended 30 June 2009, and £15,716,000 has been treated as deferred income. Should the timing of the current phase of the collaboration differ from management's estimates, there could be a material effect on the income statement and on the amount of deferred revenue in the balance sheet. For example, if the revenue recognition period had been six months longer, the amount of revenue recognised in the six months ended 30 June 2009 would be reduced by £132,000 and the amount of deferred income increased by the same amount.

Notes to the Financial Information

4 SEGMENTAL ANALYSIS

The chief operating decision-maker has been identified as the Senior Management Group (SMG). The SMG reviews the Group's internal reporting in order to assess performance and allocate resources. Management has determined the operating segments based on the internal management reports.

The SMG considers that the business comprises a single activity, which is biotechnology research and development. The SMG reviews the Group's profit or loss and its cash flows, assets and liabilities on a whole-company basis. In carrying out these reviews, the SMG considers all material items of income and expenditures that are directly attributable to individual development programmes. The internal management reports do not allocate assets and liabilities or shared overheads to individual products, as the Group does not consider it meaningful, in the present development phase, to attribute profits or losses to individual products.

Based on above considerations, there is considered to be one reportable segment: biotechnology research and development.

Internal and external reporting is on a consolidated basis, with purchases and sales between subsidiaries eliminated on consolidation. Therefore the segment financial information is the same as that set out in the consolidated statement of comprehensive income, the consolidated statement of financial position, the consolidated statement of cash flows and the statement of changes in shareholders' equity.

5 EXCEPTIONAL ITEMS

Exceptional items represent significant items of income or expense which due to their nature or the expected infrequency of the events giving rise to them, are presented separately on the face of the income statement to give a better understanding to shareholders of the elements of financial performance in the period, so as to facilitate comparison with prior periods and to better assess trends in financial performance.

	TroVax collaboration £000	TroVax clinical trials £000	30 June 2009 Total (unaudited) £000	30 June 2008 (unaudited) £000	31 December 2008 (audited) £000
Revenue	9,889	–	9,889	–	–
Cost of sales	(715)	–	(715)	–	–
Research and development costs	(694)	(3,113)	(3,807)	–	(4,561)
Administrative expenses	(169)	–	(169)	–	–
Exceptional operating profit/(loss)	8,311	(3,113)	5,198	–	(4,561)

5 EXCEPTIONAL ITEMS (CONTINUED)

On 28 April 2009 the Group's development partner, sanofi-aventis, terminated the TroVax collaboration and returned the worldwide rights to TroVax to Oxford BioMedica. In connection with the termination, sanofi-aventis made a payment of US\$16.5 million (£11,021,000), of which US\$6.5 million (£4,372,000) was a termination fee and US\$10.0 million (£6,649,000) was reimbursement of TroVax development expenditure incurred by Oxford BioMedica for the planned sanofi-aventis clinical development programme, treated as a pass-through cost to sanofi-aventis. Subsequently, sanofi-aventis agreed to increase this reimbursement by US\$925,000 (£562,000), included in trade and other receivables at 30 June 2009. Exceptional expenses in 2009 are net of reimbursement received or receivable from sanofi-aventis.

The Group has classified the following as exceptional items in connection with the sanofi-aventis collaboration: the termination fee of £4,372,000; the remaining deferred TroVax income at the date of termination (£5,517,000); prepaid cost of sales (royalty) of £715,000 attributable to the deferred income; and the write-off of £863,000 (R&D £694,000; admin £169,000) that, had the collaboration continued, was expected to be reimbursed by sanofi-aventis.

On 3 June 2009 the FDA held a type C meeting with Oxford BioMedica to discuss the TRIST clinical trial and the future development of TroVax. The FDA supported Oxford BioMedica's proposal to pursue clinical development of TroVax in metastatic disease, including colorectal, ovarian, hormone refractory prostate cancer, and triple-negative breast cancer, prior to further trials in renal cancer. Proof of concept from new Phase II studies in these indications will be key to the successful development of TroVax in the future. Data from the current TRIST study in renal cancer will support the development of TroVax, but will not be a pivotal component. It is probable that proof of concept from Phase II studies in metastatic disease will be required prior to commencing clinical trials in adjuvant settings.

The Group has classified £3,113,000 as exceptional R&D expenses in connection with the FDA review of TroVax development, comprising: a provision of £2,599,000 for the estimated costs to close out the TRIST study in renal cancer; and the write-off of £514,000 prepaid clinical trial expenses in respect of the planned Quasar clinical trial in adjuvant colorectal cancer.

Exceptional costs of £4,561,000 in the year ended 31 December 2008 resulted from impairment of intangible assets (in-process R&D and intellectual property rights).

6 BASIC LOSS AND DILUTED LOSS PER ORDINARY SHARE

The basic loss per share has been calculated by dividing the loss for the period by the weighted average number of shares of 539,094,595 in issue during the six months ended 30 June 2009 (six months ended 30 June 2008: 537,061,383; year ended 31 December 2008: 537,176,196).

The Company had no dilutive potential ordinary shares in either period which would serve to increase the loss per ordinary share. There is therefore no difference between the loss per ordinary share and the diluted loss per ordinary share.

Notes to the Financial Information

7 INTANGIBLE ASSETS

	In process R&D £000	Intellectual property rights £000	Total £000
Cost			
At 1 January 2009 and 30 June 2009	10,400	5,505	15,905
Accumulated amortisation and impairment			
At 1 January 2009 and 30 June 2009	3,598	1,188	4,786
Net book amount at 30 June 2009 (unaudited)	6,802	4,317	11,119
Cost			
At 1 January 2008	10,400	4,780	15,180
Additions	–	687	687
At 30 June 2008	10,400	5,467	15,867
Accumulated amortisation and impairment			
At 1 January 2008 and 30 June 2008	–	270	270
Net book amount at 30 June 2008 (unaudited)	10,400	5,197	15,597
Cost			
At 1 January 2008	10,400	4,780	15,180
Additions	–	761	761
Disposal	–	(36)	(36)
At 31 December 2008	10,400	5,505	15,905
Accumulated amortisation and impairment			
At 1 January 2008	–	270	270
Impairment in the year	3,598	954	4,552
Disposal	–	(36)	(36)
At 31 December 2008	3,598	1,188	4,786
Net book amount at 31 December 2008 (audited)	6,802	4,317	11,119

8 TRADE AND OTHER RECEIVABLES

	30 June 2009 (unaudited) £000	30 June 2008 (unaudited) £000	31 December 2008 (audited) £000
Amounts falling due after more than one year			
Other receivables – rent deposit	143	118	160
Amounts falling due within one year			
Trade receivables	–	103	106
Other receivables	1,139	6,463	4,394
Other tax receivable	151	240	333
Prepaid clinical trial expenses	58	966	790
Other prepayments	2,587	1,487	1,522
Accrued income	–	23	–
	3,935	9,282	7,145
Total trade and other receivables	4,078	9,400	7,305

Other receivables include £562,000 (June 2008: £5,355,000; December 2008: £3,913,000) expenditure related to TroVax to be reimbursed by sanofi-aventis. Prepaid clinical trial expenses comprise stocks of materials for use in clinical trials and advance payments to clinical trial sites.

9 CASH AND CASH EQUIVALENTS

	30 June 2009 (unaudited) £000	30 June 2008 (unaudited) £000	31 December 2008 (audited) £000
Cash at bank and in hand	17,589	4,134	3,141
Short term bank deposits	–	1,000	5,000
Total cash and cash equivalents	17,589	5,134	8,141

In addition to the cash and cash equivalents described above, the Group held bank deposits of £17,250,000 (June 2008: £21,856,000; December 2008: £13,750,000) with an initial term to maturity between three and twelve months, classified as available for sale investments.

Notes to the Financial Information

10 TRADE AND OTHER PAYABLES – CURRENT

	30 June 2009 (unaudited) £000	30 June 2008 (unaudited) £000	31 December 2008 (audited) £000
Trade payables	1,900	2,651	3,298
Other taxation and social security	128	150	136
Accruals	9,251	7,555	7,124
Total trade and other payables	11,279	10,356	10,558

Trade and other payables include the following amounts related to TroVax Phase III development:

Trade payables £1,087,000 (June 2008: £1,762,000; December 2008: £2,201,000)

Accruals £2,662,000 (June 2008: £2,952,000; December 2008: £3,042,000)

11 DEFERRED INCOME

	30 June 2009 (unaudited) £000	30 June 2008 (unaudited) £000	31 December 2008 (audited) £000
Current	5,634	9,750	4,486
Non-current	10,169	3,392	3,957
Total deferred income	15,803	13,142	8,443

On 28 April 2009 the Group entered into a new collaborative programme with sanofi-aventis to develop four gene therapy products to treat ocular diseases. An initial non-refundable payment of US\$26 million (£16,641,000) was received. This is being recognised as revenue on a straight line basis over 36 months (the expected duration of the initial stage of the collaboration). Revenue of £924,000 has been recognised under this collaboration in the six months ended 30 June 2009. The remaining £15,716,000 is classified as deferred income. £5,547,000 is expected to be recognised as income in the next 12 months and is classified as current: the remaining £10,169,000 is classified as non-current.

Deferred income at 31 December 2008 was mainly attributable to the TroVax collaboration with sanofi-aventis. On termination of this collaboration on 28 April 2009 the remaining deferred balance of £5,517,000 was released to the income statement and has been classified as exceptional revenue (see note 5 above).

12 PROVISIONS

	Clinical trial £000	Dilapidations £000	Onerous lease £000	Total £000
At 1 January 2009	–	411	308	719
Exchange adjustments	–	–	(30)	(30)
Provided in the period	2,599	–	–	2,599
Utilised in the period	(102)	–	(46)	(148)
Amortisation of discount	–	3	3	6
Change of discount rate – charged to income statement	–	–	(1)	(1)
Change of discount rate – adjustment to recognised fixed asset	–	1	–	1
At 30 June 2009 (unaudited)	2,497	415	234	3,146
At 1 January 2008	–	371	279	650
Exchange adjustments	–	–	(1)	(1)
Utilised in the period	–	–	(35)	(35)
Amortisation of discount	–	9	6	15
Change of discount rate – charged to income statement	–	–	(4)	(4)
Change of discount rate – adjustment to recognised fixed asset	–	(9)	–	(9)
At 30 June 2008 (unaudited)	–	371	245	616
At 1 January 2008	–	371	279	650
Exchange adjustments	–	–	82	82
Utilised in the year	–	–	(75)	(75)
Amortisation of discount	–	11	8	19
Change of discount rate – charged to income statement	–	–	14	14
Change of discount rate – adjustment to recognised fixed asset	–	29	–	29
At 31 December 2008 (audited)	–	411	308	719

Notes to the Financial Information

12 PROVISIONS (CONTINUED)

	30 June 2009 (unaudited) £000	30 June 2008 (unaudited) £000	31 December 2008 (audited) £000
Current	2,575	59	88
Non-current	571	557	631
Total provisions	3,146	616	719

The clinical trial provision was established following the FDA review of TroVax development in June 2009 (see note 5 above). It represents the anticipated costs to complete the TRIST study in renal cancer from the date of the FDA review. The TRIST study reached full recruitment (733 patients) in March 2008. Following an interim DSMB review, dosing of patients with TroVax was stopped in July 2008. At the most recently reported analysis to 13 March 2009, there were 399 patients (54%) remaining on study. The close-out of the study is expected to be substantially complete by 31 December 2009. In light of the relatively short time-line, this provision has not been discounted, as the Directors do not consider the impact would be material.

The dilapidations provision relates to anticipated costs of restoring the leasehold property in Oxford, UK to its original condition at the end of the present leases in 2011, discounted at 1.52% per annum (2008: 1.59%). The provision will be utilised at the end of the leases if they are not renewed.

The onerous lease provision relates to the estimated rental shortfall in respect of a redundant property in San Diego, USA which has been sub-let for the remainder of the lease term until June 2012, discounted at 2.36% per annum (2008: 2.23% per annum). The provision will be utilised over the term of the lease.

13 CASH FLOW FROM OPERATING ACTIVITIES**Reconciliation of loss before tax to net cash from operations**

	Six months ended 30 June 2009 (unaudited) £000	Six months ended 30 June 2008 (unaudited) £000	Year ended 31 December 2008 (audited) £000
Continuing operations			
Loss before tax	(1,304)	(2,008)	(12,033)
Adjustment for:			
Depreciation	155	154	307
Profit on disposal of property, plant and equipment	(1)	-	(10)
Impairment of intangible assets	-	-	4,552
Finance income	(401)	(977)	(1,662)
Finance expense	29	16	24
Charge in relation to employee share schemes	382	481	836
Changes in working capital:			
Decrease/(increase) in trade and other receivables	2,965	(5,310)	(3,074)
Increase in payables	692	817	983
Increase/(decrease) in deferred income	7,360	(5,771)	(10,470)
Increase/(decrease) in provisions	2,450	(40)	(63)
Net cash generated by/(used in) operations	12,327	(12,638)	(20,610)

Notes

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