

Osmetech plc



**Interim Statement
2001**

Chairman's Statement

Introduction

In November, Osmetech received approval from the US Food and Drug Administration (FDA) for its Urinary Tract Infection (UTI) sensor device. This landmark achievement is a first for the electronic nose (e-nose) industry and is a major step forward in the commercialisation of the Company's innovative and versatile platform technology.

Highlights

- FDA approval received for UTI screening device.
- BV clinical trials commenced at three leading US and UK hospitals.
- £5m funding facility secured through an equity line of credit.

UTI

FDA approval was secured within the timescale set out at the start of the submission process. This approval is a pre-requisite for selling a medical device into the US market and is internationally recognised as being the most significant regulatory hurdle to overcome.

UTIs represent the single largest test carried out by clinical laboratories worldwide. It is estimated that at least 50 million urine cultures are performed every year in the US alone, at a cost of approximately \$5 per test. Currently the majority of UTI tests are culture-based with test samples being sent for laboratory screening, a process that typically takes three working days. Approximately 80% return a negative result. Osmetech's screening device should enable negative samples to be screened out within minutes enabling the number of cultured samples to be greatly reduced, resulting in cost savings and improved patient treatment.

Osmetech joins a very small group of UK companies that have successfully taken new technology through the FDA process. The landmark achievement will enable the Company to step up discussions with potential commercial partners.

BV

BV is one of the most common causes of vaginal infections and has been linked to such problems in pregnancy as pre-term delivery and spontaneous abortion.

In a pre-trial study recently completed at Johns Hopkins Hospital, Baltimore, the Osmetech BV polymer sensor gave diagnostic readings that were more objective than current testing methods and in a significantly faster timescale.

Following this success, clinical trials have now commenced at three leading US and UK hospitals: Johns Hopkins Hospital; Brigham & Women's Hospital, Harvard and St George's Hospital, London. Data from the trials will support the Company's second submission for FDA approval, which we expect to be filed by the end of April 2002.

Other Projects

Our strategy continues to be to apply Osmetech's gas sensing technology to opportunities within the huge global healthcare market. The recent focus for Osmetech has been upon the two leading projects described above. With FDA approval having now been obtained for UTI and the BV project well advanced, we expect that some of the longer-term projects, including pneumonia in intensive care unit patients, will now enter a new phase of development.

Point of Care Device

Within the in-vitro diagnostics market, there is a general movement towards near patient testing and many of Osmetech's healthcare opportunities lie in this area. Development is well advanced for a device that could provide a common platform for diagnostic tests utilising our technology in the point of care setting.

Financial Review

Losses for the half-year were £2,517,000 (2000 - £2,129,000) and reflect the increased costs associated with the development of the point of care device. A temporary increase in creditors at 31 October 2001 was the principal reason for the cash outflow before financing and management of liquid resources of £2,359,000 being below the level of losses for the period.

Cash balances at 31 October of £2,690,000 have subsequently been enhanced by the 5% issue of share capital to a number of institutional investors raising £1,302,000 net of expenses.

In September, the Company secured an equity credit line of £5,000,000 with GEM Global Yield Fund Limited, the US based private investment group. The facility is available for a two-year period during which Osmetech will control the timing and the maximum amount of each draw down. The Company is not obliged to draw down on the funds on offer, but it provides important flexibility and cost-effective access to funding outside traditional equity markets.

Outlook

Our first FDA approval has been a considerable achievement for Osmetech. The Company has made the transition from the conceptual phase to one that has demonstrated the efficacy of its core technology under rigorous examination and the strictest of regulatory assessment criteria.

The UTI screener is the first of many healthcare diagnostic tests that will be built upon this same technological platform. With a strong IP position, we are confident that this combination will enable Osmetech to successfully partner major international medical devices companies looking for the next generation of diagnostic products.

Gordon Hall
Chairman

11 January 2002

Independent Review Report to Osmetech plc

Introduction

We have been instructed by the Company to review the financial information for the six months ended 31 October 2001 on pages 4 to 7. 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.

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 should be 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 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 United Kingdom Auditing Standards 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 31 October 2001.

BDO Stoy Hayward

Chartered Accountants

Manchester

11 January 2002

Group Profit and Loss Account

For the six months ended 31 October 2001

	Six months to 31st October 2001 £'000	Six months to 31st October 2000 £'000	Year Ended 30th April 2001 £'000
Turnover	21	26	56
Operating loss	(2,618)	(2,325)	(4,760)
Net interest receivable	101	196	382
Loss on ordinary activities before tax	(2,517)	(2,129)	(4,378)
Tax on loss on ordinary activities	—	—	—
Loss before and after taxation attributable to Shareholders	(2,517)	(2,129)	(4,378)
Loss per share - basic	(1.11p)	(0.98p)	(1.97p)

Group Statement of Total Recognised Gains and Losses

For the six months ended 31 October 2001

	Six months to 31st October 2001 £'000	Six months to 31st October 2000 £'000	Year Ended 30th April 2001 £'000
Loss for the period after taxation	(2,517)	(2,129)	(4,378)
Exchange (loss) / gain on consolidation	(1)	4	—
Total recognised losses for the period	(2,518)	(2,125)	(4,378)

Group Balance Sheet

As at 31st October 2001

	31st October 2001 £'000	31st October 2000 £'000	30th April 2001 £'000
Fixed assets			
Intangible assets	878	838	863
Tangible assets	<u>327</u>	<u>357</u>	<u>362</u>
	<u>1205</u>	<u>1195</u>	<u>1,225</u>
Current assets			
Stocks	107	127	75
Debtors	306	337	273
Cash at bank and in hand	<u>2,690</u>	<u>7,211</u>	<u>5,021</u>
	<u>3,103</u>	<u>7,675</u>	<u>5,369</u>
<i>Less:</i>			
Creditors: amounts falling due within one year	<u>940</u>	<u>751</u>	<u>736</u>
Net current assets	<u>2,163</u>	<u>6,924</u>	<u>4,633</u>
Total assets less current liabilities	<u>3,368</u>	<u>8,119</u>	<u>5,858</u>
Creditors: amounts falling due after more than one year	<u>—</u>	<u>8</u>	<u>—</u>
	<u><u>3,368</u></u>	<u><u>8,111</u></u>	<u><u>5,858</u></u>
Capital and reserves			
Called up share capital	2,282	2,268	2,268
Share premium account	24,124	24,109	24,110
Profit and loss account	<u>(23,038)</u>	<u>(18,266)</u>	<u>(20,520)</u>
	<u><u>3,368</u></u>	<u><u>8,111</u></u>	<u><u>5,858</u></u>
Reconciliation of movement in shareholders' funds			
Opening shareholders' funds	5,858	7,498	7,498
Loss for the period	(2,517)	(2,129)	(4,378)
New share capital subscribed (including premium)	28	2,773	2,773
Issue expenses	—	(35)	(35)
Exchange differences	<u>(1)</u>	<u>4</u>	<u>—</u>
	<u><u>3,368</u></u>	<u><u>8,111</u></u>	<u><u>5,858</u></u>

Group Cash Flow Statement

For the six months ended 31 October 2001

	Six months to 31st October 2001 £'000	Six months to 31st October 2000 £'000	Year Ended 30th April 2001 £'000
Net cash outflow from operating activities	(2,474)	(1,906)	(4,270)
Returns on investment and servicing of finance			
Interest received	194	87	333
Net cash inflow from returns on investment and servicing of finance	194	87	333
Capital expenditure and financial investment			
Payments to acquire intangible assets	(29)	(36)	(62)
Payments to acquire tangible assets	(50)	(100)	(147)
Net cash outflow from investing activities	(79)	(136)	(209)
Management of liquid resources			
Transfer from/(to) term deposits	2,448	(750)	1,250
Net cash inflow/(outflow) before financing	89	(2,705)	(2,896)
Financing			
Shares issued by parent company	28	2,773	2,773
Issue expenses	—	(35)	(35)
Net cash inflow from financing	28	2,738	2,738
Increase/(decrease) in cash	117	33	(158)

Group Cash Flow Statement (continued)

For the six months ended 31 October 2001

	Six months to 31st October 2001 £'000	Six months to 31st October 2000 £'000	Year Ended 30th April 2001 £'000
Reconciliation of net cash flow to movement in net funds			
Increase/(decrease) in cash	117	33	(158)
Movement in liquid resources	(2,448)	750	(1,250)
Exchange differences	—	2	3
Change in net funds	(2,331)	785	(1,405)
Net funds at beginning of period	5,021	6,426	6,426
Net funds at end of period	2,690	7,211	5,021
	<u> </u>	<u> </u>	<u> </u>
Reconciliation of operating loss to operating cash flow			
Operating loss	(2,618)	(2,325)	(4,760)
Depreciation and amortisation of fixed assets	92	88	185
(Increase) in stocks	(34)	(3)	(11)
(Increase) / decrease in debtors	(126)	8	8
Increase in creditors	205	309	288
Loss on disposal of fixed assets	7	17	20
	<u> </u>	<u> </u>	<u> </u>
	(2,474)	(1,906)	(4,270)
	<u> </u>	<u> </u>	<u> </u>

Notes

- The Interim Statement, which is unaudited, has been prepared on the basis of the accounting policies set out in the statutory accounts to 30th April 2001. The directors do not recommend the payment of an interim dividend. The balance sheet as at 30 April 2001 and the results for the year there ended have been abridged from the statutory accounts which have been filed with the Registrar of Companies. The auditors' opinion on those accounts was unqualified.
- The calculation of loss per share for the six months to 31 October 2001 is based upon a loss of £2,516,987 (31st October 2000: loss of £2,128,539; 30th April 2001: loss of £4,378,409) and on the weighted average number of shares in issue for the period, 227,300,727 (31st October 2000: 217,234,503 and 30 April 2001: 221,970,454).