

21 March 2006

## **Osmetech plc**

Preliminary Results for the 8 months ending 31<sup>st</sup> December 2005

Osmetech is a fast developing, international healthcare diagnostics business, targeting the high growth, near patient testing sector serving small to medium sized hospitals.

### **Highlights:**

- Sales for the 8 month period of £5.59m (12 months ended 30 April 2005 - £5.83m) – increase of 78% on the corresponding 8 month period
- Critical Care Division sales for calendar year 2005 increase by 64% to \$14.79m (2004 calendar year - \$9.04m)
- Substantial growth in sales of Critical Care Division's blood-gas analysers and consumables to both human and veterinary (IDEXX) markets
- Operating losses for the 8 month period of £5.09m before share compensation charges of £0.5m (12 months ended 30 April 2005 – operating losses of £2.15m before exceptional operating costs of £0.83m)
- Loss after tax for the 8 month period of £5.22m (12 months ended 30 April 2005 - £2.72m)
- Acquisition of Clinical Micro Sensors Inc. (CMS) in July 2005 strengthens the Group's presence in the fast growing molecular diagnostics market
- FDA clearance received for eSensor Cystic Fibrosis screening test
- Three molecular diagnostics products, eSensor, OPTI GENE and OPTI TUBE on schedule for launch in H1 2006
- Worldwide roll out of new Critical Care products, OPTI LION and OPTI R
- Excellent growth prospects in the small to medium sized hospital market

### **James White, Chief Executive, Osmetech plc said:**

'Our investment in the Critical Care Division since it was acquired from Roche in 2003 is being realised with a substantial increase in sales during the period. We expect further profitable growth in 2006 from both new products and the expansion of our veterinary business through IDEXX.

'The acquisition of CMS has enhanced our growing reputation in the rapidly developing molecular diagnostics market. We have recently received FDA clearance for a Cystic Fibrosis test run on the eSensor instrument which will be launched in the first half of 2006 together with the OPTI GENE and OPTI TUBE products.

'The growing and reliable OPTI business gives us a valuable development, manufacturing, sales and distribution infrastructure, providing a strong platform for growth and level of credibility as a successful commercial organisation as we look to exploit the considerable opportunities in the field of molecular diagnostics.'

### **For further information:**

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## **Chairman's statement**

Osmetech has adopted a December year end in order to bring its management and reporting cycle more into line with its commercial partners. The 8 month period to 31 December 2005 saw two areas of significant progress for the Group – the acquisition of Clinical Micro Sensors, Inc., (“CMS”) from Motorola to further strengthen our molecular diagnostics business and the substantial sales growth achieved by our Critical Care Division through the OPTI range of blood gas analysers and consumables.

### **Strong growth in Critical Care**

I am pleased to report that our Critical Care Division has reported exceptionally strong growth in the 8 month period with sales of £5,588,000, up by 78% (2004 – corresponding 8 month period: £3,145,000). We are now benefiting from both the new product investment made since the business was acquired from Roche in 2003 and the strong sales of VetStat by our veterinary distribution partner, IDEXX Laboratories, Inc. (“IDEXX”). We expect to see further growth in both of these areas in 2006.

### **Greater presence in molecular diagnostics**

Osmetech is creating a strong Molecular Diagnostics Division to address the considerable potential that exists in this fast growing market.

CMS was acquired in July 2005 providing us with the eSensor product to complement our existing OPTI GENE and OPTI TUBE business which targets simple, rapid near patient testing. On the back of our recent FDA clearance for a Cystic Fibrosis assay using the eSensor instrument platform we remain on target to launch all three of these products during the first half of 2006.

### **Summary and outlook**

The Group is building a strong presence in the important field of molecular diagnostics which is underpinned by a solid and profitable OPTI business with a proven commercial infrastructure and worldwide distribution network.

Osmetech is developing a strong reputation for acquiring and developing underexploited assets and non-core businesses. Under experienced management, considerable progress has now been made with all three of our recent acquisitions. New products and the IDEXX veterinary business have enabled us to broadly double the size of the Critical Care Division in a little over 2 years and now, within 6 months of the acquisition of CMS, we have gained FDA approval for a Cystic Fibrosis carrier detection test using the eSensor DNA detection instrument.

This progress is expected to continue as the Group strengthens its position in the fast growing near patient diagnostics testing market serving small to medium sized hospitals.

Gordon Hall  
Chairman  
21 March 2006

## **Chief Executive Officer's review**

### **Introduction**

Osmetech's operations now comprise two US based divisions: Critical Care based in Atlanta and Molecular Diagnostics located in Boston and Pasadena. The Group's overall business model of selling instruments leading to ongoing consumable sales has resulted in excellent growth for our Critical Care Division. The Molecular Diagnostics Division has made excellent progress in developing a pipeline of products which is expected to start generating revenues in 2006 based upon a similar business model of instruments and proprietary consumable sales.

### **Critical Care Division**

Based upon the OPTI product line of blood gas and electrolyte instruments and proprietary consumables, this profitable division has reported substantial growth in 2005. Sales for the 8 month period were up by 73% in constant currency terms compared to the equivalent period in 2004, while for 2005 as a whole, sales totalled \$14.8m and were ahead by 64% compared to the calendar year 2004.

Sales of both OPTI instruments and consumables grew strongly throughout the period boosted by increased sales of the new touchscreen version of the long established OPTI Critical Care Analyser ("CCA"). Business in China was particularly strong as our distributors build their market share in this increasingly important market.

Approximately half of the revenue growth in 2005 was due to sales to our veterinary distribution partner, IDEXX. The VetStat blood gas and electrolyte analyser launched by IDEXX this year has proved very successful with a large number of instruments already placed and in full use.

We continue to make good progress with IDEXX to create a new platform for measuring critical care parameters based on OPTI's proprietary optical fluorescence technology and we remain confident that product sales will commence in the short to medium term. We are also broadening our test menu for new critical care parameters to enhance both our competitiveness and revenue streams.

The international launch programme for the new OPTI LION and OPTI R instruments will be completed in 2006. Incorporating similar technology to our highly reliable CCA instrument, the OPTI LION is a low cost electrolyte analyser whereas the OPTI R targets the higher usage customer offering a highly competitive price per test through the use of reusable consumables.

### **Osmetech Molecular Diagnostics**

Molecular diagnostics is the fastest growing sector of the global diagnostics market and continues to develop rapidly. The Human Genome Project is regularly discovering new information linking disease with genetic markers. In turn, this is fuelling the demand for increased genetic diagnostic testing and intervention therapies in order to improve healthcare and manage costs. Innovative technology such as Osmetech's is expected to continue to facilitate cost effective and simpler testing to enable wider adoption.

Against this exciting market backdrop, Osmetech's Molecular Diagnostics Division is focused on decentralised testing by providing practical, cost effective molecular diagnostic technologies and tools that enable a broader range of hospitals and laboratories to offer molecular diagnostic services for improved patient care. Our strategy has been to design low cost products specifically for the diagnostics market rather than by adapting complicated high cost research products. During the first half of 2006, Osmetech plans to launch its first three products in this field.

#### **Product launches**

##### **1) CMS eSensor - launch date: April 2006**

The eSensor system targets relatively complex molecular tests which require the analysis of multiple genetic information. Combining universal platform design and a patented advanced electrochemical detection technology, the eSensor System can detect and identify many different targets at once. The technology is protected by strong intellectual property comprising over 70 international patents which had benefited from an investment of approximately \$100m by Motorola during its period of ownership.

In January 2006 Osmetech received 510(k) clearance from the US Food & Drug Administration ('FDA') for its Cystic Fibrosis ('CF') carrier detection test and its eSensor™4800 DNA Detection instrument platform. This FDA approval is a first for a combined instrument and consumable CF assay. The system qualitatively assesses the carrier status for Cystic Fibrosis for all adult couples contemplating pregnancy. In the clinical trials, very favourable comparison studies were made against DNA sequencing. The overall agreement of the 486 samples was 98.8% (or 99.6%

omitting samples which produced a no-call result). Of these samples, 11,178 genetic mutations were analysed producing an agreement of 99.0% (or 99.98% omitting no-calls).

The instrument platform and microarray consumable forming part of this approval will also be used for future assays. Our facility in Pasadena has now also received an FDA California State License to manufacture product and we remain on target to launch product in April 2006.

## 2) OPTI TUBE - launch date: May 2006

The OPTI TUBE product line consists of plastic tubes and ergonomically designed sealing caps and carousel for use in the Roche LightCycler as a replacement for the Roche glass capillaries, sealing cap and carousel. OPTI TUBE is a cost effective, robust alternative solution that eliminates the dangers of glass breakage and minimises the risk of laboratory personnel being exposed to potentially dangerous samples and glass shards. There are an estimated 50m glass capillaries sold each year for use on the LightCycler. The same plastic technology has been incorporated into consumables to be supplied for use with Osmetech's OPTI GENE instrument.

Osmetech has also granted a worldwide non-exclusive license with Roche Diagnostics for the manufacture and sale of plastic consumable vials using this proprietary plastic tube technology.

## 3) OPTI GENE - launch date: June 2006

The OPTI GENE is a fast and flexible system for the detection of DNA and RNA targets using technologically proven PCR or RT-PCR based assays suitable for simple molecular tests. It is a compact, self-contained instrument that employs a graphics driven touch-screen user interface and a conveniently packaged OPTI TUBE consumable. The system provides independent thermal controls for each sample position, as well as random access for each of the three 4-sample cassettes.

Osmetech will initially be launching this instrument with thrombophilia assays. A recent study of 237 patient samples at Bristol University in the UK, demonstrated that the OPTI GENE Factor V Leiden thrombophilia test was 100% concordant with an established Roche LightCycler assay kit. The study showed that the test was simple to perform, rapid and robust with excellent sensitivity, specificity and reproducibility.

## Future products

The next Osmetech molecular test targeted for FDA submission will be our Cytochrome P450 ("CYP 450") pharmacogenomics assay which is currently in development. The CYP450 family of enzymes provides relevant genetic information for drug metabolism, with the first FDA approved test having recently been launched by Roche Diagnostics at more than \$500 per test.

In general, pharmacogenomics is expected to become a very important area for the molecular diagnostics industry over the coming years with the prospect of high product sales margins. Healthcare providers and pharmaceutical companies now have both economic drivers and statutory obligations to determine the safety and efficacy of drug effectiveness and dosage rates for patients by reference to their metabolic characteristics.

There are further assays in development for the OPTI GENE utilising the HyBeacons DNA probe technology licensed from LGC Limited.

The combination of the OPTI GENE and eSensor products should enable both simple and more complex molecular diagnostic tests to be performed accurately by hospitals in a cost effective and easy to use format. Unlike many competing products, both Osmetech products combine both an instrument platform and proprietary assay-specific consumables. These products were exhibited in November 2005 at two major international shows in the US (AMP) and Europe (Medica) and generated a significant level of pre-launch interest both from potential commercial partners and end customers.

In addition, both products have significant potential in other markets, such as veterinary, environmental and forensics, which we would look to exploit through strategic partnerships. We have also seen through the \$230m acquisition of GeneOhm by Beckton Dickinson that the larger players are looking to aggressively extend their molecular diagnostics presence through acquisition.

## Acquisition of CMS

CMS was acquired cash and debt free on 26 July 2005 for a consideration satisfied by the issue of warrants that entitle Motorola to subscribe for 7,811,428 ordinary shares at 17.5 pence per share. The Black-Scholes model for pricing such a warrant indicates a fair value of the warrants of £923,000 which has been used to value the consideration of the acquisition of CMS.

## **Fund raising**

At the same time as the acquisition of CMS in July 2005, a placing of 62.9m new ordinary shares raised £11.0m gross (£10.2m net of expenses) at a price of 17.5 pence per share.

Whilst we continue to believe that the net proceeds of the funding will be sufficient for the completion of development and the launch of both the OPTI GENE and CMS Cystic Fibrosis products Osmetech will require further funding later this year. In the meantime, we continue to progress our business model and hence, build value within the Group.

## **Financial review**

Sales revenues for the 8 month period to 31 December 2005 totalled £5,588,000 (\$9,943,000) which represented a 78% increase over the corresponding 8 month period for previous year.

OPTI sales accounted for all Group revenues with new instrument sales representing 42% of the total. The relatively high proportion of lower margin instrument sales and the growth in the IDEXX business was reflected in the gross profit margin of 39% (year ended 30 April 2005: 42%) although the overall profitability of the Critical Care Division benefitted from these additional sales.

As expected, following the CMS acquisition in July 2005 operating losses increased in the 8 month period to £5,089,000 before share compensation charges of £512,000 (year ended 30 April 2005: £2,152,000 before exceptional items of £827,000 and share compensation charges of £nil). CMS losses of £2,874,000 accounted for the majority of the overall Group loss.

We anticipate that losses will increase in the coming year reflecting the full year effect of CMS's operations. However the expected sales growth from OPTI in 2006 should contribute to a further improvement in the profitability of the Critical Care Division. The leveraging of our manufacturing cost base and planned product cost savings will also drive us towards profitability. We expect to continue to operate with minimal sales and marketing costs through the use of distributors for international and veterinary market sales.

## **Outlook**

We anticipate further growth for the Critical Care Division in 2006 although this is not expected to match the exceptionally strong growth rates achieved in 2005. IDEXX sales should continue to increase significantly and we also expect good growth in our core human market with an important growing contribution coming from sales of our new OPTI R and OPTI LION instruments. The high proportion of instrument sales in 2005 and growing installed base of over 5,000 instruments in the human market alone should lead to a growth in high quality, reliable consumable sales revenues in 2006 and beyond. In turn, this will enhance the profitability of the division.

Our Molecular Diagnostics Division has progressed significantly in the current period. There are clear markets for the new OPTI GENE and OPTI TUBE products and we have demonstrated the compatibility of the HyBeacons DNA probe technology as a foundation chemistry from which to develop further diagnostic tests. The CMS business has been quickly integrated into the Group and the eSensor DNA Detection instrument platform now has FDA approval for its first assay.

Both of these new molecular diagnostics instruments together with OPTI TUBE will be launched by mid 2006 and will enhance our growing reputation in this rapidly developing market as well as installing instruments to provide the basis of future revenues by introducing a wider range of tests. Through experienced management, proven technology and a strong intellectual property position, we have already created a significant asset base and expect to be able to strengthen our market position through future commercial partnerships and licensing agreements.

We expect Osmetech to build on its recent strong progress in fulfilling its strategy to develop a medical devices and diagnostics business in the fast growing near patient testing market, principally serving small to medium sized hospitals. In addition, we will continue to search for other opportunities to grow the business and leverage our operations further through acquisition. The growing and reliable OPTI business gives us a valuable development, manufacturing, sales and distribution infrastructure, providing a strong platform for growth and level of credibility as a successful commercial organisation, as we look to exploit the considerable opportunities in the field of molecular diagnostics.

James White  
Chief Executive Officer  
21 March 2006

Osmetech plc

Consolidated profit and loss account for the 8 months ended 31 December 2005

	Notes	(unaudited) Continuing Operations 8 months ended			(audited) 12 months ended
		31 December 2005 (Existing Operations) £	31 December 2005 (Acquisitions) £	31 December 2005 £	30 April 2005 £
<b>Turnover</b>		5,588,121	-	5,588,121	5,832,870
Cost of sales		(3,428,516)	-	(3,428,516)	(3,410,903)
<b>Gross profit</b>		<u>2,159,605</u>	<u>-</u>	<u>2,159,605</u>	<u>2,421,967</u>
Exceptional administrative expenses		-	-	-	(827,184)
Share compensation charge	5	(512,000)	-	(512,000)	-
Other administrative expenses		(4,374,485)	(2,874,075)	(7,248,560)	(4,574,179)
<b>Total administrative expenses</b>		<u>(4,886,485)</u>	<u>(2,874,075)</u>	<u>(7,760,560)</u>	<u>(5,401,363)</u>
<b>Operating loss</b>	4	<u>(2,726,880)</u>	<u>(2,874,075)</u>	<u>(5,600,955)</u>	<u>(2,979,396)</u>
Net finance income				190,769	113,631
<b>Loss on ordinary activities before taxation</b>				<u>(5,410,186)</u>	<u>(2,865,765)</u>
<b>Taxation</b>				185,397	146,672
<b>Loss for the period transferred from reserves</b>				<u>(5,224,789)</u>	<u>(2,719,093)</u>
Basic and Diluted Loss per share	3			<u>(4.76p)</u>	<u>(4.20p)</u>

Consolidated statement of total recognised gains and losses for the 8 months ended 31 December 2005

	(unaudited) 8 months ended 31 December 2005 £	(audited) 12 months ended 30 April 2005 £
Loss for the financial period	(5,224,789)	(2,719,093)
Currency translation gain/(loss) on foreign currency net investments	370,553	(198,750)
<b>Total recognised losses relating to the period</b>	<u>(4,854,236)</u>	<u>(2,917,843)</u>

**Osmetech plc****Consolidated balance sheet at 31 December 2005**

		<b>(unaudited)</b>		<b>(audited)</b>
		<b>At 31.12.05</b>		<b>At 30.04.05</b>
	£	£	£	£
<b>Fixed assets</b>				
Intangible assets		2,062,949		1,396,113
Tangible assets		1,451,766		673,825
		<u>3,514,715</u>		<u>2,069,938</u>
<b>Current assets</b>				
Stocks	1,719,302		1,143,977	
Debtors	3,019,365		2,193,160	
Investments	6,300,000		1,000,000	
Cash at bank and in hand	907,177		883,712	
	<u>11,945,844</u>		<u>5,220,849</u>	
<b>Creditors: amounts falling due within one year</b>	<u>(2,676,401)</u>		<u>(1,379,412)</u>	
<b>Net current assets</b>		<u>9,269,443</u>		<u>3,841,437</u>
<b>Net assets</b>		<u>12,784,158</u>		<u>5,911,375</u>
<b>Capital and reserves</b>				
Called up share capital		6,957,640		6,894,783
Share premium account		39,654,069		29,425,051
Merger reserve		1,885,533		1,885,533
Other reserve		1,435,144		-
Profit and loss account		(37,148,228)		(32,293,992)
<b>Equity shareholders' funds</b>		<u>12,784,158</u>		<u>5,911,375</u>

Osmetech plc

Consolidated cash flow statement for the 8 months ended 31 December 2005

	(unaudited) 8 months ended 31 December 2005 £	(audited) 12 months ended 30 April 2005 £
Net cash outflow from operating activities	(4,243,732)	(2,748,191)
Returns on investments and servicing of finance	178,414	107,410
Taxation	-	158,080
Capital expenditure and financial investment	(576,498)	(435,841)
Acquisitions and disposals	(340,751)	1,691,296
Cash outflow before management of liquid resources and financing	<u>(4,982,567)</u>	<u>(1,227,246)</u>
Management of liquid resources	(5,300,000)	1,700,000
Financing	10,291,875	(58,144)
Increase in cash	<u>9,308</u>	<u>414,610</u>

(a) Reconciliation of operating loss to operating cash flows

	8 months ended 31 December 2005 £	12 months ended 30 April 2005 £
Operating loss	(5,600,955)	(2,979,396)
Depreciation and amortisation	436,643	278,996
Loss on disposal of fixed assets	136,913	17,025
Impairment of tangible fixed assets	-	29,045
Impairment of intangible fixed assets	-	731,007
Increase in stocks	(329,989)	(276,933)
Share compensation charge	512,000	-
Increase in debtors	(137,393)	(808,799)
Increase in creditors	739,049	260,864
Net cash outflow from operating activities	<u>(4,243,732)</u>	<u>(2,748,191)</u>

	8 months ended 31 December 2005 £	12 months ended 30 April 2005 £
Increase in cash in the period	9,308	414,610
Increase/(decrease) in liquid resources	5,300,000	(1,700,000)
Exchange differences	14,157	(3,215)
Change in net funds	<u>5,323,465</u>	<u>(1,288,605)</u>
Net funds at beginning of period	1,883,712	3,172,317
Net funds at end of period	<u>7,207,177</u>	<u>1,883,712</u>

## Notes

### 1 Results

The financial information set out above does not constitute the company's statutory accounts for the period ended 31 December 2005 and year ended 30 April 2005, but is derived from those accounts. The financial information for the year ended 30 April 2005 is derived from the statutory accounts for that year which have been delivered to the Registrar of Companies. The auditors reported on those accounts; their report was unqualified and did not contain a statement under s237(2) or (3) Companies Act 1985.

The statutory accounts for the eight month period 31 December 2005 will be finalised based on the financial information presented by the directors in the preliminary announcement and will be delivered to the Registrar of Companies following the company's annual general meeting. The auditors are yet to sign their report on the statutory accounts for the eight month period ended 31 December 2005 but have indicated that their auditor's report will be modified by the inclusion of an added emphasis paragraph which highlights the existence of a material uncertainty that casts significant doubt on the company's and group's ability to continue as a going concern. Further information is disclosed in note 2.

### 2 Going Concern

The document sent to shareholders at the time of the Placing in July 2005 in support of the acquisition of Clinical Micro Sensors Inc. noted that the Company was likely to require further financing. Whilst the Directors still consider that the Company has sufficient funds through to the launch of the OPTI Gene and the CMS Cystic Fibrosis products, the forecasts prepared by the directors for the next twelve months indicate that further funding will be required. The Critical Care Division grew substantially in 2005 and the Group has also made considerable progress with the commercial development of its Molecular Diagnostics Division.

The Directors have a reasonable expectation, given these recent achievements and the current strength of the Group's operations, that the Group will be able to secure sufficient funding to enable it to meet its liabilities as they fall due for the foreseeable future and are currently evaluating a number of alternatives in order to achieve this. Although there must remain some uncertainty over the ability of the Group to secure sufficient funding, the Directors have concluded that it is appropriate to prepare the accounts on a going concern basis. The accounts do not include any adjustments which may be necessary if the Group was unable to continue to operate.

### 3 Loss per share

The loss per share of 4.76p (30 April 2005 – loss per share 4.20p) has been calculated on the weighted average number of shares in issue during the period namely 109,740,819; (30 April 2005 – 64,669,039 as adjusted to take account of the subdivision and consolidation) and losses of £5,224,789; (30 April 2005 - £2,719,093).

### 4 Operating loss

	8 months ended 31 December 2005 £	12 months ended 30 April 2005 £
This is arrived at after charging:-		
Amortisation of intangible fixed assets	89,763	93,163
Depreciation	346,880	185,833
Impairment of intangible assets	-	731,007
Impairment of tangible assets	-	29,045
Auditors' remuneration	36,500	30,000
	- audit services: Osmetech plc	
	Other Group companies	45,773
	143,502	18,611
	- non audit services	17,160
Operating lease rentals	19,618	11,512
	- plant and machinery	
	428,275	224,762
	- other	
Research and development	2,665,491	2,130,533
Loss on disposal of fixed assets	136,913	17,025
	<u>                    </u>	<u>                    </u>

## **5 Share compensation charge**

A charge of £512,000 has been made to the profit and loss account in the 8 month period (year ended 30 April 2005 - £nil) relating to the Long Term Incentive Awards ('LTIPs') made during the period to senior management. In accordance with UITF 17, the charge has been calculated by reference to the market value of the shares at the date of grant less the exercise price of the options, the likelihood that the LTIP performance criteria will be met and the proportion of any gain attributed to the period. The charge also includes an estimate of future employer national insurance costs where applicable.