



I N T E R I M
R E P O R T

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Corporate Statement

Plethora Solutions Holdings plc (Plethora) is a publicly quoted UK biotech company whose goal is to build a profitable, speciality pharmaceutical business. The Company's primary strategy is to develop products for the diagnosis, treatment and management of urological disorders. Revenues will be generated by licensing on the rights to Plethora products to pharmaceutical marketing partners following the successful completion of clinical trials.

The Plethora business model is designed to minimise clinical risk and the costs associated with taking such risk, enabling Plethora to pursue multiple clinical programmes efficiently. The Company believes that this portfolio approach will increase its probability of success significantly and minimise financing dilution to its shareholders.

Financials

- Admission to AIM raising £10m gross via placement of 7.4m shares to fund the current development pipeline
- Loss after tax of £3.6m, in line with expectation
 - this includes a one-off payment of £1.6 m to Hoffman-La Roche
- Cash and short term investments at 30 June 2005 of £7.9m

Current product pipeline

- **PSD502** (treatment for premature ejaculation)
 - nearing completion of Phase II clinical trials, trials initiated on secondary use for the treatment of pain in burns and wounds
- **PSD503** (treatment of stress urinary incontinence – SUI)
 - expect to commence Phase II trials Q4 2005
- **PSD506** (treatment of overactive bladder in both male and female patients)
 - signed license agreement with Hoffman-La Roche giving Plethora exclusive access to PSD506 for Phase II development in 2006
- **PSD401** (novel device for use in diagnosis of premature ejaculation)
 - successful completion of clinical development programme
 - collaborative agreement with Johnson & Johnson for use of PSD401 in clinical trials for treatment for sexual dysfunction

New Product

- **PSD597** – new programme initiated for the treatment of interstitial cystitis.

Chairman's and Chief Executive's Statement

Overview

The first half of 2005 has been an exciting period for Plethora. In March we completed a successful flotation on AiM, raising £10 million gross through the placing of 7.4 million shares. These proceeds have given Plethora the financial resources to progress our current therapeutic programmes through Phase II studies and on to their licensing points.

Since our flotation we have made great strides forward in developing our pipeline with the completion of an in-licensing agreement with Hoffman-La Roche for PSD506, a treatment for overactive bladder, and the completion of patient enrolment into the Phase II clinical trial of PSD502, a treatment for premature ejaculation. We have also commenced a series of clinical trials for the use of PSD502 as a topical analgesic for the treatment of wounds and burns. We have also signed a collaborative agreement with Johnson & Johnson for the use of PSD401, our diagnostic for premature ejaculation, in their clinical trials.

In line with our stated strategy we have also continued to seek new products and have introduced a new clinical stage programme, PSD597, for the treatment of interstitial cystitis (IC) and chronic pelvic pain (CPP) which affects over 38% of women in the USA alone.

Product Update

■ PSD502

The most advanced programme in the portfolio, PSD502, is an aerosol mix of two known marketed drugs being developed for the treatment of premature ejaculation (PE), a condition which is believed to afflict 25-30% of the male population of the USA and Western Europe. From recent reports from major pharmaceutical companies and from comparisons with the established erectile dysfunction market, it is estimated that the PE market could be as large as \$5 billion per annum.

After conclusion of a promising clinical pilot study which demonstrated an increase in ejaculation latency time after treatment with PSD502, together with an improvement in patient/partner satisfaction in evaluable patients, the product was transferred into a Phase II double blind, placebo controlled study in eight centres in Europe. Recruitment

Chairman's and Chief Executive's Statement

in this study was completed in September 2005 and full trial results are expected later in the year. Discussions have already been initiated with potential marketing partners and we expect licensing activity to gather pace once Phase II data is available.

A significant development in the PSD502 programme was the identification of a second but highly valuable indication. The product is a novel aerosol formulation of two analgesic compounds, Lidocaine and Prilocaine, which are marketed in a number of pain indications. However, Plethora's aerosol formulation has a rapid onset of action and can be applied painlessly to wounds and burns. Having consulted with opinion leaders in the field who confirmed both the medical need and commercial potential for such a product, the Company has initiated a series of clinical studies at wound and burns units in the UK to demonstrate the clinical efficacy of the product. Data is expected towards the middle of 2006.

■ PSD503

PSD503 is a novel formulation of an alpha agonist, which is being developed for the treatment of stress urinary incontinence (SUI).

There is no product approved globally for this widespread condition which is estimated to affect over 20 million women in North America and Western Europe. The annual market for stress incontinence products is estimated to exceed US\$5 billion.

Having completed a small pilot study which demonstrated product safety, the Company has now completed the design and preparation for a Phase II clinical programme which is expected to commence in Q4, 2005.

■ PSD506

Under an exclusive license agreement entered into with Hoffman-La Roche in 2005, Plethora intends to develop the subtype selective muscarinic receptor antagonist PSD506 (formerly RO3202904) as a treatment for overactive bladder and related symptoms in men and women. The programme will benefit not only from extensive clinical data generated by Roche but also from on-going support in the form of supply of drug materials and regulatory input.

Chairman's and Chief Executive's Statement

PSD506 has been evaluated successfully in three Phase I studies by Roche in men and women. These Phase I studies involved multiple doses in healthy female and male volunteers. The drug was shown to be well tolerated at potentially therapeutic doses. Plethora intends to initiate three clinical studies in 2006 with the objectives of further establishing the efficacy and safety of PSD506 and its superiority over marketed anti-muscarinic drugs. Studies are planned in three patient groups: spinal injury patients experiencing spontaneous contraction of the bladder muscles causing incontinence; patients with BPH and LUTS and in men and women with urge incontinence.

■ PSD597

Subsequent to the reporting period, the Company announced the introduction of a new clinical stage programme, PSD597, for the treatment of interstitial cystitis (IC) and chronic pelvic pain (CPP). Approximately 38% of the female population of the USA suffer from IC/ CPP for which there is no effective treatment.

In keeping with the business model, Plethora has licensed exclusive worldwide rights to a therapy undergoing early stage clinical development for the treatment of IC from Dr. Richard Henry at Queen's University, Kingston, Ontario, Canada. This product utilises a drug marketed previously for other indications, therefore the company does not expect there to be any safety issues. The product has already been employed in two clinical studies at Queen's which have reported that PSD597 reduced pain in chronic IC patients.

This product will be moved into a full Phase II study early next year and, together with secondary indication studies for PSD502, provides a bridge into a secondary area of clinical expertise, namely pain management.

■ Medical Devices

Plethora has a small development portfolio of devices aimed at the diagnosis and management of urological conditions. The most advanced of these products is PSD401, a device for the measurement of ejaculation time used for the treatment of PE. The preliminary development phase of this product was completed in the first half of 2005 and a collaborative agreement was signed with Johnson & Johnson for use of the product in clinical studies. The Company will continue to seek further, similar collaborations with both pharmaceutical companies and medical device marketing companies.

Chairman's and Chief Executive's Statement

Financial Review

In the six months ended 30 June 2005, Plethora recorded a loss before and after taxation of £3.6m, which is in line with expectations and includes a single, one-off licensing payment to Hoffman-La Roche of £1.6m.

Cash outflow before financing for the period was £3.4m, reflecting the loss in the period. With a strong cash position at 30 June 2005 of £7.9m following the successful share placing and admission to AIM in March 2005, the Company has sufficient funds to take its lead products to the point at which they can be licensed on to pharmaceutical partners who will complete the development and commercialisation of the products.

Outlook

In the next 12 months we expect to move through a number of key valuation milestones. The most immediate will be the publication of clinical trial data from the PSD502 PE study and, with positive data, the subsequent licensing of the programme to a pharmaceutical partner. We have also demonstrated that there is additional value in the 502 programme with the wound pain indication and the introduction, post the reporting period, of PSD597 has created a modest foundation in the secondary disease area of pain management. Within the core urology franchise we look forward to moving PSD503 into a Phase II programme for the treatment of Stress Urinary Incontinence.

The Plethora team, although small in number, has achieved considerable momentum and everyone concerned should be congratulated on the progress made during our first half year as a public entity and for showing such commitment in building a leading pharmaceutical product development operation.

We look forward to updating shareholders on our progress in the months ahead.

Stuart Wallis
Non-Executive Chairman

Steven Powell
Chief Executive Officer

Consolidated Summarised Profit and Loss Account for the six months ended 30 June 2005

		6 months ended 30 June 2005	Year ended 31 December 2004
	Note	Unaudited £'000	Audited £'000
Turnover		-	-
Cost of sales		-	-
Gross profit		-	-
Administrative expenses			
Research and development expenses		(3,025)	(1,955)
Other administrative expenses		(587)	(693)
Operating loss		(3,612)	(2,648)
Net interest receivable/(payable) and other charges		37	(110)
Loss on ordinary activities before taxation		(3,575)	(2,758)
Tax on loss on ordinary activities		-	-
Loss on ordinary activities after taxation		(3,575)	(2,758)
Dividends		-	-
Loss transferred from reserves	3	(3,575)	(2,758)
Basic loss per share	2	(20.5p)	(26.1p)

There were no recognised gains or losses other than the loss for the financial period.

Consolidated Summarised Balance Sheet

at 30 June 2005

	Note	At 30 June 2005 Unaudited £'000	At 31 December 2004 Audited £'000
Fixed assets			
Tangible assets		60	43
Current assets			
Debtors		186	17
Cash at bank and in hand		7,889	49
		8,075	66
Creditors: amounts falling due within one year		(575)	(1,874)
Net current assets/(liabilities)		7,500	(1,808)
Total assets less current liabilities		7,560	(1,765)
Net assets/(liabilities)		7,560	(1,765)
Capital and reserves			
Called up share capital		222	–
Share premium account		8,825	993
Other reserves		4,846	–
Profit and loss account		(6,333)	(2,758)
Equity shareholders' funds/(deficit)	3	7,560	(1,765)

Consolidated Summarised Cash Flow Statement

for the six months ended 30 June 2005

	6 months ended	Year ended
	30 June	31 December
	2005	2004
Note	Unaudited	Audited
	£'000	£'000
Net cash (outflow) from operating activities	4 (3,423)	(2,381)
Returns on investments and servicing of finance		
Interest received	37	3
Net cash inflow from returns on investments and servicing of finance	37	3
Capital expenditure and financial investment		
Purchase of tangible fixed assets	(24)	(53)
Net cash (outflow) from capital expenditure and financial investment	(24)	(53)
Cash outflow before financing	(3,410)	(2,431)
Financing		
Issue of ordinary share capital	14,063	1,000
Share issue costs	(1,163)	(7)
Loans advanced	2,000	1,487
Loans repaid	(3,650)	–
Net cash inflow from financing	11,250	2,480
Increase in cash	5 7,840	49

Notes to the Interim Statement

for the six months ended 30 June 2005

1 BASIS OF PREPARATION

The consolidated interim financial statements have been prepared in accordance with applicable accounting standards and under the historical cost convention. The principal accounting policies of the group have remained unchanged from those set out in Plethora Solutions Limited's 2004 annual report and financial statements. In addition to those accounting policies adopted in the Plethora Solution Limited's 2004 annual report and financial statements the following accounting policy has been added.

Basis of consolidation

The group financial statements consolidate those of the Company and of its subsidiary undertaking. Profits or losses on intra-group transactions are eliminated in full. On 17th March 2005, as part of a group reorganisation, the Company acquired the entire issued share capital of Plethora Solutions Limited, the consideration being satisfied by the issue of ordinary shares in the Company. In preparing the consolidated financial statements merger accounting has, therefore, been applied.

The financial information set out in this interim report does not constitute statutory accounts as defined by section 240 of the Companies Act 1985. The figures for the year ended 31 December 2004 have been extracted from the statutory financial statements of Plethora Solutions Limited which have been filed with the Registrar of Companies. The auditors' report on those financial statements was unqualified and did not contain a statement under section 237(2) of the Companies Act 1985.

2 LOSS PER SHARE

The calculation of the basic and diluted loss per share is based on the loss on ordinary activities after tax and on the weighted average number of ordinary shares in issue during the period. The impact of the share options and convertible debt are anti dilutive. The loss and weighted average number of shares used in the calculations are set out below:

	Loss	Weighted average number of shares	Loss per share pence
	£'000		
Basic loss per share			
Six months ended 30 June 2005	(3,575)	17,467,648	(20.5)
Year ended 31 December 2004	(2,758)	10,571,055	(26.1)

Notes to the Interim Statement

for the six months ended 30 June 2005

3 RECONCILIATION OF MOVEMENTS IN SHAREHOLDERS' FUNDS/(DEFICIT)

	6 months ended	Year ended
	30 June	31 December
	2005	2004
	Unaudited	Audited
	£'000	£'000
Loss for the financial period	(3,575)	(2,758)
Issue of ordinary share capital	12,900	993
Net increase/(decrease) in shareholders' funds/(deficit)	9,325	(1,765)
Shareholders' funds/(deficit) at beginning of period	(1,765)	-
Shareholders' funds/(deficit) at end of period	7,560	(1,765)

4 NET CASH INFLOW/(OUTFLOW) FROM OPERATING ACTIVITIES

Operating (loss)	(3,612)	(2,648)
Depreciation	7	10
(Increase) in debtors	(169)	(17)
Increase in creditors	351	274
Net cash (outflow) from operating activities	(3,423)	(2,381)

5 RECONCILIATION OF NET CASH FLOW TO MOVEMENT IN NET (DEBT)/FUNDS

Increase in cash in the period	7,840	49
Cash outflow from financing	1,650	(1,487)
Change in net funds/(debt) resulting from cash flows	9,490	(1,438)
Non cash movements	(131)	(32)
Movement in net funds/(debt) in the period	9,359	(1,470)
Net (debt)/funds at beginning of period	(1,470)	-
Net funds/(debt) at end of period	7,889	(1,470)

Independent Review

report to Plethora Solutions Holdings plc

Introduction

We have been instructed by the Company to review the financial information for the six months ended 30 June 2005 which comprises the Summarised Consolidated Profit and Loss Account, Summarised Consolidated Balance Sheet, Summarised Consolidated Cash Flow Statement and the related notes. We have read the other information contained in the Interim Report which comprises only the Chairman and Chief Executive's Statement and considered whether it contains any apparent misstatements or material inconsistencies with the financial information. Our responsibilities do not extend to any other information.

This report is made solely to the Company's members, as a body, in accordance with guidance contained in APB Bulletin 1999/4 "Review of Interim Financial Information". Our review work has been undertaken so that we might state to the Company's members those matters we are required to state to it in a 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 and the Company's members as a body, for our review work, for this report or for the conclusion 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 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 "Review of Interim Financial Information" issued by the Auditing Practices Board for use in the United Kingdom. A review consists principally of making enquiries of management and applying analytical procedures to the financial information and

Independent Review

report to Plethora Solutions Holdings plc

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 30 June 2005.

GRANT THORNTON UK LLP
Chartered Accountants
Birmingham
23 September 2005

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