

For Immediate Release

29<sup>th</sup> April 2008

## **Plethora Solutions Holdings plc (AIM: PLE)**

### **Preliminary Results for the Year Ending 31 December 2007**

Plethora Solutions Holdings plc ('Plethora'), the developer of products for the treatment of urological disorders, today announces preliminary results for the year ended 31 December 2007.

#### **Highlights**

- Achievement of significant commercial and development milestones in 2007
- 10% growth in product sales
- Licensing agreement signed for PSD502 PE in the USA with Sciele Pharma, Inc.
- Progress across portfolio:
  - Positive Phase II data from three development products (PSD503, PSD506 and PSD597) and licensing discussions initiated
  - Two products (PSD502 and PSD510) entered Phase III pivotal studies
  - PSD508 Phase II study initiated
- \$28m financing from Paul Capital Healthcare post year-end

#### **Financials**

- Revenues increased to £5.8m (2006: £5.2m)
- Development expenditure increased to £8.2m (2006: £5.4m) reflecting the forecast investment in Phase II and Phase III, all of which are scheduled to complete by the end of 2008
- Cash and short term investments at 31 December 2007 of £2.6m (2006: £3.4m)
- Net decrease in cash and cash equivalents lower (£0.8m) than 2006 (£2.8m) as a result of the completion of a licensing agreement with Sciele Pharma, Inc. (\$7m equity investment in Plethora at £2 per share), venture debt financing with ETV Capital S.A. and increased product sales
- Non-dilutive financing post year end reporting period totalling \$28m, of which \$15m committed on signing
  - Secured against male health portfolio only
  - Provides capital requirements for the Company without further recourse to the market

#### **Commenting, Dr Steven Powell, CEO of Plethora, said:**

"Sales continue to grow through our Timm Medical subsidiary in the US and we continue to invest to complete our Phase III programmes for PSD502 and PSD510 with an expectation that headline data will be reported before year end. We anticipate a significant reduction in development expenditure in the second half of this year (2008) as our clinical programmes come to an end. Development costs will reduce further in 2009 as we enter a full commercialisation phase, with our focus then being on acceleration of product sales in the US and increased licensing income following successful completion of clinical programmes in 2007 and 2008.

With the conclusion of the Paul Capital Healthcare financing agreement, Plethora now has adequate financial resources to execute its development pipeline and accelerate towards its goal of delivering a profitable urology business."

**A meeting for equity analysts will take place at 0930h today (29.04.08) at Collins Stewart, 9<sup>th</sup> Floor, 88 Wood St, London, EC2V 7QR.**

**Enquiries:**

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**About Plethora:**

Plethora is focused on the development and marketing of products for the treatment of urological disorders. The Company has products in clinical development for the treatment of overactive bladder, stress urinary incontinence, interstitial cystitis, gynaecological pain, erectile dysfunction and premature ejaculation. In January 2006, Plethora acquired Minneapolis (Mn) based Timm Medical Technologies Inc., which markets products for the treatment of erectile dysfunction (ED) to urology clinics through a US-based specialty sales team. The Company is headquartered in the UK and is listed on the London Stock Exchange (AIM:PLE).

Further information is available at [www.plethorasolutions.co.uk](http://www.plethorasolutions.co.uk)

## **CHAIRMAN AND CHIEF EXECUTIVE'S STATEMENT**

### **INTRODUCTION**

The fulfilment of key objectives during 2007 in three core areas of our business – namely in product sales, licensing and product development – continues to drive Plethora towards our goal of becoming a sustainable urology business. The signing of the licensing agreement with Sciele Pharma, Inc. (Sciele) provides Plethora with a platform to begin the transition from a development-led organisation to a more commercially driven operation with future revenues derived from both licensing and product sales.

Our US operation, Timm Medical, has again reported revenues showing double digit growth with a particularly strong sales performance in the second half of the year. The addition of new products to the sales portfolio and the retention of co-promotion rights to PSD502 in the US represent the start of the development of Timm Medical towards becoming a multi-product organisation.

2007 has also been a year of major investment in clinical development, resulting in successful completion of Phase II studies for PSD597 in interstitial cystitis (IC) and PSD503 in stress urinary incontinence (SUI). We also met a major milestone by moving PSD502 into Phase III clinical trials in premature ejaculation (PE) and another of our products, PSD508, into a Phase II study in dysmenorrhoea.

### **PRODUCT SALES AND MARKETING**

Plethora markets a range of Vacuum Erection Devices (VEDs) through its subsidiary, Timm Medical, for the treatment of erectile dysfunction (ED). Products are marketed in the USA via a recently expanded field sales force calling on specialist urology clinics. Their efforts are supplemented by an in-house support team interacting directly with patients and products are marketed internationally via an extensive distributor network.

Timm Medical reported increased sales for 2007 of £5.8m (2006: £5.2m). Gross margin increased from 79% to 86% as a result of the Board's decision to transfer component manufacture to China in the latter part of 2006. The double digit growth in sales has been achieved by demonstrating the effectiveness of the product in treating ED patients who are either excluded from, or choose not to use, oral therapeutics for the treatment of ED and, in particular, the continued demonstration of the safety and clinical efficacy of ErecAid<sup>®</sup> in patients post radical prostatectomy.

### **LICENSING ACTIVITY**

In May 2007, Plethora signed an exclusive agreement with Sciele Pharma, Inc., in which commercial rights were licensed to Sciele for PSD502 for premature ejaculation in the USA. As part of their commitment to this agreement, Sciele purchased a \$7m equity stake in the company priced at £2 per share. Under the terms of the license Plethora will also receive milestone payments on the achievement of regulatory and sales milestones and royalties on sales after product approval and launch.

Within the license agreement with Sciele, Plethora has retained co-promotion rights that will leverage our Timm Medical sales and marketing expertise in urology. By retaining co-promotion rights in the US and negotiating non-US rights separately, Plethora aims to maximise the value of this development asset.

Negotiations are continuing with potential partners for PSD502 for territories outside of the USA. In addition, licensing discussions have now been initiated regarding PSD597 for IC and PSD503 for SUI following the successful outcome of Phase II clinical studies with these products.

## PRODUCT DEVELOPMENT

Significant advances have been made across the Plethora development portfolio during 2007 culminating in successful outcomes to Phase II studies for PSD597 and PSD503. Our two most advanced projects, PSD502 and PSD510 for the treatment of PE and ED, respectively, have now entered their final stage of development and we hope to have completed these studies before the end of 2008.

The Group's product pipeline therefore now comprises two Phase III products and four Phase II drugs. It is expected that all 6 products will have reached their next key milestones before the end of 2008.

### Male Sexual Dysfunction

Plethora is marketing and developing products for the treatment of erectile dysfunction (ED) and the unmet medical need of premature ejaculation (PE). The status of these products is summarised in Table 1 below.

**Table 1:** Plethora Male Sexual Health Portfolio

Product	Indication	Description	Status
ErecAid <sup>®</sup>	ED	Device	Marketed
PSD502	PE	Therapeutic	Phase III
PSD510 'Invicorp <sup>®</sup> '	ED	Therapeutic	Phase II/III

#### PSD502: A Topical Treatment for PE

PE is the most commonly reported form of sexual dysfunction in men, with a prevalence of around 30%. There are currently no approved pharmaceutical treatments for PE.

In February 2007, the Group filed an Investigational New Drug submission (IND) with US regulatory authorities and opened the IND with a US clinical study, which was completed successfully in July 2007. This study confirmed that PSD502 was both well tolerated and has a rapid (less than 5 minutes) onset of action. The pharmacokinetic data also demonstrated that plasma levels of the drug and its metabolites were low – confirming that the risk of any systemic toxicity is negligible. In October 2007, PSD502 reached a further key milestone with the announcement of the start of the Phase III programme in the USA and this was followed by the initiation of the European Phase III study in December 2007. It is expected that headline data will be available towards the end of 2008 which would mark another major milestone for both the product and the company. The start of the pre-registration studies and the licensing agreement with Sciele for rights to PSD502 in the US means that this project is well on track and continues to be the subject of significant interest from potential, additional commercial partners.

#### PSD510 (Invicorp<sup>®</sup>): A Non-Oral Therapeutic for the Treatment of ED

Invicorp<sup>®</sup> (PSD510) is a non-oral treatment for ED. Completed Phase II and III studies in Europe have demonstrated that, in contrast to, marketed non-oral therapeutics where pain is a common adverse event (for over 30% of users), the reported incidence of pain associated with Invicorp<sup>®</sup> in clinical studies, to date, is substantially less. Invicorp<sup>®</sup> is already approved in the UK, Denmark and New Zealand. Following discussions with the US Food & Drug Administration (FDA), Plethora will

initiate the final stage of the North American clinical development programme for Invicorp<sup>®</sup>, a Phase III programme, this year.

Invicorp<sup>®</sup> complements the Timm Medical ED franchise and will leverage Timm's current access to urologists active in ED management; particularly those men who fail treatment with oral ED drugs or are unable to utilise them because of contraindications. We believe that the superior adverse event profile and clinical efficacy of Invicorp<sup>®</sup> will enable this product to not only compete for market share, but also to attract and retain new users.

## Female Health

Plethora's development activities in female health are focused on the treatment of urinary incontinence and gynaecological pain. Both clinical fields encompass substantial patient populations and poorly met clinical need. The female health portfolio is summarised in Table 2.

**Table 2:** Plethora Female Health Portfolio

Product	Indication	Description	Status
PSD597	Interstitial cystitis (IC)	Therapeutic	Phase II
PSD503	Stress Urinary Incontinence (SUI)	Therapeutic	Phase II
PSD506	Overactive Bladder (OAB)	Therapeutic	Phase II
PSD508	Dysmenorrhoea	Therapeutic	Phase II
PSD509	Uterine Pain	Therapeutic	Pre Phase II

## Urogynaecological Pain

### PSD597: A Treatment for IC

PSD597 is a proprietary formulation of a marketed analgesic drug for the treatment of interstitial cystitis and painful bladder syndrome (IC/PBS). A 2006 Datamonitor report, "*Interstitial Cystitis – Few Treatments, Poor Outcomes*", stated that IC prevalence translated to a global patient population of 16 million, with 6.4 million patients in the US alone.

In September 2007, we reported a positive outcome of a PSD597 Phase II study in 102 IC and PBS patients in the US and Canada. Patients who received PSD597 showed clear and substantial improvements in the primary endpoint measure, Global Response Assessment (GRA). This is a patient-rated scale of improvement in bladder symptoms which is now an international standard in IC/PBS trials. Analysing the response across all GRA categories, the difference with PSD597 treatment at Day 15 was significantly different from placebo ( $p=0.005$ ). These positive results were replicated across all secondary endpoints with improvements reported in bladder pain, urinary frequency and urgency.

The efficacy of the drug was confirmed in an extension to the study. In this voluntary part of the trial, patients were offered open label treatment with PSD597 for 5 days from Day 15. Notably, 86% of patients elected to receive a second treatment. This provides direct evidence of treatment acceptability and the lack of alternative treatment options. At Day 22, 63% of those patients who had received PSD597 in the double-blind study phase reported moderate or marked improvement in GRA

after the second treatment. Of the patients who were randomised to placebo, 44% now responded to active treatment. By Day 29, GRA response rates were still maintained at 56% and 39%, respectively, in the two groups.

The results complement those seen in an initial double-blind study phase and, together, they suggest that the benefits of PSD597 are sustained for a considerable period after treatment and, secondly, confirmed that clinical benefit can be increased with repeated PSD597 administration. Importantly, the treatment effect appeared to be maintained for several weeks and the drug was safe, well tolerated and devoid of systemic side effects.

### **PSD508: A Treatment for Dysmenorrhoea**

In 2006, Plethora acquired exclusive licenses to two clinical-stage product candidates and access to an underlying drug delivery technology from Metris Therapeutics Limited. This technology facilitates local delivery, via the vaginal wall, of drug actives which have established or potential benefits in women's health indications. This may enable delivery of higher doses of drug than might otherwise be achieved through oral delivery whilst minimising systemic exposure.

PSD508 is a locally-delivered formulation of a well-characterised non-steroidal anti-inflammatory drug (NSAID) for the treatment of dysmenorrhoea; a painful, often incapacitating, menstrual cramp which afflicts more than 50% of women of reproductive age.

PSD508 entered a Phase IIb study for patients with dysmenorrhoea in December 2007. The study is a double-blind, placebo-controlled, multiple-dose, crossover proof of concept study which compares the efficacy of vaginally delivered PSD508 to that of oral NSAID and placebo in relieving menstrual-related pain. The safety and tolerability of PSD508 will also be evaluated.

### **Urinary Incontinence**

Urinary incontinence (UI) is a condition where involuntary loss of urine is a social or hygienic problem. UI may be broadly divided into two types: Stress Urinary Incontinence (SUI) and urge incontinence or overactive bladder (OAB), although "mixed" incontinence is not uncommon.

### **PSD503: Topical Therapy for SUI**

Plethora developed PSD503 to provide an 'on demand' treatment for women suffering from mild to moderate SUI. The product has a potential patient population of over 20 million in North America and Western Europe.

In November 2007, we reported a positive outcome for a PSD503 Phase II clinical trial. The preliminary analysis, in 12 patients, of the double-blind, crossover, placebo controlled study reported that PSD503 produced a 44% overall reduction in leakage (as measured from pad weight), whereas placebo was largely without effect (11% increase in pad weight). Improvement with PSD503, beyond that of placebo, was reported in 50% of the women with SUI which represents a good responder rate for a urological condition such as incontinence. In addition, the cardiovascular side effect profiles of placebo and PSD503 were indistinguishable, with no evidence of blood pressure elevation in any subject and only very low systemic plasma concentrations of phenylephrine.

These data are consistent with an earlier Plethora-sponsored open-label study conducted at the Institute of Urology in London which demonstrated that, at this dose, PSD503 can have a positive effect on urethral resistance and overall urodynamic parameters.

### **PSD506: An Oral Treatment for OAB**

Plethora is undertaking clinical development of a novel, selective, muscarinic receptor antagonist ("antimuscarinic") PSD506 as an oral treatment for OAB and related symptoms in men and women. Based on preclinical and Phase I clinical studies undertaken by F. Hoffmann-La Roche Ltd, PSD506

may have a superior side effect profile, specifically, a reduced propensity to cause dry mouth than currently available antimuscarinics. Plethora has initiated two Phase II clinical studies in spinal injury patients experiencing spontaneous contraction of the bladder muscles causing incontinence and in women with OAB.

## **OUTLOOK**

Major achievements, in both product development and our commercial activities, in 2007 have created a platform for the next phase in the evolution of Plethora. In the current year (2008), we aim to report on the outcome of the Phase III programme for PSD502 and, if positive, this product will then move forward into its registration phase. We also expect to continue the progress of PSD510 in pre-registration studies for ED and complete the remaining phase II studies with our other pipeline products. By the end of 2008, all of our development programmes will have reached their next value inflection point and product licensing and product sales will dominate the activities of the company from then on.

As we fulfil the potential of our products and projects, we will continue to seek opportunities to accelerate revenue growth and expand our commercial operations. Sales growth is expected to continue through our US subsidiary, Timm Medical, and the convergence of our development and commercial activities, coupled with our recent financing agreement with Paul Capital Healthcare, will see us well on our way to becoming a profitable and rapidly maturing specialty healthcare company.

**Stuart Wallis**  
**Non-Executive Chairman**

**Steven Powell**  
**Chief Executive Officer**

## **FINANCIAL REVIEW**

### **IFRS**

Plethora Solutions Holdings plc's consolidated financial statements were prepared in accordance with United Kingdom Accounting Standards (United Kingdom Generally Accepted Accounting Practice) until 31 December 2006. The date of transition to IFRS was 1 January 2006. The comparative figures in respect of 2006 have been re-stated to reflect changes in accounting policies as a result of adoption of IFRS.

### **Results of Operations**

Revenues for the year ending 31 December 2007 were £5.8m (2006: £5.2m). The gross margin for ErecAid<sup>®</sup> sales improved from 79% to 86% as a result of the transfer of manufacture of key components to China in the second half of 2006.

Overall, the Group recorded a loss for the year ending 31 December 2007 of £10.5m (2006: £5.9m). The Group's research and development expenditure for the year, which is expensed as it is incurred, increased from £5.4m in 2006 to £8.2m. This reflects increased development expenditure associated with running multiple Phase II studies and the entry of PSD502 into Phase III. Other administrative expenses increased to £7.3m from £4.8m in 2006 which reflects investment in sales and marketing activities at the Timm Medical operation in the US and increased business and corporate development activities within the Group. Research and development expenditure includes a non-cash charge relating to share based compensation of £210,000 (2006: £107,000) and other administrative expenses include a non-cash charge relating to share based compensation of £526,000 (2006: £225,000)

### **SHARE ISSUE**

In May 2007, the Group raised \$7m (£3.5m) via a placing of 1,772,505 shares at 200p per share with Sciele Pharma, Inc. as part of a PSD502 licensing agreement.

### **LIQUIDITY AND CASH RESOURCES**

In June 2007, the Group secured a £4m convertible loan facility with ETV Capital S.A. The secured facility has a 39 month term and was drawn down fully at close.

Net cash outflow from operating activities for 2007 was £8.9m (2006: £5.1m), however, net decrease in cash and cash equivalents for the Group was reduced to £0.8m (2006: £2.8m) following successful conclusion of financing and licensing activities to strengthen the Group's cash requirements.

The Group's cash resources consist of cash balances together with amounts held on short term deposit and totalled £2.6m at 31 December 2007 (2006: £3.4m).

Post the reporting period, the Group entered into a revenue interest financing agreement with Paul Capital Healthcare. Through this agreement, Plethora will receive up to \$28m in cash with \$15m paid at signature and a further \$10 million upon first commercial sale of PSD502 in the USA, subject to certain conditions. In addition, under certain pre-agreed conditions, Plethora will have the option to have Paul Capital Healthcare invest an amount of \$3m by way of equity subscription in 2008.

**Brad Hoy**  
**Chief Financial Officer**

**GROUP INCOME STATEMENT**  
**For the year ended 31 December 2007**

	Note	2007 £'000	2006 £'000
<b>Revenue</b>	3	<b>5,766</b>	5,158
Cost of sales		<u>(789)</u>	<u>(1,071)</u>
<b>Gross profit</b>		<b>4,977</b>	4,087
Administrative expenses			
- research and development expenses		<b>(8,196)</b>	(5,402)
- amortisation of intangibles		<b>(464)</b>	(418)
- selling and marketing		<b>(4,078)</b>	(3,191)
- other administrative expenses		<b>(3,217)</b>	(1,568)
		<u>(15,955)</u>	<u>(10,579)</u>
<b>Operating loss</b>	3	<b>(10,978)</b>	(6,492)
Finance costs		<b>(484)</b>	(83)
Finance income		<b>220</b>	336
		<u>(11,242)</u>	<u>(6,239)</u>
<b>Loss for the year before taxation</b>		<b>(11,242)</b>	(6,239)
Tax credit		<b>764</b>	344
		<u>764</u>	<u>344</u>
<b>Loss for the year</b>	3	<b>(10,478)</b>	(5,895)
<b>Attributable to equity shareholders</b>		<b>(10,478)</b>	(5,895)
<b>Total and continuing loss per ordinary share</b>			
Basic loss per share	4	<b>(38.4p)</b>	(23.3p)
Diluted loss per share	4	<b>(38.4p)</b>	(23.3p)

**GROUP STATEMENT OF CHANGES IN EQUITY**  
**For the year ended 31 December 2007**

	Share capital £'000	Share premium £'000	Other reserves £'000	Translation reserve £'000	Share based payment reserve £'000	Profit and loss account £'000	Total £'000
Balance at 1 January 2006	222	8,813	4,908	-	232	(8,425)	5,750
Exchange movement on translation of foreign entities	-	-	-	(113)	-	-	(113)
Net losses recognised directly in equity	-	-	-	(113)	-	-	(113)
Loss for the year	-	-	-	-	-	(5,895)	(5,895)
Total recognised expense for the year	-	-	-	(113)	-	(5,895)	(6,008)
Issue of new shares	36	7,754	-	-	-	-	7,790
Cost of issue of new shares	-	(495)	-	-	-	-	(495)
Employee share based compensation	-	-	-	-	332	-	332
Balance at 31 December 2006	258	16,072	4,908	(113)	564	(14,320)	7,369
Exchange movement on translation of foreign entities	-	-	-	(13)	-	-	(13)
Net losses recognised directly in equity	-	-	-	(13)	-	-	(13)
Loss for the period	-	-	-	-	-	(10,478)	(10,478)
Total recognised expense for the year	-	-	-	(13)	-	(10,478)	(10,491)
Issue of new shares	22	4,123	-	-	-	-	4,145
Cost of issue of new shares	-	(92)	-	-	-	-	(92)
Employee share based compensation	-	-	-	-	736	-	736
<b>Balance at 31 December 2007</b>	<b>280</b>	<b>20,103</b>	<b>4,908</b>	<b>(126)</b>	<b>1,300</b>	<b>(24,798)</b>	<b>1,667</b>

**GROUP BALANCE SHEET**  
**At 31 December 2007**

	2007 £'000	2006 £'000
<b>Assets</b>		
<b>Non current</b>		
Goodwill	1,463	1,463
Other intangible assets	4,192	4,656
Property, plant and equipment	231	199
Deferred tax	213	353
Long term other receivables	24	35
	<u>6,123</u>	<u>6,706</u>
<b>Current</b>		
Inventory	308	186
Trade and other receivables	1,303	733
Corporation tax	632	400
Cash and cash equivalents	2,595	3,439
	<u>4,838</u>	<u>4,758</u>
<b>Total assets</b>	<u>10,961</u>	<u>11,464</u>
<b>Liabilities</b>		
<b>Current</b>		
Trade and other payables	3,458	2,027
Borrowings	1,951	-
	<u>5,409</u>	<u>2,027</u>
<b>Non-current</b>		
Borrowings	2,627	671
Deferred tax	1,258	1,397
	<u>3,885</u>	<u>2,068</u>
<b>Total liabilities</b>	<u>9,294</u>	<u>4,095</u>
<b>Net assets</b>	<u>1,667</u>	<u>7,369</u>
<b>Equity</b>		
Share capital	280	258
Share premium	20,103	16,072
Other reserves	4,908	4,908
Translation reserve	(126)	(113)
Share based payment reserve	1,300	564
Retained loss	(24,798)	(14,320)
<b>Total equity</b>	<u>1,667</u>	<u>7,369</u>

**GROUP CASH FLOW STATEMENT**  
**For the year ended 31 December 2007**

	2007 £'000	2006 £'000
<b>Cash flows from operating activities</b>		
Loss after taxation	(10,478)	(5,895)
Finance income	(220)	(336)
Finance costs	484	83
Adjustment for foreign exchange	(1)	(9)
Employee equity settled share options	736	332
Depreciation of plant and equipment	96	69
Amortisation	464	418
Change in inventories	(122)	84
Change in trade and other receivables	(559)	(160)
Change in trade and other payables	1,411	671
Taxation credit per income statement	(764)	(344)
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<b>Cash utilised from operations</b>	<b>(8,953)</b>	<b>(5,087)</b>
Interest paid	(433)	(2)
Income taxes paid	-	(117)
Income taxes received	533	-
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<b>Net cash outflows from operating activities</b>	<b>(8,853)</b>	<b>(5,206)</b>
<b>Cash flows from investing activities</b>		
Purchases of property, plant and equipment	(128)	(142)
Acquisition of subsidiary undertaking	-	(5,009)
Cash acquired on acquisition	-	23
Interest received	211	265
	<hr/>	<hr/>
<b>Net cash from / (used in) investing activities</b>	<b>83</b>	<b>(4,863)</b>
<b>Cash flows from financing activities</b>		
Proceeds from issue of shares	4,145	7,790
Proceeds from receipt of borrowings	3,873	-
Share issue costs	(92)	(495)
	<hr/>	<hr/>
<b>Net cash from financing activities</b>	<b>7,926</b>	<b>7,295</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(844)</b>	<b>(2,774)</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>3,439</b>	<b>6,213</b>
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<b>Cash and cash equivalents at end of period</b>	<b>2,595</b>	<b>3,439</b>
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## **1 BASIS OF PREPARATION**

These consolidated financial statements have been prepared under the historical cost convention and in accordance with applicable International Financial Reporting Standards as adopted by the European Union and IFRS as issued by the International Accounting Standards Board.

Plethora Solutions Holdings plc's consolidated financial statements were prepared in accordance with United Kingdom Accounting Standards (United Kingdom Generally Accepted Accounting Practice) until 31 December 2006. The date of transition to IFRS was 1 January 2006. The comparative figures in respect of 2006 have been restated to reflect changes in accounting policies as a result of adoption of IFRS. The disclosures required by IFRS 1 concerning the transition from UK GAAP to IFRS were summarised in the interim statement for the period ended 30 June 2007.

Notably, the acquisition of Timm Medical Technologies, Inc. occurred during the transition period to IFRS. The acquisition has been considered in line with IFRS 3 on transition to IFRS. All assets and liabilities acquired as part of the transaction, including intangible assets (patents, trademarks and anti compete contracts), have been valued at fair value. All purchase consideration has been recorded at fair value. The main change caused from the movement to IFRS from UK GAAP is the recognition of intangible assets of £5,074,000 on acquisition with a corresponding reduction in the value of goodwill recognised under UK GAAP. A deferred tax provision of £1,522,000 was recognised on acquisition based on the fair value of intangible assets acquired, with a corresponding entry to goodwill on consolidation.

## **2 ACCOUNTING POLICIES**

### **Overall considerations**

The significant accounting policies that have been used in the preparation of these consolidated financial statements were summarised in the interim statement for the period ended 30 June 2007.

The consolidated financial statements have been prepared using the measurement bases specified by IFRS for each type of asset, liabilities, income and expense.

The accounting estimates and assumptions are consistent with the Group's latest approved budget forecast where applicable. Judgements are based on the information available at each balance sheet date. All estimates are based on the best information available to management.

### **Going concern**

The Group has prepared forecasts that demonstrate that it is a going concern. The forecasts include the funding recently received of \$25 million from the revenue interest financing agreement with Paul Capital Healthcare and future licensing transactions. If the future licensing transactions are not forthcoming, the Group would either utilise available alternate funding or curtail certain research and development activities. Accordingly, the Group has sufficient cash resources to allow it to continue in business for a period of at least twelve months from the date of approval of these financial statements.

## Significant accounting estimates and judgements

*Certain estimates and judgements need to be made by the directors of the Group which affect the results and position of the Group as reported in the financial statements. Estimates and judgements are required for example as at the reporting date not all liabilities have been settled and certain assets/ liabilities are recorded at fair value which requires a number of estimates and assumptions to be made.*

The major area for estimation within the financial statements is as follows:

- valuation of the carrying value of intangible assets.

The directors have reviewed the acquisition of Timm Medical Technologies, Inc., which led to the recognition of intangible assets, in detail and taken professional advice to arrive at the fair value of intangible assets acquired, namely trademarks and patents.

The major areas for judgements within the financial statements are as follows:

- useful economic life of the intangible assets recognised on consolidation
- the treatment of research costs
- the recognition of a tax receivable for research and development tax refunds
- the recognition of a deferred tax asset relating to utilisable tax losses in the Group's USA subsidiary Timm Medical Technologies, Inc.

The useful economic life over which the acquired intangible assets are amortised represents the directors' judgement of the period over which these trademarks and patents will provide benefit to the Group.

The research costs of the Group are incurred for the development and sale of drugs and medical devices for the diagnosis, treatment and management of urological disorders. At the time the costs are incurred, the directors have concluded that there is insufficient evidence to support the capitalisation of these costs. It is unclear whether the products will achieve medical and safety approval and yield income in excess of costs incurred to date. As such, the costs are not capitalised.

Within the United Kingdom, a tax credit is claimed for research costs incurred in the year. The Group financial statements do not include a receivable for these research tax credit until the claim has been agreed with the local tax authorities.

A deferred tax asset is recognised within the Group financial statements for prior year trading losses incurred by Timm Medical Technologies Inc. Given the profits achieved in the current and previous years by the Company, and those forecast, the directors have concluded that a deferred tax asset should be recognised based on losses that can be relieved over the next 3 years. Details of the value of the deferred tax asset is given within the notes to the financial statements.

### 3 SEGMENTAL REPORTING

The Group's revenue and loss on ordinary activities after tax were all derived from the principal activities of development and sale of products for the diagnosis, treatment and management of urological disorders. These activities can be segmented by research and development and sale of products which match the Group's geographic segments, the UK and the USA. All of the Group's revenue has been derived from external customers.

These activities may be analysed as follows:

	UK/ Research and development £'000	USA/ Sale of products £'000	Total £'000
<b>Year to 31 December 2007</b>			
Revenue	13	5,753	5,766
Operating (loss)/ profit	(11,365)	387	(10,978)
Finance charge net	(205)	(59)	(264)
Tax credit	644	120	764
<b>Net (loss)/ profit for the year</b>	<b>(10,926)</b>	<b>448</b>	<b>(10,478)</b>
<b>Year to 31 December 2006</b>			
Revenue	12	5,146	5,158
Operating (loss)/profit	(6,997)	505	(6,492)
Finance income net	248	5	253
Tax credit/(charge)	400	(56)	344
<b>Net (loss)/ profit for the year</b>	<b>(6,349)</b>	<b>454</b>	<b>(5,895)</b>
<b>31 December 2007</b>			
<b>Segment assets</b>			
<b>Consolidated total assets</b>	<b>1,038</b>	<b>9,923</b>	<b>10,961</b>
<b>Segment liabilities</b>			
<b>Consolidated total liabilities</b>	<b>7,371</b>	<b>1,923</b>	<b>9,294</b>
Depreciation	34	59	96
Amortisation	-	464	464
<b>31 December 2006</b>			
<b>Segment assets</b>			
<b>Consolidated total assets</b>	<b>2,065</b>	<b>9,399</b>	<b>11,464</b>
<b>Segment liabilities</b>			
<b>Consolidated total liabilities</b>	<b>2,216</b>	<b>1,879</b>	<b>4,095</b>
Depreciation	38	31	69
Amortisation	-	418	418

#### 4 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 year. 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 £'000	Weighted average number of shares	Loss per share Pence
<b>Year ended 31 December 2007</b>	<b>(10,478)</b>	<b>27,232,275</b>	<b>(38.4)</b>
Year ended 31 December 2006	(5,895)	25,279,300	(23.3)

#### 5 POST BALANCE SHEET EVENT

Since the year end the Group has entered into a \$25 million revenue interest financing agreement with healthcare investor Paul Capital Healthcare with an option for an additional \$3 million equity investment, concerning its premature ejaculation and erectile dysfunction treatments. In return for the investment, Paul Capital has received an interest in the revenues generated from Plethora's male health portfolio.

An initial payment of \$15 million will provide working capital to underwrite Phase III programmes in premature ejaculation and erectile dysfunction as well as strengthening the Plethora balance sheet to facilitate potential product and corporate transactions. A further \$10 million will be payable upon first commercial sale of PSD502, Plethora's development-stage product for the treatment of premature ejaculation, in the United States, subject to certain conditions.

In addition, under certain pre-agreed conditions, Plethora will have the option to have Paul Capital Healthcare invest an amount of \$3 million by way of equity subscription in 2008.

#### 6 PUBLICATION OF NON-STATUTORY ACCOUNTS

The financial information set out in this preliminary announcement does not constitute statutory accounts as defined in section 240 of the Companies Act 1985.

The group income statement, group statement of changes in equity, the group balance sheet, the group cash flow statement and the associated notes for the year then ended have been extracted from the Group's financial statements. Those financial statements have not yet been delivered to the Registrar.

#### 7 REPORT AND ACCOUNTS

The Group's annual report and financial statements will be posted to shareholders shortly. Further copies will be available on request from the Company's Registered Office: Fourth Floor, 233 High Holborn, London, WC1V 7DN.