e-Therapeutics plc
('e-Therapeutics' or the 'Company')

Discovery Platform Exceeding Expectations; Company Focus Now on Commercialisation

29 September 2015: e-Therapeutics plc (AIM: ETX), the drug discovery and development company, today announces its half year results for the six months ended 31 July 2015.

Operational highlights

- **ETS2101 –** entered phase Ib trials for hepatocellular carcinoma and pancreatic cancer
- **ETS6103 -** recruited the final patient in H1 in the phase IIb trial for major depressive disorder. Results are expected at the end of FY16
- **Discovery platform –** fully operational and has generated 10 active discovery projects. Selection of best compounds for formal preclinical development in H1 2016
- **Directorate changes –** plans to strengthen the Board to reflect new emphasis on commercialisation of assets

Financial highlights

- Cash and liquid resources at £30.2 million (31 January 2015: £33.8 million); operating cash burn in H1 was £5.8m and is expected to increase in H2
- Loss before tax of £5.8 million (H1 2014: loss £5.1 million)
- R&D tax credit of £2.0m received three months earlier than prior year

Professor Malcolm Young, CEO of e-Therapeutics, said:
"The company has made strong progress in all areas during the first six months of the financial year.

"A number of important milestones have been achieved in relation to ETS2101 in cancer and we expect to report the Phase II study results for ETX6103 at the end of the financial year.

"As we stated at the FY results, the discovery platform has exceeded our expectations with respect to productivity and the quality of the candidates being generated. Our primary focus is now on the commercialisation of these opportunities. We are targeting programmes in immuno-oncology and addressing drug resistance in targeted cancer therapies.

"The Company is well positioned for the future, with solid funding, progress in the clinical development programmes as expected and the discovery platform and projects offering exciting prospects for value creation. The second half of the year and 2016 are looking very promising."

-Ends-

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About e-Therapeutics plc

e-Therapeutics (AIM: ETX) is a drug discovery and development company with a proprietary discovery platform based on advances in network pharmacology and chemical biology.

The Company is applying its platform to the discovery of new drug candidates. The therapeutic focus of the Company's discovery activity is in immuno-oncology and addressing drug resistance in targeted cancer therapies. The platform is yielding multiple, highly potent, selective and diverse molecules at much higher yields than is reported for conventional drug discovery.

e-Therapeutics is also advancing its most promising programmes through clinical trials. There is a phase IIb clinical stage drug candidate for major depressive disorder, ETS6103; and a phase Ib clinical stage candidate in hepatocellular and pancreatic cancer, ETS2101. The Company also has a variety of preclinical stage assets, including ETX1153c, a functionally resistance-less antibiotic; ETS2300, telomerase inhibition in anti-cancer; ETS3100, small molecule anti-TNFα; ETS2400 and Hedgehog pathway inhibition.

The Company is fully funded to advance its existing development programmes in cancer and depression and a further programme from its discovery platform. It is based at sites in Oxford and Newcastle, UK. For more information about the Company, please visit www.etherapeutics.co.uk.

Overview

e-Therapeutics is a drug discovery and development company with two clinical stage assets, multiple preclinical stage assets and projects, and a productive drug discovery platform.

We have two compounds undergoing clinical trials: ETS2101, our cancer drug, entered phase Ib trials for both hepatocellular carcinoma (HCC) and pancreatic cancer in H1. All three of our phase Ia trials have now been completed successfully. ETS6103, for the treatment of major depressive disorder, is in a phase IIb trial and recruited its final patient in H1. The results of this trial are expected at the end of the current financial year.

e-Therapeutics' discovery platform, which uses network science and chemical biology to find promising molecules, has been fully operational throughout the period. The platform has been working on multiple projects and has demonstrated what we believe to be world-leading productivity. We currently have 10 live discovery projects and have identified many hundreds of highly active compounds through cell-based screening of the molecules the platform identifies.

Our present aim is to select the best of these compounds for formal preclinical development early next year, with the intention that the most promising of these will enter clinical development in 2017.

Our cash resources stood at £30.2m at the end of July, after receiving an R&D tax credit of £2m in June, three months earlier than in the prior year. Operating cash burn in H1 was £5.8m. This rate of cash burn is expected to increase in H2.

The Company continues to make strong progress in all areas. Clinical development has seen good progression in the three trials that have now completed and in both current trials. A number of important milestones have been achieved in the first half in relation to the safety, tolerability, dosing and activity of ETS2101 in cancer. The productivity of the discovery projects has exceeded our expectations, and this has enabled us to refine the commercial focus of our discovery and early development activities, as discussed in greater detail below. We remain greatly encouraged by the clinical and discovery results of the first half year and look forward to continued success in H2 and into 2016.

We envisage also that we will shortly be able to report the strengthening of our Board, including the appointment of a new non-executive Chairman.

Operational Review

Development programme – clinical highlights

During the first half, our phase I programme for ETS2101 saw the completion of our three phase Ia studies in UK and US, and the commencement of phase Ib trials in HCC and pancreatic cancer in the UK, Spain, Poland and Germany.

ETS2101 – phase Ib trials commenced

The phase Ia trials with the infused dose form previously established the maximum tolerated dose (MTD) at 30mg/kg and these trials closed in the first half.

We gained Regulatory approval and began recruitment into our phase Ib study during the period, and dosed our first patient in May. The phase Ib study is investigating the safety, tolerability and anti-tumour activity of ETS2101 in combination with the standard of care (SoC) for newly diagnosed HCC (liver) or pancreatic cancer patients, or as a monotherapy in patients with primary HCC or pancreatic cancer who have relapsed or refractory disease.

Where the trial involves combination with SoC, the first three patients enrolled are dosed at 22mg/kg to establish the safety and tolerability of the combination. Once established, the following cohorts are dosed at the MTD of 30 mg/kg. It is expected, for both HCC and pancreatic cancer, that this re-escalation will occur in Q4 2015.

The trials are being held in 15 locations in four countries. To date, we have recruited eight HCC and 14 pancreatic cancer patients.

ETS2101 – US brain cancer trial

This phase Ia study followed a dose-escalating design, with the primary objective being to demonstrate the safety and tolerability of the drug and to establish its pharmacokinetic (PK) profile in brain cancer. This study was conducted at the Moores Cancer Centre at the University of California, San Diego, by Dr Santosh Kesari.

A total of 26 patients were recruited into the study and the final patient was dosed in the first half of 2015. We are pleased to confirm that, following a review of the data by the Cohort Review Committee, the primary endpoint for this study has been achieved. Consequently the recommended phase II dose of ETS2101 in patients with brain cancer is in line with the MTD of 30 mg/kg determined in the UK trial.

Of note, two patients experienced a prolonged period of stable disease (20 weeks and 32 weeks respectively) whilst receiving ETS2101, although in both cases this was at a higher dose level of 36 mg/kg rather than the current MTD. All patients included on this study have now completed the treatment phase.

ETS6103 – patient recruitment completed

ETS6103 is aimed at major depressive disorder that is refractory or relapsing from first-line treatment with a selective serotonin reuptake inhibitor (SSRI). The phase IIb trial is designed to evaluate dosing of ETS6103 as a second-line therapy for patients whose illness has not responded satisfactorily to an SSRI. The phase IIb trial commenced at the end of 2013. The study is designed to establish whether ETS6103 has non-inferior antidepressant activity and a better tolerance profile than amitriptyline.

The trial is being conducted in Glasgow and is a randomised double-blind controlled study including two doses of ETS6103 and one of amitriptyline. We have enrolled 383 patients into the study. 164 patients who did not respond adequately to the first-line SSRI treatment have been randomised into each of the three study arms. We expect to unblind the results at the end of the current financial year, and will announce the results soon afterwards.

Discovery platform – focussed commercial strategy

Over the last 12 months we have reported very pleasing success in the identification of new compounds across a range of target indications. Indeed, the platform has enabled us to identify many active compounds across multiple chemotypes in every discovery project.

We believe this level of productivity to be world-leading. The consequence is that we have moved from the position of having only a handful of compounds under internal review some 18 months ago, to the position of having many hundreds of potentially important compounds.

This level of success greatly exceeded our most optimistic expectations, and allowed us to plan with confidence a much more finely targeted commercial focus, which we articulated at the time of our half year trading update.

One of the primary benefits of our approach to drug discovery is agility. The time from initiating a new project to identifying highly active compounds in cell-based laboratory assays can be less than six months. Consequently, we have focussed current discovery activities into areas of high and immediate commercial demand. This has resulted in emphasising discovery activities in immuno-oncology and in mitigating the therapeutic resistance that is frequently and unfortunately observed for modern ‘targeted’ cancer therapies.

We are maintaining a caucus of 10 live discovery projects at any one time. The three most advanced current projects are now in lead optimisation. The purpose of this stage is to improve the stability and PK of the lead compounds, and to ensure we are able to secure strong protection for these lead compounds by establishing composition of matter patent protection.

We anticipate these three projects should complete the lead optimisation stage in the first half of 2016, after which the best will enter formal pre-IND development.

The other live discovery activities include projects in immuno-oncology, specifically focussed on diminishing the ability of tumour tissue to suppress immune clearance of cancer, cytokine modulation, and in deriving molecules that make it much more difficult for cancer cells to evolve resistance to specifically targeted cancer medicines.

Balance sheet supports increased spending in both Discovery and Development

The Company's half year operating loss was £5.9m (six months to 31 July 2014: loss £5.3m) reflecting increased spend in both Discovery and Development offset slightly by lower administrative costs. Within Discovery, the external project-based spend increased by over £0.6m compared to the prior period and accounted for virtually all of the increase in spend. External project spend in July reflects the increased level of activity; we anticipate a further increase in the level of spend in the second half.

Costs within Development increased by around £0.1m over the prior period reflecting a £0.2m increase in spend in ETS6103 offset by a slight reduction in spend on ETS2101. The transition to the phase Ib ETS2101 study resulted in lower year on year costs but as recruitment into this study increases we expect this position to reverse in H2. Conversely, having completed recruitment of the ETS6103 trial we expect lower costs from this trial in the second half.

The Company is considering an opportunity to consolidate full control over the intellectual property used in its discovery technology. The value of any such acquisition will not exceed £2.5m (which may include shares as well as cash). Discussions are continuing and a further announcement will be made at the conclusion of that process.

Interest receivable was £0.1m in the period (six months to 31 July 2014: £0.2m) reflecting the low interest rate environment and the lower average cash position, resulting in a pre-tax loss for the period of £5.8m (six months to 31 July 2014: £5.1m).

The Company's cash balance at the end of July was £30.2m, this is a £3.6m reduction on the start of the year and compares favourably to the £6.1m reduction that was reported in the first six months of the prior year. The primary reason for the reduced cash burn in a period when operating losses actually increased is that we received a £2m R&D tax credit in respect of the year ended 31 January 2015 in June of this year, this was three months earlier than the equivalent receipt in the prior year.

Outlook

e-Therapeutics is very well positioned for the future. We remain well funded; the clinical development programmes continue to move forward in line with expectations; and the discovery platform and projects offer very exciting prospects for value creation, either through internal clinical development or out-licensing. We look forward to the second half and 2016 with increasing confidence.

GROUP INCOME STATEMENT

FOR THE SIX MONTHS ENDED 31 JULY 2015

	6 months ended 31 July 2015 (un-audited) £000	6 months ended 31 July 2014 (un-audited) £000	12 months ended 31 January 2015 (audited) £000
Revenue	**-**	-	-
Cost of sales	**-**	-	-
Gross profit	**-**	**-**	**-**
Research & Development expenditure	**(5,140)**	(4,403)	(8,549)
Administrative expenses	**(804)**	(921)	(1,626)
Operating loss	**(5,944)**	(5,324)	(10,175)
Financial income	**147**	189	357
Financial expenses	**-**	-	-
Loss before taxation	**(5,797)**	(5,135)	(9,818)
Taxation	**1,278**	1,006	2,041
Loss for the period	**(4,519)**	(4,129)	(7,777)
Loss per share - basic and diluted	**(1.71)p**	(1.56)p	(2.94)p

The results shown above relate entirely to continuing operations. There are no recognised gains and losses other than those passing through the income statement.

GROUP STATEMENT OF COMPREHENSIVE INCOME

FOR THE SIX MONTHS ENDED 31 JULY 2015

	6 months ended 31 July 2015 (un-audited) £000	6 months ended 31 July 2014 (un-audited) £000	12 months ended 31 January 2015 (audited) £000
Loss for the period	**(4,519)**	(4,129)	(7,777)
Other comprehensive income	**-**	-	-
Total comprehensive income for the period	**(4,519)**	(4,129)	(7,777)

GROUP BALANCE SHEET

AT 31 JULY 2015

	Notes	**31 July 2015 (un-audited) £000**	31 July 2014 (un-audited) £000	31 January 2015 (audited) £000
ASSETS				
Non-current assets				
Intangible assets	2	**683**	529	637
Goodwill		**-**	-	-
Property, plant and equipment		**79**	106	96
		762	635	733
Current assets				
Tax receivable		**1,282**	2,083	2,032
Trade and other receivables		**1,633**	1,938	1,570
Fixed-term deposits		**27,000**	28,000	32,000
Cash and cash equivalents		**3,201**	9,022	1,822
		33,116	41,043	37,424
Total assets		**33,878**	41,678	38,157
LIABILITIES				
Current liabilities				
Trade and other payables		**1,253**	1,116	1,133
Total liabilities		**1,253**	1,116	1,133
Net assets		**32,625**	40,562	37,024
EQUITY				
Share capital	3	**264**	264	264
Share premium	3	**64,572**	64,528	64,560
Warrant reserve	3	**-**	-	-
Retained earnings	3	**(32,211)**	(24,230)	(27,800)
Total equity attributable to equity holders	3	**32,625**	40,562	37,024

GROUP CASH FLOW STATEMENT

FOR THE SIX MONTHS ENDED 31 JULY 2015

	6 months ended 31 July 2015 (un-audited) £000	6 months ended 31 July 2014 (un-audited) £000	12 months ended 31 January 2015 (audited) £000
Cash flows from operating activities			
Loss for the period	**(4,519)**	(4,129)	(7,777)
Adjustments for:			
Depreciation, amortisation and impairment	**31**	35	72
Financial income	**(147)**	(189)	(357)
Equity-settled share-based payment expenses	**108**	28	106
Taxation	**(1,278)**	(1,006)	(2,041)
	(5,805)	(5,261)	(9,997)
Increase in trade and other receivables	**(60)**	(1,485)	(1,075)
Increase in trade and other payables	**120**	109	130
Tax received	**2,027**	-	1,087
Net cash from operating activities	**(3,718)**	(6,637)	(9,855)
Cash flows from investing activities			
Interest received	**145**	521	642
Acquisition of property, plant and equipment	**(3)**	(14)	(31)
Acquisition of other intangible assets	**(57)**	(40)	(158)
Decrease in fixed-term deposits	**5,000**	8,250	4,250
Net cash from investing activities	**5,085**	8,717	4,703
Cash flows from financing activities			
Net proceeds from issue of share capital	**12**	45	77
Net cash from financing activities	**12**	45	77
Net increase / (decrease) in cash and cash equivalents	**1,379**	2,125	(5,075)
Cash and cash equivalents at the beginning of the period	**1,822**	6,897	6,897
Cash and cash equivalents at the end of the period	**3,201**	9,022	1,822

GROUP STATEMENT OF CHANGES IN EQUITY

FOR THE SIX MONTHS ENDED 31 JULY 2015

	Share capital £000	Share premium £000	Warrant reserve £000	Retained Earnings £000	Total £000
As at 1 February 2014	264	64,483	132	(20,261)	44,618
Total comprehensive income for the period					
Loss for the period	-	-	-	(4,129)	(4,129)
Total comprehensive income for the period	-	-	-	(4,129)	(4,129)
Transactions with owners, recorded directly in equity					
Issue of ordinary shares	-	45	-	-	45
Lapse of warrants	-	-	(132)	132	-
Equity-settled share-based payment transactions	-	-	-	28	28
Total contributions by and distribution to owners	-	45	(132)	160	73
As at 31 July 2014	**264**	**64,528**	**-**	**(24,230)**	**40,562**
As at 1 August 2014	264	64,528	-	(24,230)	40,562
Total comprehensive income for the period					
Loss for the period	-	-	-	(3,648)	(3,648)
Total comprehensive income for the period	-	-	-	(3,648)	(3,648)
Transactions with owners, recorded directly in equity					
Issue of ordinary shares	-	32	-	-	32
Equity-settled share-based payment transactions	-	-	-	78	78
Total contributions by and distribution to owners	-	32	-	78	110
As at 31 January 2015	**264**	**64,560**	**-**	**(27,800)**	**37,024**
As at 1 February 2015	264	64,560	-	(27,800)	37,024
Total comprehensive income for the period					
Loss for the period	-	-	-	(4,519)	(4,519)
Total comprehensive income for the period	-	-	-	(4,519)	(4,519)
Transactions with owners, recorded directly in equity					
Issue of ordinary shares	-	12	-	-	12
Equity-settled share-based payment transactions	-	-	-	108	108
Total contributions by and distribution to owners	-	12	-	108	120
As at 31 July 2015	**264**	**64,572**	**-**	**(32,211)**	**32,625**

Notes

1. Basis of Preparation

These unaudited interim financial statements do not comprise statutory accounts as defined within section 434 of the Companies Act 2006. The Company is a public limited company; it is listed on the London Stock Exchange's AIM market and is incorporated and domiciled in the United Kingdom. The address of its registered office is 17 Blenheim Office Park, Long Hanborough, Oxfordshire, OX29 8LN, UK.

Statutory accounts for the year ended 31 January 2015 were approved by the Board of Directors on 30 March 2015 and delivered to the Registrar of Companies. The report of the Auditor on the accounts was unqualified, did not contain an emphasis of matter paragraph and did not contain any statement under section 498 of the Companies Act 2006.

This interim statement, which is neither audited nor reviewed, has been prepared in accordance with the measurement and recognition criteria of Adopted IFRSs. It does not include all the information required for the full annual financial statements, and should be read in conjunction with the financial statements of the Group as at and for the year ended 31 January 2015. It does not comply with International Accounting Standard (IAS) 34 'Interim Financial Reporting' as is permissible under the rules of AIM. The accounting policies applied in preparing these interim financial statements are the same as those applied in the preparation of the annual financial statements for the year ended 31 January 2015 (as defined therein) other than standards, amendments and interpretations which became effective after 1 February 2015 and were adopted by the Group. These have had no significant impact on the Group's result for the period or its equity.

2. Intangible Assets

Group

	Patents and trademarks	**Total**
	£000	**£000**
Cost		
Balance as at 1 February 2014	**856**	856
Other acquisitions - internally developed	**40**	40
Balance as at 31 July 2014	**896**	896
Other acquisitions - internally developed	**118**	118
Balance as at 31 January 2015	**1,014**	1,014
Other acquisitions - internally developed	**57**	57
Balance as at 31 July 2015	**1,071**	1,071
Amortisation and impairment		
Balance as at 1 February 2014	**360**	360
Amortisation	**7**	7
Balance as at 31 July 2014	**367**	367
Amortisation	**10**	10
Balance as at 31 January 2015	**377**	377
Amortisation	**11**	11
Balance as at 31 July 2015	**388**	388
Net book value		
As at 31 July 2014	**529**	529
As at 31 January 2015	**637**	637
As at 31 July 2015	**683**	683

3. Capital and Reserves

Reconciliation of movement in capital and reserves

Group

	Share capital £000	Share premium £000	Warrant reserve £000	Retained earnings £000	Total equity £000
As at 1 February 2014	264	64,483	132	(20,261)	44,618
Total recognised income and expense	-	-	-	(4,129)	(4,129)
Issue of ordinary share capital	-	45	-	-	45
Lapse of warrants	-	-	(132)	132	-
Equity-settled share-based payments	-	-	-	28	28
Balance at 31 July 2014	**264**	**64,528**	**-**	**(24,230)**	**40,562**
Balance at 1 August 2014	264	64,528	-	(24,230)	40,562
Total recognised income and expense	-	-	-	(3,648)	(3,648)
Issue of ordinary share capital	-	32	-	-	32
Equity-settled share-based payments	-	-	-	78	78
Balance at 31 January 2015	**264**	**64,560**	**-**	**(27,800)**	**37,024**
Balance at 1 February 2015	264	64,560	-	(27,800)	37,024
Total recognised income and expense	-	-	-	(4,519)	(4,519)
Issue of ordinary share capital	-	12	-	-	12
Equity-settled share-based payments	-	-	-	108	108
Balance at 31 July 2015	**264**	**64,572**	**-**	**(32,211)**	**32,625**

All 875,761 warrants outstanding at 1 February 2014 lapsed unexercised during March 2014.

Share capital

	31 July 2015 (un-audited) '000	31 July 2014 (un-audited) '000
In issue - fully paid		
Ordinary shares of £0.001 each	**264,456**	264,177
	£000	£000
Allotted, called up and fully paid		
Ordinary shares of £0.001 each	**264**	264
Shares classified as liabilities	**-**	-
Shares classified in shareholders' funds	**264**	264
	264	264

During the period, exercise of options over shares by staff led to an increase in share capital of £93 and a credit of £12,797 to the share premium account.