e-Therapeutics' interim results for the six months ended 31 July 2013

16 October 2013 e-Therapeutics plc (AIM: ETX), the drug discovery and development company, today announces its interim results for the six months ended 31 July 2013.

Highlights

(*Announced or updated today)

Lead cancer drug ETS2101 progressing in clinic

- Early findings reported from phase I trials in brain cancer and solid tumours
- Dose escalation proceeding; 33 patients now enrolled*
- No serious adverse events attributed to drug*
- Development of oral formulation begun, potentially adding to future opportunity*
- Key phase I results expected in Q4 2013 (brain cancer) and Q1 2014 (solid tumours)

Progress and decisions on other programmes

- Phase IIb trial of ETS6103 in major depressive disorder expected to start in next few weeks*
- New positive preclinical data for ETX1153c vs *C.difficile*; decision not to take drug into clinical trials*

Increasing investment in network pharmacology-based drug discovery

- Discovery and informatics capabilities expanded*
- Commitment to add new candidates to development portfolio in parallel with ETS2101 efficacy programme*

Substantial equity raise supports growth plans

- £40 million (£38.9 million net) raised on AIM in equity placing in March 2013
- Cash and liquid resources of £45.4 million at 31 July 2013 (31 July 2012: £11.7 million) sufficient to fund business into 2018, complete multiple efficacy studies of ETS2101 and enhance drug pipeline
- Half-year net loss of £2.3 million (H1 2013: loss of £1.8 million) reflects investment in business

Commenting on the results, Professor Malcolm Young, CEO of e-Therapeutics, said: "Following our successful fundraising we are investing in further development of our network pharmacology platform, in applying this technology to add to our drug portfolio and in advancing our leading compounds, notably the cancer drug ETS2101, through clinical trials. We are confident this strategy will lead to value-realising partnering deals."

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e-Therapeutics plc

Chairman's statement

Overview
We are building a business around the new science of network pharmacology. This science can be applied both to identify existing drug molecules that have unexpected potential for 'repositioning' into different disease areas and as a basis for inventing new drug molecules. We have taken two repositioned drugs into the clinic: ETS2101 is in phase I trials for cancer and ETS6103 will advance into phase IIb development for major depressive disorder in the next few weeks. We are seeking further candidates for cancer and central nervous system disorders at our network pharmacology centre near Oxford.

ETS2101 – cancer trials on track
Our phase I programme for ETS2101 includes a US trial in brain cancer and a UK trial in patients with a variety of solid tumours. Both have a dose-escalating design in which successive groups of patients receive higher doses of the drug in order to determine a maximum tolerated dose for use in subsequent studies. In May we reported that the trials had enrolled a total of 17 patients and that no serious drug-related adverse events had been recorded. One patient had experienced severe fatigue and continued on a lower dose of drug and one had shown a partial response according to RECIST, a standard method for assessing the impact of treatments on tumour burden (see Notes). At that time patients had received doses of ETS2101 up to 12 mg/kg body weight. The two trials have now enrolled 33 patients at doses up to 24 mg/kg. There have still been no serious adverse events related to treatment and no further cases of severe fatigue have been noted. The trials remain on track to complete their planned dose escalation steps and report key safety data in Q4 2013 (brain cancer) and Q1 2014 (solid tumours). If by these dates the trials have not identified a maximum tolerated dose, one or both may be extended by addition of one or two extra dose levels beyond those originally planned.

Provided the phase I data are supportive, we intend to move ETS2101 rapidly into further studies. We indicated previously that the next phase of development would likely include a randomised controlled phase II trial in one indication, probably glioma, in addition to a more exploratory phase Ib/II study in four to six other cancer types. We now plan to conduct phase Ib/II work in all of our priority indications so that we can consider data on ETS2101 in combination with standard-of-care treatments before launching a randomised trial in any particular setting. We intend to complete the programme of phase Ib/II and randomised phase II trials in time to conclude a potential licensing deal for ETS2101 within the lifespan of our existing cash resources.

We have begun a programme to evaluate an oral formulation of ETS2101, which might be preferable in some cancer settings to the intravenous formulation currently under evaluation. A phase I trial in healthy volunteers will begin shortly.

Pipeline progress and decisions
In the next few weeks we expect to initiate a phase IIb trial of ETS6103 in major depressive disorder. The trial has been approved by the UK MHRA (Medicines and Healthcare Products Regulatory Agency) but its start has been delayed by several months because the Agency required stability data on the special tablet-in-capsule form of ETS6103 used in the trial to blind patients to their treatment. The phase IIb trial builds on encouraging data from an earlier, small phase IIa study that compared ETS6103 with the approved tricyclic anti-depressant amitriptyline. Given the delay in starting we now expect to report results in the first half of 2015 rather than in the second half of 2014. We regard ETS6103 as a smaller commercial opportunity than ETS2101 but one that justifies the limited further investment needed to complete a proof-of-concept trial designed to demonstrate the product's value to potential partners.

New tests on our preclinical anti-infective candidate ETX1153c have shown strong synergy between its two constituents, miconazole and nisin, against a wide variety of *C. difficile* strains including hypervirulent isolates. In addition, extensive testing suggested that it was very hard to induce any resistance to the drug. Despite these encouraging data we do not plan to take ETX1153c forward into clinical trials for *C. difficile*. Practical challenges in delivering the drug to its site of action in the bowel, together with our view that there will be a limited commercial opportunity for new entrants to the *C. difficile* market by the time these challenges are surmounted and trials completed, persuade us that there are better investment opportunities elsewhere in our portfolio. We will, however, evaluate some alternative ways to build directly on the positive results seen in our tests.

Platform key to development of portfolio
We continue to evolve our approach to drug discovery and are making significant progress in adding to and refining the techniques used in our network pharmacology platform and in identifying how best to apply these to therapeutic challenges. Some of our projects are based around repositioning of existing drugs and others are expected to produce new chemical entities. We have several discovery programmes in which multiple candidates have been generated and

are under evaluation, although we are not yet ready to progress any of our leads into formal development. Our major goal is to ensure that we have a well-diversified portfolio of product assets by the time ETS2101 is scheduled to complete phase II development. With this in mind we are channelling additional investment into our discovery and informatics capabilities: we have just appointed four new scientists, all of whom will join our team by the end of 2013.

Strong balance sheet supports investment

Increasing investment in discovery and development increased our operating expenses from £2.3 million in the six months ended 31 July 2012 to £3.1 million in the six months to 31 July 2013. We had no revenues in the period (H1 2013: nil), but the offsetting impact of R&D tax credits receivable of £0.5 million (H1 2013: £0.3 million) and interest on our cash balances of £0.3 million (H1 2013: £0.1 million) limited our net loss to £2.3 million (H1 2013: £1.8 million).

In March 2013 we concluded an equity placing that raised £40 million through the issue of 125 million shares to new and existing investors at 32 pence per share. Net proceeds of £38.9 million are reflected in a greatly enhanced balance of £45.4 million of cash and short-term investments at 31 July 2013 (31 July 2012: £11.7 million; 31 January 2013: £9.8 million).

The Company's strategy is to license its products to pharmaceutical companies for late-stage development and commercialisation. In addition, the Company may enter discovery collaborations with selected partners. We anticipate continuing losses until revenues from these sources exceed investment in R&D. Based on our latest projections, we expect to be able to support our discovery and development plans into calendar 2018 even in the absence of any income from partners. This should enable us to complete key efficacy-focused trials of ETS2101 and, if the data from those trials are positive, conclude a licensing deal for the drug.

Outlook

We look forward to reporting results from our phase I trials of ETS2101 over the next six months and are ready to take this drug rapidly into the next stage of trials if data are supportive. At the same time we are working to build a broader business with a diversity of product assets. We believe that continuing investment in network pharmacology-based drug discovery will lead to sustained value creation in our business over the medium and long term.

Professor Oliver James
16 October 2013

Notes

About the RECIST criteria used to assess tumour responses

RECIST (Response Evaluation Criteria in Solid Tumours) provide a standardised way of assessing the response of solid tumours to treatment. Under the criteria, a partial response is recorded when the linear dimensions of the tumour lesions selected for measurement at the start of the study reduce by at least 30% from baseline and no new lesions appear.

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GROUP INCOME STATEMENT
FOR THE SIX MONTHS ENDED 31 JULY 2013

	6 months ended 31 July 2013 (un-audited) £000	6 months ended 31 July 2012 (un-audited) £000	12 months ended 31 January 2013 (audited) £000
Revenue	**-**	-	-
Cost of sales	**-**	-	-
Gross profit	**-**	**-**	**-**
Research & Development expenditure	**(2,550)**	(1,616)	(4,093)
Administrative expenses	**(540)**	(673)	(1,154)
Operating loss	**(3,090)**	(2,289)	(5,247)
Financial income	**306**	127	223
Financial expenses	**-**	(1)	-
Loss before taxation	**(2,784)**	(2,163)	(5,024)
Taxation	**503**	332	846
Loss for the period	**(2,281)**	(1,831)	(4,178)
Loss per share - basic and diluted	**(0.93)p**	(1.33)p	(3.02)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 2013

	6 months ended 31 July 2013 (un-audited) £000	6 months ended 31 July 2012 (un-audited) £000	12 months ended 31 January 2013 (audited) £000
Loss for the period	**(2,281)**	(1,831)	(4,178)
Other comprehensive income	**-**	-	-
Total comprehensive income for the period	**(2,281)**	(1,831)	(4,178)

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GROUP BALANCE SHEET
AT 31 JULY 2013

	Notes	**31 July 2013 (un-audited) £000**	31 July 2012 (un-audited) £000	31 January 2013 (audited) £000
ASSETS				
Non-current assets				
Property, plant and equipment		**130**	163	150
Goodwill		**-**	-	-
Intangible assets	2	**458**	426	378
		588	589	528
Current assets				
Tax receivable		**1,348**	909	845
Trade and other receivables		**588**	357	320
Fixed-term deposits		**41,000**	6,050	5,550
Cash and cash equivalents		**4,364**	5,607	4,225
		47,300	12,923	10,940
Total assets		**47,888**	13,512	11,468
LIABILITIES				
Current liabilities				
Trade and other payables		**584**	610	888
		584	610	888
Total liabilities		**584**	610	888
Net assets		**47,304**	12,902	10,580
EQUITY				
Share capital	3	**264**	138	138
Share premium	3	**64,439**	25,552	25,567
Warrant reserve	3	**132**	132	132
Retained earnings	3	**(17,531)**	(12,920)	(15,257)
Total equity attributable to equity holders	3	**47,304**	12,902	10,580

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GROUP CASH FLOW STATEMENT
FOR THE SIX MONTHS ENDED 31 JULY 2013

	6 months ended 31 July 2013 (un-audited) £000	6 months ended 31 July 2012 (un-audited) £000	12 months ended 31 January 2013 (audited) £000
Cash flows from operating activities			
Loss for the period	**(2,281)**	(1,831)	(4,178)
Adjustments for:			
Depreciation, amortisation and impairment	**37**	46	194
Loss on disposal of fixed assets	**-**	-	1
Financial income	**(306)**	(127)	(223)
Financial expenses	**-**	1	-
Equity-settled share-based payment expenses	**7**	9	19
Taxation	**(503)**	(332)	(846)
	(3,046)	(2,234)	(5,033)
Increase in trade and other receivables	**(65)**	(42)	(52)
(Decrease) / increase in trade and other payables	**(296)**	66	344
Tax received	**-**	-	578
Net cash from operating activities	**(3,407)**	(2,210)	(4,163)
Cash flows from investing activities			
Interest received	**103**	122	266
Acquisition of property, plant and equipment	**(5)**	(49)	(60)
Acquisition of other intangible assets	**(92)**	(112)	(189)
(Increase) / decrease in fixed-term deposits	**(35,450)**	1,700	2,200
Net cash from investing activities	**(35,444)**	1,661	2,217
Cash flows from financing activities			
Net proceeds from issue of share capital	**38,990**	-	15
Net cash from financing activities	**38,990**	-	15
Net increase / (decrease) in cash and cash equivalents	**139**	(549)	(1,931)
Cash and cash equivalents at the beginning of the period	**4,225**	6,156	6,156
Cash and cash equivalents at the end of the period	**4,364**	5,607	4,225

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GROUP STATEMENT OF CHANGES IN EQUITY
FOR THE SIX MONTHS ENDED 31 JULY 2013

	Share capital £000	Share premium £000	Warrant reserve £000	Retained Earnings £000	Total £000
As at 1 February 2012	138	25,552	132	(11,098)	14,724
Total comprehensive income for the period					
Loss for the period	-	-	-	(1,831)	(1,831)
Total comprehensive income for the period	-	-	-	(1,831)	(1,831)
Transactions with owners, recorded directly in equity					
Equity-settled share-based payment transactions	-	-	-	9	9
Total contributions by and distribution to owners	-	-	-	9	9
As at 31 July 2012	**138**	**25,552**	**132**	**(12,920)**	**12,902**
As at 1 August 2012	138	25,552	132	(12,920)	12,902
Total comprehensive income for the period					
Loss for the period	-	-	-	(2,347)	(2,347)
Total comprehensive income for the period	-	-	-	(2,347)	(2,347)
Transactions with owners, recorded directly in equity					
Issue of ordinary shares	-	15	-	-	15
Equity-settled share-based payment transactions	-	-	-	10	10
Total contributions by and distribution to owners	-	15	-	10	25
As at 31 January 2013	**138**	**25,567**	**132**	**(15,257)**	**10,580**
As at 1 February 2013	138	25,567	132	(15,257)	10,580
Total comprehensive income for the period					
Loss for the period	-	-	-	(2,281)	(2,281)
Total comprehensive income for the period	-	-	-	(2,281)	(2,281)
Transactions with owners, recorded directly in equity					
Issue of ordinary shares	126	38,872	-	-	38,998
Equity-settled share-based payment transactions	-	-	-	7	7
Total contributions by and distribution to owners	126	38,872	-	7	39,005
As at 31 July 2013	**264**	**64,439**	**132**	**(17,531)**	**47,304**

e-Therapeutics plc

Notes

1. Basis of Preparation

These unaudited interim financial statements do not comprise statutory accounts within the meaning of 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 2013 were approved by the Board of Directors on 24 June 2013 and delivered to the Registrar of Companies. The report of the auditors on those 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 2013. 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 2013 (as described in those financial statements) other than standards, amendments and interpretations which became effective after 1 February 2013 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 2012	**517**	517
Other acquisitions - internally developed	**112**	112
Balance as at 31 July 2012	**629**	629
Other acquisitions - internally developed	**77**	77
Balance as at 31 January 2013	**706**	706
Other acquisitions - internally developed	**92**	92
Balance as at 31 July 2013	**798**	798
Amortisation and impairment		
Balance as at 1 February 2012	**180**	180
Amortisation and impairment charge	**23**	23
Balance as at 31 Jul 2012	**203**	203
Amortisation and impairment charge	**125**	125
Balance as at 31 January 2013	**328**	328
Amortisation	**12**	12
Impairment	**-**	-
Balance as at 31 July 2013	**340**	340
Net book value		
As at 31 July 2012	**426**	426
As at 31 January 2013	**378**	378
As at 31 July 2013	**458**	458

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 2012	138	25,552	132	(11,098)	14,724
Equity-settled share-based payments	-	-	-	9	9
Total recognised income and expense	-	-	-	(1,831)	(1,831)
Balance at 31 July 2012	**138**	**25,552**	**132**	**(12,920)**	**12,902**
Balance at 1 August 2012	138	25,552	132	(12,920)	12,902
Issue of ordinary share capital	-	15	-	-	15
Equity-settled share-based payments	-	-	-	10	10
Total recognised income and expense	-	-	-	(2,347)	(2,347)
Balance at 31 January 2013	**138**	**25,567**	**132**	**(15,257)**	**10,580**
Balance at 1 February 2013	138	25,567	132	(15,257)	10,580
Issue of ordinary share capital	126	38,872	-	-	38,998
Equity-settled share-based payments	-	-	-	7	7
Total recognised income and expense	-	-	-	(2,281)	(2,281)
Balance at 31 July 2013	**264**	**64,439**	**132**	**(17,531)**	**47,304**

Share capital

	31 July 2013 (un-audited) '000	31 July 2012 (un-audited) '000
In issue - fully paid		
Ordinary shares of £0.001 each	263,579	138,126
	£000	£000
Allotted, called up and fully paid		
Ordinary shares of £0.001 each	264	138
Shares classified as liabilities	-	-
Shares classified in shareholders' funds	264	138
	264	138

During the period, the Company raised £40.0m (£38.9m net of related expenses) through placings of 125,000,000 new ordinary shares of 0.1p. Shareholder approval was provided at a general meeting on 27 February; 4,750,000 shares were duly issued on that day, and a further 120,250,000 on 28 February. This is reflected in an increase in share capital of £125,000, and a credit of £38,802,802 to the share premium account. All the new shares carry the same rights as the 138,198,359 ordinary shares in issue immediately prior to the placings. The new shares represented 90.4% of the Company's issued ordinary share capital immediately prior to the placings.

During the period, exercise of options over shares by former staff and issues of shares to Non-Executive Directors in part-payment of their fees led to an additional increase in share capital of £381 and a credit of £69,599 to the share premium account.