

1 August 2011

Proximagen

Year End	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
11/09	0.9	(3.5)	(7.4)	0.0	N/A	N/A
11/10	1.0	(7.3)	(11.0)	0.0	N/A	N/A
11/11e	0.5	(8.9)	(13.7)	0.0	N/A	N/A
11/12e	0.5	(9.2)	(14.1)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding goodwill amortisation and exceptional items.

Investment summary: Taking the next steps

Proximagen's strategic goal is sustainable revenue generation, with a longer-term plan to become a European speciality FIPCO in neurology. It has built a potentially valuable pipeline of 15 programmes through acquisition or in-licensing, and is now embarking on the next steps in its strategy. Proximagen expects to secure further industry partnerships to co-fund development of core assets (retaining European rights), to monetise non-core assets in oncology and inflammation, and add later-stage clinical assets to its pipeline.

Funded clinical development in epilepsy

Partners fund the two clinical epilepsy assets: tonabersat (Upsher Smith holds North American rights) and naluzotan (Proximagen retains global rights). Tonabersat should enter Phase II and data from the NIH-funded naluzotan Phase II will read out in 2012.

Partnering to advance pipeline

Preclinical progress or acquisition of later-stage assets would expand the clinical pipeline. Proximagen plans to fund some development on its own, but is also seeking partners for both its core central nervous system (CNS) and non-core assets. The latter include first-in-class oral drugs for novel targets with limited competition in oncology and inflammation, which may appeal to large pharma.

Financials: H111 cash of £44.7m

Development funding deals have limited Proximagen's R&D spending, even though up to £16-20m had been allocated for R&D in 2011-12. £22-26m is available for new acquisition/development of new assets; these funds could be supplemented by out-licensing (wholly, or in select markets/indications) or divesting non-core assets.

Valuation: EV of £28m, clinical rNPV of £63m

Our risk-adjusted NPV of Proximagen's three core clinical R&D assets (tonabersat, naluzotan and sabcomeline) is £63m. It does not explicitly value the earlier-stage assets as there is currently little visibility on development/partnering plans and timelines (which could represent upside). The valuation also only takes into account the lead indication and does not capture associated milestones.

Price 127.5p
Market Cap £73m

Share price graph



Share details

Code PRX
Listing AIM
Sector Pharmaceuticals & Biotech
Shares in issue 57.4m

Price

52 week High 156.5p Low 106.0p

Balance Sheet as at 31 May 2011

Debt/Equity (%) N/A
NAV per share (p) 79
Net cash (£m) 44.7

Business

Proximagen is a UK biotech company specialising in the development of treatments for CNS diseases. It has an acquisitive strategy, seeking to expand its pipeline through acquisition and in-licensing.

Valuation

	2010	2011e	2012e
P/E relative	N/A	N/A	N/A
P/CF	N/A	N/A	N/A
EV/Sales	N/A	N/A	N/A
ROE	N/A	N/A	N/A

Revenues by geography

UK	Europe	US	Other
0%	0%	100%	0%

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Investment summary: Steps towards sustainability

Company description: Acquiring scale in neurology

Proximagen is a UK-based R&D company. It was spun out of the King's College London Neurodegenerative Research Centre in November 2003, and was listed on AIM in 2005 by current management, raising £12.5m at 148p per share. Proximagen's origins are in discovery and development of drug candidates for Parkinson's disease. However, since raising £50m (gross) in June 2009 (35.7m new shares at 140p), it has executed a strategy of broadening its R&D pipeline through in-licensing and acquisition. Completed acquisitions include companies (Cambridge Biotechnology, Minster Pharmaceuticals) and assets (naluzotan from Epix Pharmaceuticals, two positive allosteric modulators from GSK and various from Swedish Orphan Biovitrum), which have expanded the pipeline from five preclinical assets to 15 projects (latest-stage in Phase II).

Proximagen has 45 employees (30 in Cambridge).

Exhibit 1: Proximagen's key clinical R&D programmes

Programme	Indication(s)	Development stage/notes
tonabersat	Epilepsy (refractive)	Phase II-ready. Licensing deal with GSK; N. American rights sub-licensed to Upsher Smith .
Naluzotan (PRX00023)	Epilepsy (refractive) and PD-LID	Phase II in localisation related epilepsy (funded by NINDS). Preclinical studies in Parkinson's disease models (L-dopa induced dyskinesia). Global rights retained by Proximagen.
BCI-224 (sabcomeline)	Cognition / depression	Phase II-ready: trial as add-on to SSRIs in major depressive disorder planned. Sale and purchase agreement with BrainCells Inc.

Source: Edison Investment Research

Valuation: Deals or pipeline progress to boost value

Proximagen's current EV of £28m compares to Edison's £63m rNPV of its three core clinical R&D assets (tonabersat, naluzotan and sabcomeline). Our model does not explicitly value the earlier-stage programmes as there is currently limited visibility on development and partnering plans and timelines: deals or progress into the clinic would represent upside. This valuation may also be conservative as it only values the lead indication for each programme and does not capture associated milestones as the payment schedules and their magnitude are undisclosed.

Sensitivities: Further execution of deals and development

In addition to the usual risks associated with drug development (ie clinical failure, patent risk/litigation, regulatory and commercial risks), there are also specific sensitivities to Proximagen's investment case. These include the continued ability to identify/execute attractive deals, lack of visibility on specific deal terms, Proximagen's limited track record in clinical development and reliance on partners for clinical progress of partnered programmes.

Financials: £44.7m in cash to fund R&D and further deals

End-H111 cash of £44.7m indicates that Proximagen has protected its funding position via cost-sharing deals. H111 revenues of £191k were lower than H110, although R&D spend (£2.5m) and G&A expenses decreased by £200k to £1.5m; translating into a H111 operating loss of £3.9m (H110: £3.7m loss) and £3.6m pre-tax loss (H110: £3.4m loss). Expected R&D expense of £16-20m over the next two years assumes programmes are taken through to proof of concept, but could be lower due to attrition/partnering and is also dependent on pipeline prioritisation. G&A costs remain c £3m pa, leaving £22-26m for acquisition/development of new projects. There is little short-term revenue visibility: revenues are contingent on grants or milestones from partners. Edison assumes gross cash burn of less than £10m pa; net, this should be less.

Review: The promise of future growth

Proximagen's strategic goal is to move towards sustainable revenue generation, with a longer-term plan to become a European speciality FIPCO¹ in neurology. Its primary business development focus has been on identifying interesting assets and/or companies to build a potentially valuable pipeline of 15 programmes across CNS for future partnering (with retention of EU rights to key assets). Proximagen is now embarking on the next steps in its strategy. It is seeking further industry partnerships to co-fund development of core assets, monetise non-core assets in oncology and inflammation, and acquire/in-license later-stage clinical assets to add to its pipeline.

With cash of £44.7m at end-May 2011, Proximagen remains well funded and has the resources for both internal pipeline development and acquisitions. Further evidence of execution on both of these fronts should bring the company closer to its sustainability goal. To date, Proximagen has reviewed c 160 product/company opportunities, although only a fraction of these have met the key deal criteria (strength of underlying science/technology and a clear path to market/market opportunity) resulting in a deal. The transactions that have been executed² have expanded Proximagen's pipeline (while in many cases also being structured to share financial risk), with subsequent business development activity securing partners/development funding for the clinical assets. Proximagen expects to build on this initial progress over the next two years: focusing its resources on promising pipeline assets³ and engaging in further deals to progress its pipeline towards commercialisation. This deal activity is likely to fall into the categories presented in Exhibit 2.

Exhibit 2: Expected business development activity

Activity	Aim
Co-development partnerships	Execution of deals that meet some of the clinical development costs, limiting Proximagen's cash burn. Prior partnerships of this type include: the NIH for naluzotan and Upsher Smith for tonabersat. Out-licensing deals with retention of EU marketing rights (eg tonabersat) retain a greater economic share and provide the option of either building a targeted sales infrastructure in future (central to its strategy of evolving into a neurology FIPCO) or strike a regional deal with more attractive terms when the programme is more clinically advanced.
Monetisation of non-core assets	Potential out-licensing (wholly, or in select markets or non-CNS indications) or divestment (as with sabcomeline) of non-core assets (ie those in non-CNS indications, eg inflammation [VAP-1 or PAR-2] and oncology) could provide additional funds to support the further development of programmes in which Proximagen retains rights.
Acquisition of later stage clinical assets	Exploiting potential CNS acquisition/in-licensing opportunities from biotech or larger pharma companies looking to divest non-core assets. Adding pipeline programme(s) which are nearer to market should accelerate the realisation of Proximagen's aim of sustainability.

Source: Edison Investment Research

Proximagen aims to further expand its clinical pipeline (Exhibit 3, overleaf), through acquisition of late-stage clinical assets, and to advance its preclinical pipeline (Exhibit 4, overleaf), either on its own or with a partner. Its current clinical development focus is on two epilepsy assets: tonabersat (under development by North American partner Upsher Smith) and naluzotan (in an ongoing NIH-funded Phase II trial). Upsher Smith should initiate Phase II tonabersat trials in 2012 once dosing work is complete, while data from the Phase II naluzotan trial is also expected to report next year. Proximagen has also confirmed collaborative interest in its positive allosteric modulator programmes acquired from GlaxoSmithKline in December: in particular for the α -7 PAM, following the clinical validation of the target provided by the positive results of two Phase II schizophrenia trials of competing projects (EnVivo Pharmaceuticals' EVP-6124, and Targacept's TC-5619).

¹ FIPCO = fully integrated pharmaceutical company.

² For further detail on Proximagen's transaction history, please see the Edison Outlook note '[Steps to sustainability](#)' published April 26, 2011.

³ Investing up to 'identifiable value inflection points' or, if justified by the potential economic return, to maximise value prior to selective partnering.

Exhibit 3: Proximagen's clinical R&D pipeline

Programme	Indication(s)	Development stage/notes
tonabersat	Epilepsy in refractive patients	Phase II. North American rights (US, Canada, Mexico) sub-licensed to Upsher Smith Labs in April 2010 (undisclosed terms: includes upfront payment and royalties); USL responsible for N. American development, filings and commercialisation, Proximagen retains European rights (with royalty-free access to USL's clinical data); economics from any future non-N. America/non-Europe deals to be shared equally. Non-clinical one-year NIH study provided proof of concept in epilepsy (Red Book). USL is carrying out enabling work ahead of dose-ranging epilepsy trials which should initiate in 2012. Proof of principle Phase II studies in other indications under consideration. Data package includes exposure in >1,250-pts. Prior negative trials in acute migraine (GSK) and migraine prophylaxis (Minster). Licensing deal with GSK (via Minster) included £5m milestone on initiation of first Phase III trial, £10m on first sales in a major market plus 4% royalties on net sales <£500m/year and 6% on net sales >£500m/year. Gap junction blocker.
Naluzotan (PRX00023)	Temporal lobe epilepsy (refractive) / L-dopa induced dyskinesia	Phase II. Oral 5HT _{1A} agonist. Dual strategy (epilepsy and Parkinson's disease). NIH CRADA, with the NINDS, fully funds ongoing 30-pt double-blind, crossover, placebo-controlled Phase II trial in localisation related epilepsy (results: Aug 2015 according to clinicaltrials.gov, but management expect read out in 2012). Preclinical activity seen in models of Parkinson's disease (effectively is a Phase II-ready asset). Seeking to partner US rights post-Phase II. Safety/tolerability demonstrated in 400-pts: prior negative Phase IIb depression and Phase III anxiety trials carried out by EPIX Pharmaceuticals. IP to 2025 (includes composition of matter).
BCI-224 (sabcomeline)	Depression / cognition	Phase II-ready. Licensed from GSK (via Minster): obligations taken on by BrainCells Inc (Aug 2010) under a global sale and purchase agreement. Total BrainCells deal value of \$51m in upfront and milestone payments plus (presumably single-digit) sales royalties. BrainCells owns global rights and is responsible for development, filing and commercialisation. Phase II planned as add-on to SSRIs in major depressive disorder (also measuring improvement in cognitive function). IP covering the combination of muscarinic agents with SSRI issued in March 2010. Prior exploratory Phase II trial showed activity against negative symptoms and cognitive decline in schizophrenia (no details published). Data package includes >3,000-pt exposures from prior development, including some > a year. Phase III Alzheimer's disease studies conducted by SmithKline Beecham did not achieve primary endpoints (but showed improvement in behavioural endpoints).
PRX00933 (BVT.933)	Obesity	Phase IIb. 5-HT _{2C} agonist. 154-pt Phase IIa (2002) showed sig. reduction in body weight without serious side-effects: 300-pt Phase IIb study ended in 2003. Further preclinical studies carried out by development partner GSK, which returned rights to Swedish Orphan Biovitrum in 2007 after development discontinued. Undisclosed profit-share to Swedish Orphan Biovitrum . Seeking partner for development in obesity (would require significant investment, and in part contingent on fortunes of Arena's lorcaserin: FDA Complete Response Letter issued Oct 2010) or other indications.

Source: Edison Investment Research

Exhibit 4: Proximagen's preclinical pipeline

Programme	Indication(s)	Development stage/notes
α7 PAM	Cognition disorders	Positive allosteric modulator targeting the α7 nicotinic acetylcholine receptor (nAChR). Phase I ready: positive efficacy in disease models. Near-term R&D collaboration possible (retaining EU marketing rights). Acquired from GSK (terms undisclosed).
PRX1 / PRX1354	Symptomatic treatment of Parkinson's disease	L-dopa prodrug partnered with Upsher-Smith Laboratories (deal value = \$232m in total milestones and equity investments, plus escalating high single/double digit royalties on global sales). USL responsible for development/commercialisation globally. Preclinical data triggered a \$6m equity investment at 250p per share (Oct 2008). Lead candidate (PRX1354) expected to reduce/overcome shortcomings of existing L-dopa therapy (poor/variable oral bioavailability, unpredictability of response, short half-life, loss of drug effect over time, motor complications and dyskinesia onset). Preclinical data showed extended half-life vs L-dopa and reduced dyskinesia. Phase I pending: USL unlikely to disclose clinical progress prior to Phase II.
VAP-1	Inflammatory disease (rheumatoid arthritis)	VAP-1 mediates inflammatory cell movement to sites of chronic inflammation and contributes to free radical load. Novel small molecule with potential in therapy and prophylaxis of acute/chronic inflammatory disease (eg RA, MS, Crohn's disease, ulcerative colitis, psoriasis and COPD). Final preclinical efficacy studies underway: targeting Phase I studies and proof of principle for inflammation late 2011/early 2012. Intention to out-license post-Phase II data.
5-HT ₆ (BVT.74316)	Cognition in Alzheimer's disease	5-HT ₆ antagonist. 98-pt Phase I completed (2007) identified safe/tolerable dose. Most advanced compound acquired from Swedish Orphan Biovitrum is Phase II-ready; but development focused on optimising a preclinical backup with superior PK properties. Plan to develop to Phase II proof-of-concept. Non-peptide.
PAR2	IBD/atopic dermatitis	Small molecule. Lead molecule has demonstrated efficacy in preclinical IBD models at both therapeutic and prophylactic doses. Target Phase I start in IBD in 2011-12: intention to partner pre-Phase II.
GPCR antagonist	Renal inflammation	Seeking to partner in 2011/12.
CXCR4 antagonist	Glioblastoma Multiforme	Targeting Phase I start and partnership in 2011/12. Exclusive rights from Ligand Pharmaceuticals (for an upfront, undisclosed future milestones and royalties).
D1 PAM	Parkinson's disease	Acquired from GSK (terms undisclosed). Positive allosteric modulator.
TrkA	Inflammatory pain	Acquired from Swedish Orphan Biovitrum (terms undisclosed).
SSAO inhibitor	Cancer progression	Acquired from Swedish Orphan Biovitrum (terms undisclosed).

Source: Edison Investment Research

Other preclinical programmes of interest include the non-core assets which have potential in large and lucrative indications, and may be of interest to larger pharma players, unlocking value for Proximagen through partnerships. The value of these programmes (profiled in Exhibit 5) cannot be explicitly assessed at present, but should not be overlooked. The common shared feature is that they are largely first-in-class orally available drugs which hit novel molecular targets, and where competition is presently limited.

Exhibit 5: Select preclinical assets for further development/partnering

Target	Indication	Target comment/notes	Development plans/notes
VAP-1	Rheumatoid arthritis	Vascular adhesion protein-1 is expressed on endothelial cells lining blood vessels. It mediates leukocyte migration to inflamed tissue, a common feature in many autoimmune diseases (eg RA, MS, ulcerative colitis and psoriasis). A key feature of VAP-1 is its specificity: it is unregulated during inflammation.	First-in-class oral small molecule. Initiation of Phase I targeted 2011/12: intention to partner after proof of concept Phase II data. Preclinical studies showed comparable efficacy to methotrexate and anti-TNF α , but without their side-effect profile. Biotie's BTT-1023, a fully human monoclonal antibody in Phase II preparation, is the only other VAP-1 in development.
PAR-2	Inflammation (IBD and atopic dermatitis)	Protease activated receptor-2 is a protease activated G-protein coupled receptor (GPCR). It has pro-inflammatory properties and is expressed on certain immune (eg neutrophils, monocytes, eosinophils, lymphocytes), endothelial (vascular and intestinal) and smooth muscle cells.	First-in-class non-peptide small molecule: orally available. Plan to partner during 2011-12 (pre-Phase II), and potentially start Phase I trials for IBD in similar timeframe. Non-clinical studies have shown sub-micromolar affinity and potential for reduced/no side-effects. No known competition.
GPCR	Renal inflammation	Undisclosed target: G-protein coupled receptor (GPCR) antagonist which inhibits agonist-mediated responses on binding to the receptor, rather than provoking a biological response itself.	First small molecule therapy (oral). Plan to partner prior to clinical development (in 2011/12). Targeting renal inflammation (potential in diabetic nephropathy and retinopathy). Complete prevention of diabetes-induced renal damage in non-clinical studies.
CXCR4	Cancer of the CNS – glioblastoma multiforme (GBM)	CXCR4 is a membrane-bound chemokine GPCR, expressed by cells in the immune system and central nervous system. It has been strongly implicated in tumour neo-vascularisation, protection of cancer stem cells, tumour spread and metastasis. CXCR4 inhibitors are capable of 'mobilising' hematopoietic stem cells into the bloodstream as peripheral blood stem cells.	First orally available, high-affinity inhibitor capable of crossing the blood-brain barrier (BBB), with high CNS penetration. Plan to carry out IND-enabling work in 2011 and partner prior to clinical development. Potentially best in class: competitive CXCR4 inhibitors limited to Genzyme's (Sanofi-Aventis's) Mozobil , approved for stem cell mobilisation (not brain penetrant nor orally available).

Source: Edison Investment Research

Clinical pipeline update: epilepsy assets

Tonabersat and naluzotan are re-profiled drug assets which represent two different, novel approaches to treating epilepsy, which may have the potential to benefit treatment-refractory patients. A status update is shown in Exhibit 6.

Exhibit 6: Proximagen's clinical epilepsy programmes

	Tonabersat	Naluzotan
Mechanism of action	Gap junction blocker	5HT _{1A} agonist
Partner	Upsher Smith Laboratories: North American development and commercialisation rights. Deals terms are undisclosed but are understood to include an upfront payment, royalties on sales and royalty-free access to any clinical data generated.	CRADA (Cooperative Research and Development Agreement) with the NINDS (National Institute of Neurological Disorders and Stroke) funds the ongoing 30-pt Phase IIa study in epilepsy.
Partnering plans	Proximagen retains commercialisation rights in Europe and 50% of the rest of the world rights: potential for further deals (eg for Japan).	Proximagen has global rights. Partnering plans will be informed and supported by data from ongoing clinical trial: a territorial deal with retention of European rights would be consistent with Proximagen's strategy.
Development progress	Proof of concept from one year non-clinical NIH study (anti-convulsant profile demonstrated in predictive models of efficacy). Phase II epilepsy trials are expected to be initiated in 2012.	30-pt Phase IIa trial in temporal lobe epilepsy began recruitment in January 2011: results anticipated 2012.
Other indications	Potential in migraine (dose refinement may overcome its chequered history in this indication) or neuropathic pain: additional exploratory studies required.	Preclinical studies in Parkinson's disease models confirmed activity in reducing dyskinesia without off-target effects. Merck Serono's sarizotan provided clinical proof of concept for 5HT _{1A} agonists, although its efficacy was compounded by dopaminergic effects.

Source: Edison Investment Research

Despite numerous anti-epileptic drugs (AEDs) being available on the market, there is still a need for new AEDs, in particular with respect to improved efficacy. Second-generation drugs are safer and better tolerated with fewer serious side-effects than the older first-generation drugs, but there still remains significant unmet medical need as c 30% of patients with partial-onset seizures are refractory to current monotherapy regimes. Thus there is a clear need for new therapeutic options for epilepsy with new mechanisms of action which would be complementary to existing therapies.

Exhibit 7 provides an updated summary of select late-stage clinical programmes in development as adjunctive therapies for epilepsy.

Exhibit 7: Late-stage epilepsy development programmes

Product	Company	Development stage/notes
Trobalt (EU)/Potiga (US) (retigabine)	GSK/ Valeant	Approved by FDA (June 2011: although review into abuse potential necessary pre-launch) and EMA (March 2011) as adjunctive therapy. Potassium channel opener.
Stedesa (eslicarbazepine)	Sunovion	Registration as adjunctive therapy: FDA Complete Response Letter (May 2010).
perampanel (E2007)	Eisai Co	Registration as adjunctive therapy: MAA and NDA filed Q211 (MAA accepted but FDA issued refusal to file). One 1,430-pt Phase III trial ongoing (results: Oct 2016). Oral selective AMPA antagonist.
Epilga	Supernus	Eight clinical trials in refractory partial onset seizures competed, 360-pt Phase III ongoing (results: July 2011). NDA submission (under a 505(b)(2)) expected H211. Controlled release formulation of oxcarbazepine (Trileptal : Novartis).
IV carbamazepine	Lundbeck	Phase III. 105-pt open label study assessing safety, tolerability and PK and bioequivalence vs oral carbamazepine (Tegretol : Novartis) (results: Sept 2011).
Rikelta (brivaracetam)	UCB	Three Phase III trials (c1,300-pts) in refractory partial onset seizures complete: mixed data (primary endpoint met in US study, missed in EU/RoW trial; efficacy also differed between subgroups). Confirmatory 720-pt Phase III ongoing (results: H113). Cholinergic antagonist.
Ganaxolone	Marinus Pharma	Positive Phase II (partial onset seizures as adjunctive therapy): open-label extension ongoing). First in class neurosteroid: positive allosteric modulator of GABA-A receptors.

Source: Edison Investment Research

Valuation

Proximagen has a current EV of £28m (market cap minus latest reported cash), which compares to Edison's risk-adjusted net present value (rNPV) of £63m. This valuation is based on an rNPV of the three core clinical R&D programmes (tonabersat, naluzotan and sabcomeline) using a 12.5% cost of capital. Our model uses industry standard development probabilities, our estimates of market size and potential, and estimates of the economics of partnering deals; it also includes a base running cost for the business. The model assumptions are presented in Exhibit 8.

Exhibit 8: Proximagen rNPV model

Product(s)	Status	Probability of success	Est launch year	Est peak market share	Current market value	Est maximum royalty	Est peak sales
Tonabersat (N. America)	Phase II	35%	2017	10%	\$2,500m	12%	\$269m
Tonabersat (Europe)	Phase II	35%	2018	10%	\$1,250m	100%	\$135m
Naluzotan - epilepsy	Phase II	35%	2019	5%	\$5,000m	100%	\$273m
Sabcomeline - depression	Phase II	35%	2018	3%	\$11,000m	5%	\$203m

Source: Edison Investment Research

We highlight that our model may err on the side of conservatism as it only takes into account the potential value of the lead indication for each programme (label extension would boost potential value), and while milestones are assumed payable on tonabersat (for North America) and sabcomeline, they are not captured in our model as the payment schedules and their magnitude are undisclosed. This model also only ascribes value to Proximagen's clinical assets, as there is currently limited visibility on development and partnering plans and timelines for its earlier-stage assets. In addition, as the model fully values European tonabersat rights and global naluzotan rights, there is an underlying assumption that this will be at least partially funded by unlocking the value in some of the preclinical assets through deals.

Nevertheless, there remains room for upside from preclinical assets moving into clinical development. Progress with development is necessary for a higher valuation: our rNPV valuation will increase as products move successfully through clinical development and justify higher probabilities of success. Conversely, any delay to our assumed timelines, or clinical failures would result in a lower valuation.

Sensitivities

Proximagen's business is subject to the usual risks associated with biotech drug development, ie the possibility of clinical trials failing or reporting inconclusive/contradictory results, patent litigation, regulatory and commercial risks (eg approval timelines may exceed expectations, thus delaying potential launch, or may result in a negative recommendation/not approvable decision). Pricing and reimbursement decisions may also have either a positive or negative impact on sales.

The specific sensitivities to Proximagen's investment case, both on the upside and downside, are: the ability to identify and execute attractive deals, limited visibility on specific deal terms, clinical development capability, reliance on partners for clinical and regulatory progress of key assets and the potential impact of cornerstone investors on liquidity/the share price.

Financials

Proximagen's current revenues are contingent on milestone recognition from partnering (ie for PRX1 and tonabersat) or grants; hence, due to lower revenue recognition H111 revenues of £191k were lower than H110 (£1.13m). R&D spend of £2.5m was flat on the prior period, while G&A expenses decreased by £200k to £1.5m. This translated into a H111 operating loss of £3.9m (H110: loss of £3.7m) and a pre-tax loss of £3.6m (H110: £3.4m).

For FY11 and FY12, there continues to be little visibility on revenues in the short term, as these are only recognised as development progresses. On the costs side, management guidance broadly allocated £16-20m to R&D over the next two years (although this assumes that programmes are successfully taken through to proof of concept – and therefore could be lower with pipeline attrition – and is also dependent on which programmes are prioritised/partnered), with admin costs of c £3m per year, leaving £22-26m for acquisition/development of new programmes.

However, as Proximagen has invested less in R&D than expected at the time of the June 2009 fundraise as costs of the later stage clinical assets have been borne by partners, Edison has trimmed its R&D spending assumptions by £1m to £7m in both FY11 and FY12. Edison now assumes gross cash burn of less than £9.5m per year for FY11 and FY12, although in reality the net figure is likely to be lower, as further risk and cost sharing transactions are secured. The Proximagen financial model is shown in Exhibit 9.

Exhibit 9: Proximagen financial model

Note: The forecasts below do not assume any future acquisitions/in-licensing deals, or the out-licensing of any existing programmes.

	£'000s	2008	2009	2010	2011e	2012e
Year ending 30 November						
PROFIT & LOSS						
Revenue		272	945	1,027	500	500
Cost of Sales		(32)	(59)	(27)	(13)	(13)
Gross Profit		240	886	1,000	487	487
EBITDA		(3,296)	(3,806)	(7,633)	(9,274)	(9,425)
Operating Profit (before GW and except.)		(3,386)	(3,901)	(7,829)	(9,374)	(9,525)
Goodwill Amortisation		0	0	0	0	0
Exceptionals		0	0	0	0	0
Other		(73)	153	(66)	(150)	(150)
Operating Profit		(3,459)	(3,748)	(7,895)	(9,524)	(9,675)
Net Interest		491	372	545	480	375
Profit Before Tax (norm)		(2,895)	(3,529)	(7,284)	(8,894)	(9,150)
Profit Before Tax (FRS 3)		(2,968)	(3,376)	(7,350)	(9,044)	(9,300)
Tax		661	518	924	1,050	1,050
Profit After Tax (norm)		(2,234)	(2,757)	(6,297)	(7,844)	(8,100)
Profit After Tax (FRS3)		(2,307)	(2,858)	(6,426)	(7,994)	(8,250)
Average Number of Shares Outstanding (m)		20.2	37.1	57.3	57.4	57.4
EPS - normalised (p)		(11.1)	(7.4)	(11.0)	(13.7)	(14.1)
EPS - FRS 3 (p)		(11.4)	(7.7)	(11.2)	(13.9)	(14.4)
Gross Margin (%)		88.2%	93.8%	97.4%	97.4%	97.4%
EBITDA Margin (%)		N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A	N/A
BALANCE SHEET						
Fixed Assets		262	336	1,080	1,425	1,325
Intangible Assets		0	0	858	1,286	1,286
Tangible Assets		262	336	222	139	39
Investment in associates		0	0	0	0	0
Unquoted investments		0	0	0	0	0
Current Assets		10,777	58,188	49,934	41,216	32,566
Stocks		0	0	0	0	0
Debtors		296	2,093	831	405	405
Cash		10,213	55,577	48,170	39,761	31,112
Other		268	518	933	1,050	1,050
Current Liabilities		(2,738)	(3,922)	(2,701)	(2,201)	(1,701)
Creditors		(299)	(3,843)	(2,701)	(2,201)	(1,701)
Other creditors		(2,439)	(79)	0	0	0
Short term borrowings		0	0	0	0	0
Minority interests		0	0	0	0	0
Long Term Liabilities		0	0	0	0	0
Long term borrowings		0	0	0	0	0
Other long term liabilities		0	0	0	0	0
Net Assets		8,301	54,602	48,313	40,440	32,190
CASH FLOW						
Operating Cash Flow		(1,240)	(4,187)	(7,994)	(9,498)	(10,075)
Net Interest		604	317	496	480	375
Tax		393	268	509	1,050	1,050
Capex		2	(14)	(103)	(17)	0
Acquisitions/disposals		0	22	(386)	(425)	0
Financing		1,881	49,058	8	1	0
Dividends		0	0	0	0	0
Other		66	(100)	63	0	0
Net Cash Flow		1,706	45,364	(7,407)	(8,409)	(8,650)
Opening net debt/(cash)		(8,507)	(10,213)	(55,577)	(48,170)	(39,761)
HP finance leases initiated		0	0	0	0	0
Other		0	0	0	0	0
Closing net debt/(cash)		(10,213)	(55,577)	(48,170)	(39,761)	(31,112)

Source: Edison Investment Research

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