

Biomedical Catalyst Scheme seminar

Hamburg, 12 November 2012-11-13

Abstract: The Biomedical Catalyst Fund is supported by the BIA, who are leading a call from UK stakeholders to extend the BMC and capitalise on its early success. Feedback from companies at seminar organised by BioPartner and UK Trade & Investment at BIO-Europe in Hamburg, was overwhelmingly positive. The BMC is acknowledged as a source of non-dilutive cash with a low administrative burden that is highly effective in generating growth from innovative research that would otherwise not take place.

BioPartner supports the recent announcement of £29.6 million in funding to UK life science companies under the Biomedical Catalyst Scheme administered by the Technology Strategy Board (TSB). Two Cambridge-based BioPartnership Programme members, Arecor and Domainex, outlined their initial experiences of the bidding process and project set up, at a seminar organised by BioPartner and UK Trade & Investment. Dan Rutstein, Director of Trade for Germany at UK Trade & Investment provided an international trade perspective, with routes to assistance for UK companies seeking new business in Germany.

Programme:

12.00pm Coffee and Welcome

12.10pm Introduction: Alasdair Stamps, BioPartner.co.uk

12:15pm Guy Hill, Senior Business Development Manager, Arecor

12.25pm Eddy Littler, CEO, Domainex

12.35pm Dan Rutstein, Director of Trade and Investment, UKTI Germany

12.45pm Q&A and Discussion

12.50pm Wrap-up, thanks and business card exchanges

Arecor is a biotechnology company enabling new delivery and use options for biologics. Arecor focus on improving patients experience and a major focus for their business is moving antibody therapeutics delivered by infusion to high-concentration forms, administrable at home instead of under a clinical setting.

Arecor has a long track record in heat stabilisation of biologics, including ambient-stable vaccines, and offers an alternative to current methods e.g. infusion requires clinical expertise where healthcare administration costs can outweigh drug costs. It has to date worked only on adding FDA approved molecules to help with stabilisation of high concentrated forms, as there is less development risk. Until the project is awarded funding, Arecor will be able to complete the commercialisation of new technology that they have been able to demonstrate has the potential to enable these high-concentrated forms of antibodies, and reduce costs and improve patient benefit.

Areacor's BMC grant was awarded in part for toxicology work to complete development of novel molecules. The project had been nurtured but commercialisation was not possible as there were no funds for in this kind of work and the project sat waiting for input before the decision to apply for BMC funds. There was a strong evidence of the viability of the approach but essentially it was a new venture within the existing company, which requires resources that are risky for a small company to deploy. A 40% input from the company still requires care, but the 60% injection from BMC enables the company to grow its activities where it wouldn't have otherwise. The application process is valuable. Critical feedback from the initial Expression of Interest was surprisingly useful and gave the team good input into the business value. Staff were confident about the technology section of the application but the business input from the BMC team was invaluable.

Guy was asked how much time was spent on the award process: Scientists spent about a month full time on preparing the application, and a lot more was spent on company strategy, but it was useful. Eddy Littler pointed out that the time spent is generally proportional to the award amount – higher levels are worth it. Dan Rutstein said the TSB (Technology Strategy Board) are trying to be business friendly, but need to be audit friendly too. Guy concluded that even if the grant had not been awarded, the experience would have been worth it.

Eddy Littler of **Domainex** spoke about how to use the grant strategically rather than the focusing on the application process. He feels the BMC has appropriately targeted the "Valley of death" experienced by early stage companies. What is most significant is that the BMC grant is non-dilutive, and he raised the possibility that the company contribution (40% for early/late stage grants) could take the form of services in kind from external partners. CRO collaboration deals are encouraged as part of the projects. The Feasibility application form includes bullet points on which it is possible to score highly just by following instructions and giving all of the answers required. TSB feedback is given within weeks. The Early stage application is a 2 stage process, but is also quick. The company is allocated a Monitor, who is process-driven, but will be a useful advisor if provided with all the information they need, and the administrative burden is low.

Domainex has raised £3m since 2001 and has earned £15m from the service business to take its pipeline forward. Its IKKe.molecules are being advanced in oncology, but a recently publicised pharma project prompted Domainex to investigate their applicability to immune mediated disorders such as COPD, asthma, lupus and other disease states. The BMC funding Domainex won in November will enable testing of compounds that will enhance (double) the value of the programme in just one year. Eddy's opinion was that the process had been well worthwhile, commenting that most CEOs would prefer to gouge their own eyes out with a teaspoon than raise money... Domainex's next application will be for clinical development in oncology in 2 years.

Domainex has lots of experience in bid writing: 2 BMCs completed, and 2 STDIs – unlike BMC, these are diluting and are harder monitored. BMC monitoring is relevant and not too heavy handed. Eddy finished by offering to share his experience and provide advice to others embarking on the process.

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Dan Rutstein, works for **UK Trade & Investment** as Head of the Commercial section based at the British Embassy in Berlin, helping UK companies to trade overseas. He sees the benefits of using funds like these as using Government money to reduce financial burden, a positive effect on other investors, and recognition of government support leading to deals – this is a shining example to Ministers.

Dan pointed out that several companies had accessed UK Trade & Investment (UKTI) money to attend BIO-Europe, and networking opportunities had been provided for UK delegates by UKTI and BioPartner. The UK economy is back in growth, the UK has a 50% export rate to Europe and during the Eurozone crisis it has been a difficult time to trade. Debt fuelled consumption was one of the mistakes that have been made. International trade and FDI (foreign direct investment) is now seen as the sustainable way of boosting the economy. Government wants to increase the number of exporting companies from 20 to 25%. Exporting companies are also seen to be more productive at home. Part of UKTI's work is trade shows. Dan highlighted the usefulness of Embassies and Consulates. He gave a recent example where an Embassy launch event in Berlin led to £5m sales of the new Range Rover. UKTI employs 40 people in Germany across all sectors – providing services like visit programmes, networking, press releases, and competitor analysis. UK companies are invited to take up Consultant services, provided by bilingual staff with local knowledge and contacts.

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Internationalising UK Life Sciences

The BioMedical Catalyst Fund

Making UK Life Sciences more Competitive

Alasdair Stamps, Executive Director

BioPartner.co.uk is an independent, accredited trade organisation, promoting international partnering for trade, investment and collaborations with UK life science companies





£90m
Academic led



£180 million over 3 years

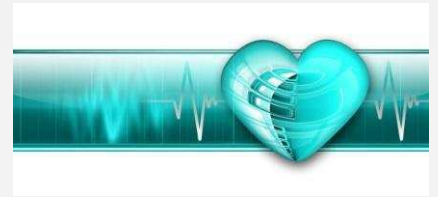
- **Grant funding**
- **Non-dilutive**

£90m
Business led

Technology Strategy Board

UK  **Booth #73**

Objectives



- Create a more competitive Life Sciences sector in the UK
- Deliver growth to the UK life sciences sector
- Move innovative life sciences products and services to market more quickly and effectively, ensuring maximum healthcare impact
- Leverage in significant private investment
- Create new employment opportunities
- Support academically- and commercially-led R&D, encouraging partnership between clinicians, academics and industry
- Increase the amount of R&D investment in the UK

BMC Awards

Feasibility Awards

- Grant of **75%**
- Max £150k in grant

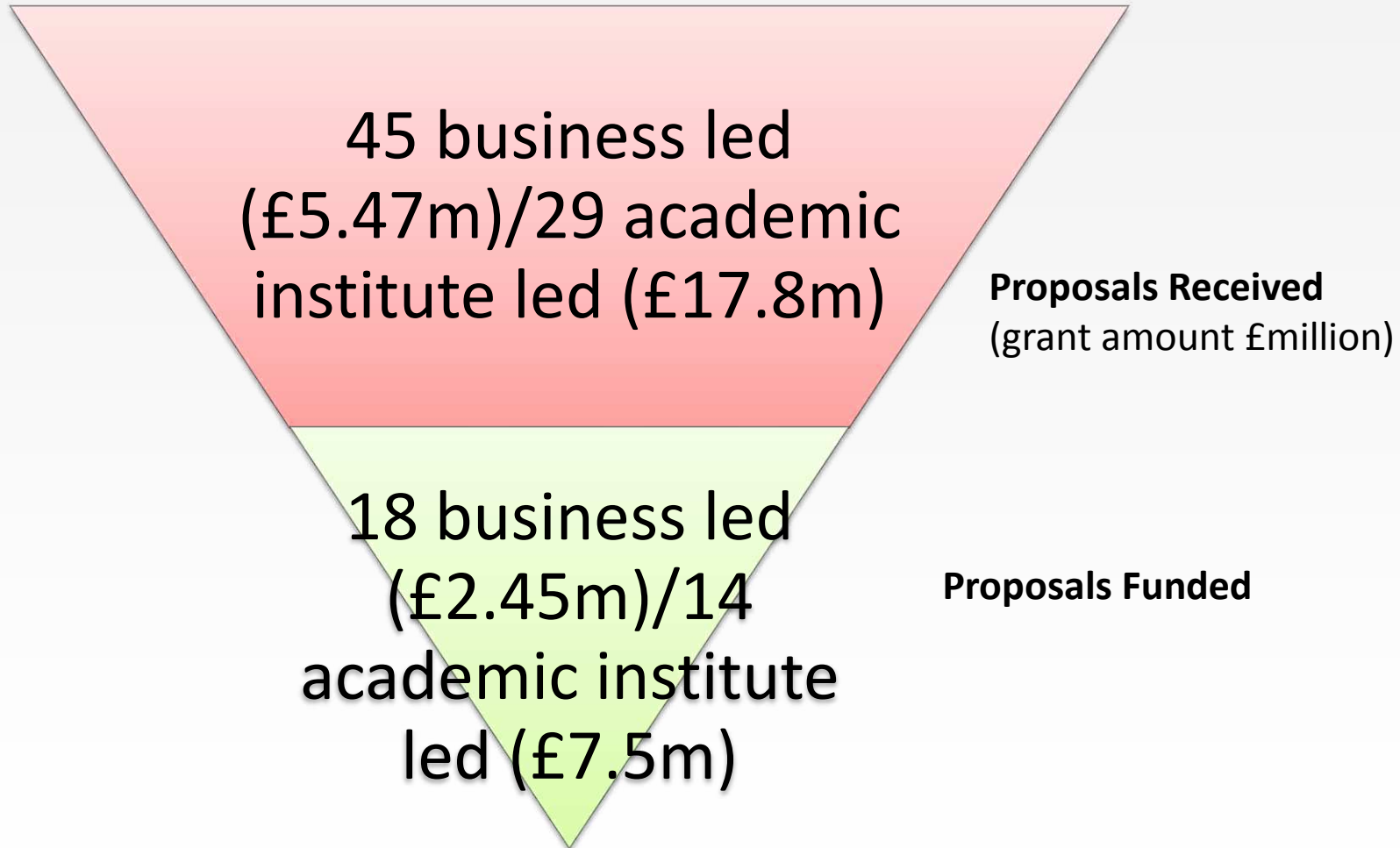
Early and Late Stage Awards

- Grant of **60%**
- Max of £2.4m in grant (flexible)

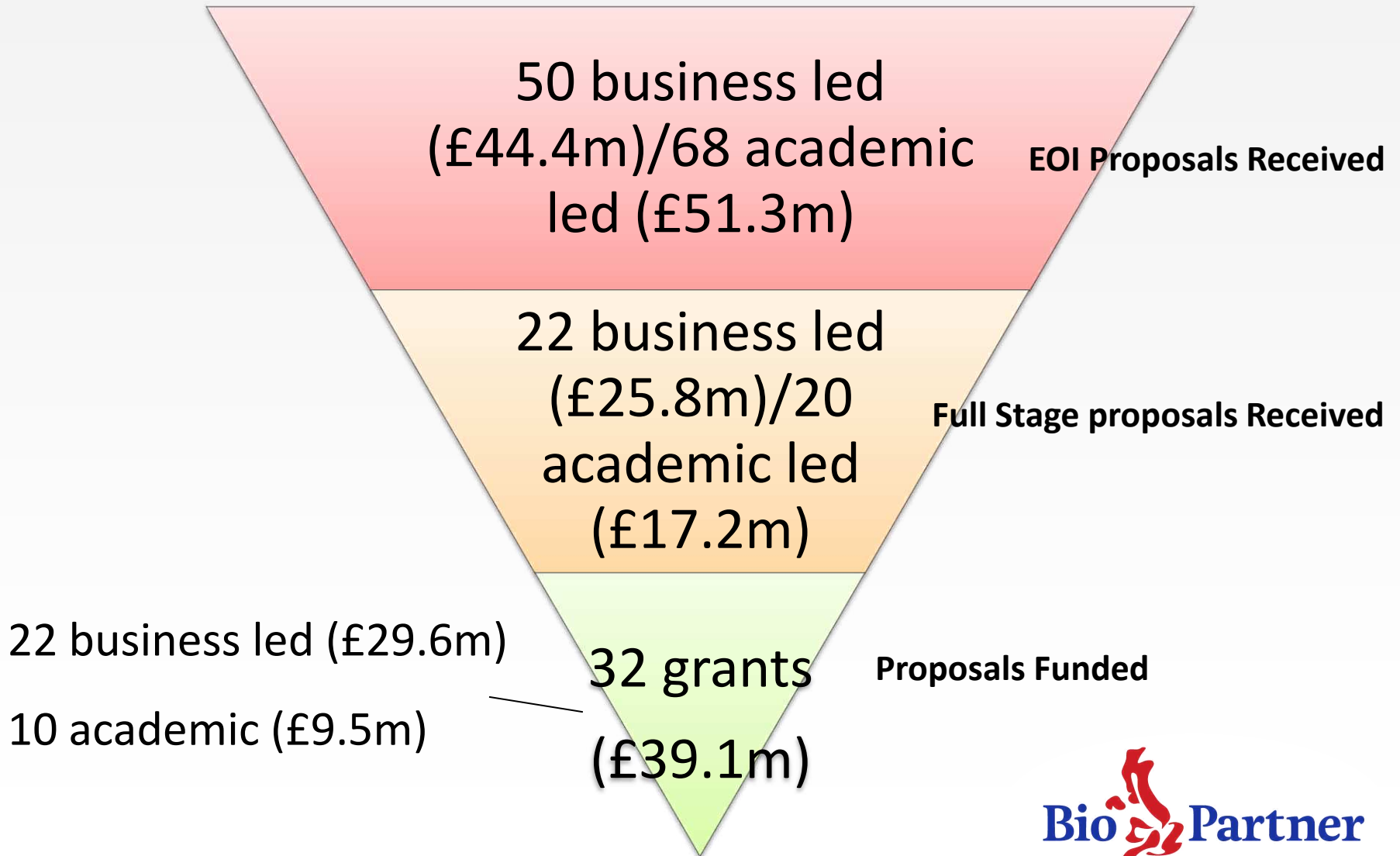
Competitive



Feasibility/Confidence in Concept Awards Round 1 (awarded August 2012)



Early/Late Stage Awards Round 1 awarded November 2012



What next?

“the most effective government policy supporting innovative emerging life sciences companies for years”

- £32m awarded of £90m total
- Further rounds tba



The UK BioIndustry Association is engaged with the UK government in promoting the Biomedical Catalyst for SMEs

BIA is leading a call from UK stakeholders to extend the BMC and capitalise on its early success



Get involved

Twitter: @innovate_uk or join the conversation using #BMC

Find innovators on: _connect <https://connect.innovateuk.org>

Visit: www.innovateuk.org



Internationalising UK Life Sciences

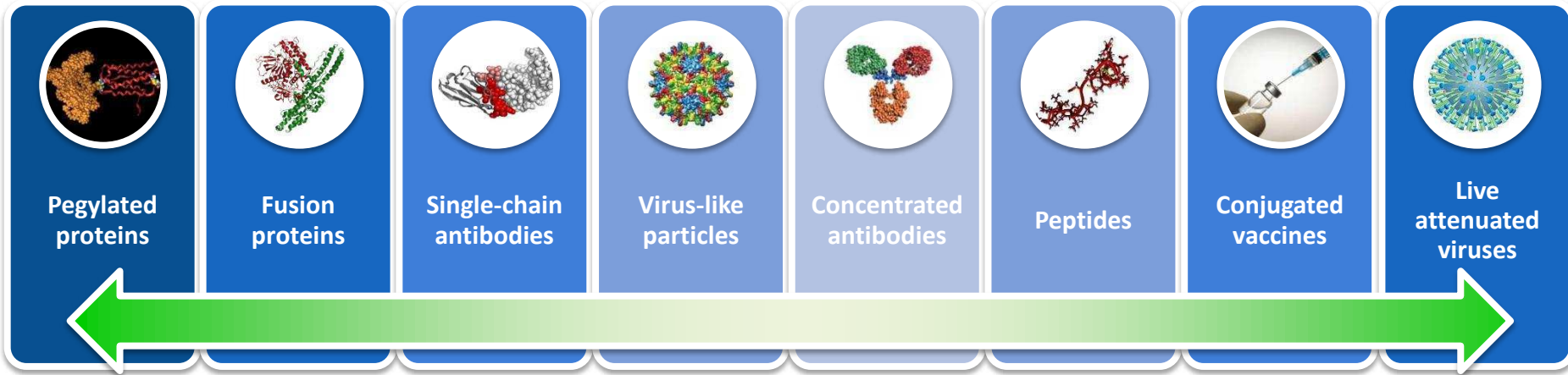
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Arecor

Advanced Formulation of Biologics

Arestat™ Technologies Have Been Successfully Applied To a Diverse Range of More Than 30 Biological Molecules



Only standard development & commercial manufacturing techniques required

No covalent modification

Core technology based on approved excipients

In-house research into novel excipients for specific applications underway

Sectors



Biopharmaceuticals



Vaccines

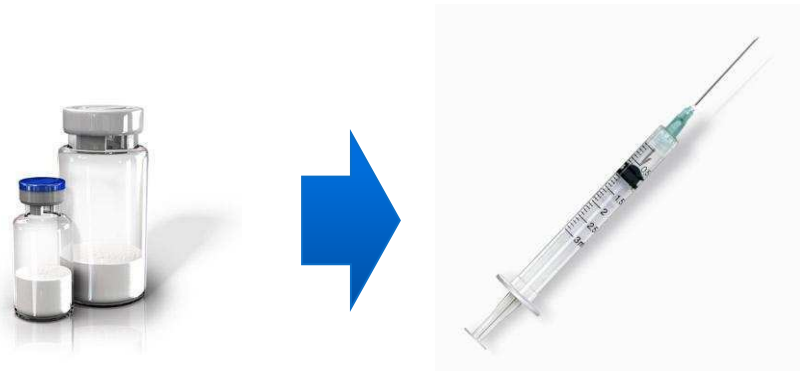


Animal



Manufacturing

Simple Formulation Changes of Biologics Can Enable



Convert Lyophilized Powders to Stable Liquids



High Concentrations Permit More Convenient Administration



Distribution and use outside Cold Chain



Simplified Administration of Incompatible Components

Many antibody therapeutics cannot currently be delivered at high concentration



Arecor Application Biomedical Catalyst Fund

- Technology developed at Arecor to stabilise high-concentration antibodies
- Good market potential & known route to market
- Complete commercialisation of technology
- Reduce healthcare costs and improve patients experience

Comments

New venture – within company

A careful decision

Valuable process - worthwhile irrespective of outcome

Takes time – do a few things well



Areacor

Advanced Formulation of Biologics

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domainex

excellence in drug discovery



Impact of BioMedical Catalyst

- It covers early phase 'valley of death' phase
- Its easy to apply
- Its quick to get feedback
- Low administrative burden to run
- Its non-diluting

- Can be used strategically

Domainex Projects

- TBK1/IKKe
 - In advanced LO
 - Potent, selective, drug like inhibitors
 - Being developed for oncology indications
- KMTs
 - Early LO
 - Potent, selective drug like inhibitors
 - Being developed for oncology indications

Exploration of SAR and Subsequent Optimisation

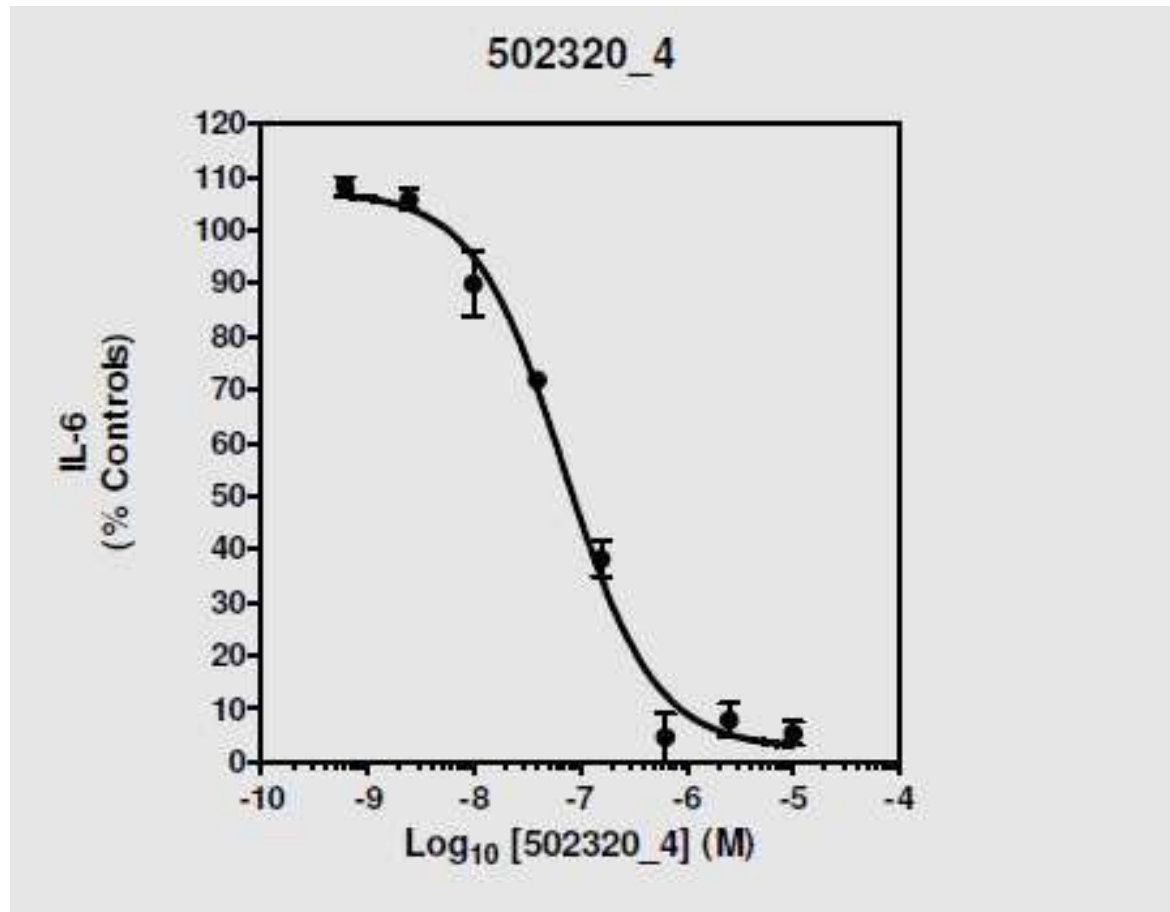
- Potent compounds with good microsomal stability and solubility have been identified
- Good drug-like properties (e.g. MW<450, HBD = 1-3, HBA = 4-6, logD = 2-4, etc.).
- No adverse structural features (reactive metabolites, genotox alerts, etc).

Series	TBK1 IC ₅₀ (nM)	IKKe IC ₅₀ (nM)	Status of Series
A	5	5	Good RLM stability Analogues with better hepatocyte stability in preparation. Patent published
B	8	6	Moderate <i>in vivo</i> PK. Hepatocyte stability to be optimised.
C	8	10	Good <i>in vivo</i> PK for analogue tested. Potency to be optimised
E	2	8	Series with alternative core motif. Good <i>in vitro</i> hepatocyte stability, <i>in vivo</i> PK underway. To be optimised.

Opportunity for IKKe

- Domainex is progressing IKKe for oncology
- A number of studies report that IKKe is well-validated targets for range of inflammatory/ autoimmune disorders including:
 - (Interferon mediated) systemic lupus erythematosus, rheumatoid arthritis, psoriasis, inflammatory bowel disease, scleroderma, Sjögren's syndrome, and polymyositis
 - (IL-17 mediated) multiple sclerosis, rheumatoid arthritis, psoriasis, and allergic asthma.

The Ability Of Study Compounds To Inhibit IL-6 Release From NHBE Cells Stimulated With IL-17



BioMedical Catalyst Award contribution to TBK1 and IKKe

- First TSB award supported
 - Development of series B, C and E from original series A
 - Provided back-up series that enhances value
- Second BioMedical Catalyst award will
 - Allow series A to be developed for COPD
 - Domainex resources develop series B,C and E for oncology
- In 1 year should have candidates for COPD and cancer

Future Applications

- Domainex is raising £1.5m to develop its KMT pipeline around G9a
- Early award submitted
- Will allow the programme to reach a CD for oncology in 2 years

Ways to Use BMC awards

- Encourage investors
 - If they invest £1m and a BMC award of £1m attracts investors
- Encourage deal making
 - Financial contribution from partner from any location alongside BMC
 - Financial contribution can be in 'kind'
 - Can stimulate a collaborative deal
 - Fits around option deal at end of program