

A review of notable deals from Medius Associates

By Sharon Finch

In this regular review of deals we focus on transactions announced during the month of September. As part of this series of articles we typically focus on deals where financial terms are disclosed, however here we have also included a number of deals for which financials were not published where notable.

Antibody Deals Continue Apace

This month there was a distinct decline in the number of deals that were reported in the press. However leading the deal table in terms of value are the biologics agreements – and following a recurring theme, these are antibody-based transactions. With a headline value of US\$708 million, the antibody pact between **Merck Serono** and **F-Star** had developed from an original investment made by Merck Serono's venture arm, Merck Serono Ventures. The deal focuses on a collaboration to discover two types of therapeutics based on F-Star's Modular Antibody Technology, which allows the engineering of antibody fragments and full size antibodies to enhance their activity.

As part of the collaboration Merck Serono is able to nominate three inflammatory disease targets and the parties will collaborate to jointly discover mono-specific Fc-based targeted and bi-specific IgG-based targeted molecules.

Merck Serono's parent, Merck KGaA, will have exclusive worldwide development

and commercialisation rights to the therapeutics emerging from this collaboration. Other than the headline value quoted, there were no further details of the financials for this deal: F-Star will receive an undisclosed, initial technology access fee and research-based funding as well as licence fees, development, regulatory and commercialisation milestones and royalties on product sales.

Two days before the Merck Serono – F-Star deal became public, **Astellas** and Japanese biotech **Evvec** announced a US\$176 million licensing deal for one of Evvec's preclinical stage, fully human antibodies against an infectious disease target. This fits perfectly into the Astellas anti-infectives franchise and strategy. The Astellas pipeline across all therapeutic areas demonstrates a good mix of small molecules and biologics. This deal brought an upfront payment of US\$8 million to Evvec with a further US\$168 million potentially available in development and sales milestones.

Renegotiated Rights / Terminations

The announcements of renegotiated rights or deal terminations are interesting features in this month's deals. Of note is the licensing deal between **Roche** and **Evotec** with a prominent headline of US\$830 million, in which Roche regains rights to a compound it out-licensed to Evotec in 2006.

This deal focuses on Evotec's monoamine oxidase inhibitor (EVT 302) for Alzheimer's disease. In the initial deal, Evotec in-licensed the compound from Roche in January 2006 when it had completed a first Phase I study for another indication. Evotec subsequently initiated the regulatory process in the treatment of Alzheimer's disease. Under the new licensing arrangement, Roche will initiate further studies on EVT 302 in 2012 to demonstrate proof of concept and will be responsible for all clinical development, manufacturing and commercialisation activities. As part of this deal Evotec will receive US\$10 million in upfront fees as well as tiered double digit royalties.

This deal is in addition to that signed between Roche and Evotec in June of this year for a collaboration in novel protein-activity based biomarkers for Roche's oncology drugs under development.

Reflecting the high amount of activity in CNS the return by **Merck & Co** of the metabotropic glutamate receptor 4 programme rights to **Addex Pharmaceuticals** was seen positively by Addex, which remains committed to this development in Parkinson's disease. Citing pipeline prioritisation, Merck returned rights to intellectual property including the know-how. On a positive note, it is far preferable that the rights to a project are returned rather than seeing development languish due to lack of commitment by the partner, however re-partnering can prove to be a challenge.

Of course other reasons for not continuing with a deal include the fall out post-merger using a change of control clause in the contract. **Genzyme** is taking the opportunity now it is part of **Sanofi** to walk away from **PTC Therapeutics** after investing US\$100 million in 2008 for rights outside North America to Ataluren in rare diseases.

Ataluren is an oral, small molecule, protein restoration therapy designed to enable the formation of a functioning protein in patients with genetic disorders caused by a nonsense mutation. Development of Ataluren was set back in 2010 after a Phase IIb trial for Duchenne/Becker muscular dystrophy did not show a statistically significant benefit for the drug.

Under the renegotiated agreement, PTC Therapeutics regains worldwide rights to Ataluren and Genzyme retains an option to commercialise the therapeutic in indications other than nonsense mutation Duchenne/Becker muscular dystrophy outside North America.

The reversion of rights on termination is often an area of intense negotiation but being able to regain the full rights plus access to any additional know-how and other intellectual property is critical for the originator to be able to take the asset forwards.

CNS Deals

Proving that there is life after disappointing project results, **Newron** is being acquired by the Finnish bio technology company **Biotie** in a share deal valued at US\$63 million. The combined company will have a CNS focus. Newron ran into trouble in early 2010 when its pain drug, ralfinamide, failed a Phase IIb/III study in patients with at least moderate neuropathic low back pain. As a result, the company was forced to restructure to conserve cash.

One of Newron's other developmental compounds, safinamide, an oral once daily adjunct for Parkinson's disease (PD), is partnered with Merck Serono.

Licensor acquired / Licensee Acquirer	Collaboration	Product / technology	Headline (\$m)
Evotec/ Roche	Renegotiation of rights	EVT 302 in Alzheimers	830
F star / Merck Serono	Research licence and commercialisation	fragment antibody technology in inflammatory diseases	708
Evec / Astellas	Development & commercialisation	Fully human antibodies in infectious diseases.	176.29
Novagil/ Santen	Acquisition	Ophthalmology	139
Intellect Neuro/ Viropharma	Patent license	OX1 Antioxidant in CNS	126.5
Addex/ Merck	Termination	mGluR4 allosteric modulator in Parkinsons disease	106.5
PT therapeutics/ Genzyme	Termination	ataluren in nonsense mutations Duchenne muscular dystrophy	100
Biomedical AR / GSK	Grant to GSK	GSK 2251052 antibacterial	94.5
CureTech / Teva	Investment	CT 011 lymphoma	69
Newron/ Biotie	Acquisition	Safinamide	63
ChimPharm/ Polpharma	Acquisition of majority stake	Generics	49.16
Proximagen/ Lundbeck	Investment	CNS	16
Lonza/ Fosun Pharma	Joint venture	Products in CVS oncology and infectious diseases	15.6
Moberg/ Meda	Commercialisation licence	Nalox dermatology	4.83
AtheroNova/ Maxwell Biotech	Commercialisation licence	plaque regression compound [atherosclerosis]	4.1
Beacon/ Alliance	Product acquisition	Dermatology products	3.85
Synageva Biopharma/ Mitsubishi Tanabe	R&D collaboration	Protein expression technology in orphan disease	3

Safinamide is currently being assessed in Phase III trials as add-on treatment to dopamine agonist or levodopa in early to late stage PD. Data from two late-stage studies are expected in the first half of 2012.

It is interesting to note that part of the Biotie-Newron deal comprises contingent value rights (CVRs) based on certain milestone achievements. The use of CVRs was noted in earlier issues of Deal Watch (see Deal Watch issues 8 and 12) and CVRs have featured in some of the recent transactions, e.g. the **Sanofi** acquisition of **Genzyme** earlier this year [issue 8] and the **Celgene** acquisition of **Abraxis BioScience** last year.

One of Biotie's partners is **Lundbeck** and keeping with the theme of CNS deal activity, Lundbeck also made the headlines with its strategic partnership with **Proximagen**. Lundbeck has made an investment of US\$16 million in Proximagen with the aim of cooperating on several fronts – in epilepsy, pain and inflammatory disorders.

In return for its investment, Lundbeck will receive certain negotiation rights emanating from these programmes.

Dermatology

Two dermatology deals were reported during September and both of these were on a regional rather than global basis. **Meda** secured the rights to exclusively market Nalox in several major markets, including Germany, France, Spain, United Kingdom, Austria, the Netherlands and Belgium. Under the terms of the deal Meda paid a total of US\$5 million, US\$2 million on signature and the remaining US\$3 million in future milestones.

Building its product portfolio, **Alliance Pharma** acquired the UK marketing rights to six products from **Beacon Pharmaceuticals Limited** for US\$4 million. The six products had total sales of approximately US\$3 million with a gross margin of US\$1.4 million, the majority of the sales and margin comes from Rizuderm (isotretinoin), which is used in the treatment of severe acne.

It is interesting to monitor therapy areas in terms of deal activity and dermatology has certainly featured more the usual over the last few months (see Deal Watch issue 13).



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Sharon is the founder and CEO of Medius Associates, one of the first dedicated business development consultancy companies. Sharon has worked in business development since joining the industry bringing more than 30 years proven experience. With a comprehensive knowledge of business development and licensing, she has extensive experience of identifying, creating, implementing and directing international business deals. In the last 12 months, Sharon has closed on three major client deals.

As a leading authority, Sharon is a frequent speaker at international licensing conferences. She is the Editor of the Business Development and Licensing Journal of the Pharmaceutical Licensing Groups as well as a member of the Editorial Board for the Journal of Commercial Biotechnology. Sharon has a BSc in Chemistry and Administration and studied for an MA in Business Law. Sharon is a past President of the European Pharma Licensing Council and a member of the LES Healthcare Committee in the UK. In addition, Sharon is the Course Director for the MSc in Pharmaceutical Business Development and Licensing, which is run by The University of Manchester.

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