

euroPLX



Business Developer

Vol. 14 # 7/8 | July/August | 2018

## M&As, Distribution and Promotion Agreements Only Gradually Slowing Down

\* Licensing: **AbbVie** announced patent license agreements with **Mylan** over its proposed biosimilar adalimumab product. Under the terms of the agreements, AbbVie will grant Mylan a non-exclusive license on specified dates to AbbVie's intellectual property relating to HUMIRA in the United States and in various other countries around the world in which AbbVie has intellectual property, excluding Europe. 17 Jul 2018 ([www.abbvie.com](http://www.abbvie.com))

\* Co-development: **Novartis** and **Albumedix Ltd.** have entered into an agreement to evaluate the development of several first-in-class therapeutics using Albumedix's Veltis® technology platform and associated technologies. Novartis will evaluate molecules in combination with Albumedix's engineered albumin variants for enhanced delivery across multiple therapeutic areas and against multiple targets. 1 Aug 2018 ([albumedix.com](http://albumedix.com))

\* Distribution: **Alvogen** and **Prestige BioPharma** have entered into a binding agreement for the exclusive partnership and supply for the commercialization of Prestige BioPharma's Trastuzumab biosimilar (HD201; Havelous™) in Central and Eastern Europe. The partnership arrangement includes

the exclusive rights for Alvogen to commercialize Havelous™ (trastuzumab) in all of its CEE markets, leveraging the company's strong sales and marketing capabilities and experience in successfully bringing new biosimilars to market. Whilst the terms of the deal are not being disclosed, Prestige BioPharma will assume responsibility for full development, product registration with EMA, and commercial supply of Havelous™, out of its manufacturing facilities in Osong, Korea. 2 Jul 2018 ([www.alvogen.com](http://www.alvogen.com))

\* Acquisition: **Cambrex Corporation**, a manufacturer of small molecule innovator and generic Active Pharmaceutical Ingredients (APIs), has entered into a definitive agreement to acquire **Halo Pharma**, a dosage form Contract Development and Manufacturing Organization (CDMO), majority owned by funds managed by the private investment firm **SK Capital Partners**, for approximately \$425 million. 23 Jul 2018 ([www.cambrex.com](http://www.cambrex.com))

\* Acquisition: **Catalent, Inc.** has agreed to acquire **Juniper Pharmaceuticals, Inc.**, including its Nottingham, U.K.-based Juniper Pharma Services division. When combined with Catalent's existing industry-leading drug develop-

ment and manufacturing capabilities in the U.S. and Europe, the acquisition of Juniper will expand and strengthen Catalent's offerings in formulation development, bioavailability solutions and clinical-scale oral dose manufacturing. 3 Jul 2018 ([www.catalent.com](http://www.catalent.com))

\* Acquisition: **Cheplapharm** acquired the worldwide rights (except for the US) to VISUDYNE® from **Novartis**. 18 Jul 2018 ([www.cheplapharm.com](http://www.cheplapharm.com))

\* Distribution: **DKSH**, a market expansion services provider, has been appointed by **Abitec**, developer and manufacturer of specialty lipids, as the exclusive distributor of Abitec's range of lipid-based excipients and nutritional supplements in Thailand, Spain and Portugal. DKSH will also distribute these products in Italy and Greece on a non-exclusive basis. Abitec's trademarked specialty lipids include Capmul, Captex, Caprol, Acconon, Sterotex, Nutri Spense, Hydro-Kote and Pureco. Their application area varies from pharmaceutical, nutritional and cosmetic products, to the manufacturing of foams, creams, ointments and lotions. 25 Jul 2018 ([www.dksh.com](http://www.dksh.com))

\* Commercialisation: **Endo International plc's** subsidiary **Endo**

**Ventures Limited** has entered into definitive agreements with **Bioprojet SCR** to register, commercialise, and distribute pitolisant on an exclusive basis in Canada. **Paladin Labs Inc.**, an operating company of Endo, will be commercializing pitolisant in Canada. Pitolisant is a selective histamine H3-receptor antagonist/inverse agonist that enhances the activity of histaminergic neurons. The drug is approved in the European Union for the treatment of narcolepsy in adult patients with or without cataplexy and is distributed under the tradename WAKIX®, but is not approved in Canada. Pitolisant has an orphan designation in the EU and the US for the treatment of narcolepsy. 25 Jul 2018 ([www.endo.com](http://www.endo.com))

\* Acquisition: **EUSA Pharma** has entered into a definitive agreement with **Janssen Sciences Ireland UC**, a subsidiary of **Janssen R&D Ireland (Janssen)** to acquire the global rights to SYLVANT® (siltuximab) for \$115 million in cash. SYLVANT® is approved in more than 40 countries worldwide, including the United States, the European Union, the Republic of Korea and Canada, for the treatment of idiopathic multicentric Castleman's disease (iMCD), a rare, life threatening and debilitating orphan condition. 18 Jul 2018

(www.eusapharma.com)

\* Licensing: **Hikma Pharmaceuticals PLC** has signed a licensing and distribution agreement with **Omega Pharma Trading NV**, an affiliate of **Perrigo Company plc**, one of the largest providers of over-the-counter healthcare solutions in Europe. Under the terms of the agreement, Hikma has the exclusive right to license and distribute more than 30 consumer healthcare products, including Davitamon, Prevalin, XLS Medical, Dermalex and Paranix, in all its MENA markets, with the exception of current agreements in place. 9 Jul 2018 (www.hikma.com)

\* Licensing: **Jazz Pharmaceuticals plc** entered into a definitive agreement to sell its rights related to Prialt® (ziconotide) intrathecal infusion to **TerSera Therapeutics LLC** for \$80 million in cash at closing. The transaction is expected to close in the third quarter of 2018 and is subject to the satisfaction of customary closing conditions. As part of the transaction, TerSera will offer employment positions to a majority of the Jazz employees dedicated to Prialt. 29 Jun 2018 (www.jazzpharma.com)

\* Acquisition: **LEO Pharma A/S** has entered into a definitive agreement to buy **Bayer's** global prescription dermatology unit. The portfolio to be acquired includes branded topical prescription treatments for acne, fungal skin infections and rosacea, and a range of topical steroids with an annual turnover in 2017 of more than 280 million euros. It will enable LEO Pharma to expand significantly in key markets worldwide and broaden its therapeutic areas. Bayer's global medical dermatology portfolio, which includes prescription treatment solutions for acne (Skinoren®), fungal skin infections (Travogen® and Travocort®) and rosacea (Finacea®), and a range of topical steroids (Advantan®, Nerisona®, and Desonate®), will

add complementary treatment areas and strengthen the existing business of LEO Pharma worldwide, allowing the company to more than double sales in some markets. The transaction does not include Bayer's over-the-counter dermatology portfolio of brands such as Bepanthen® and Canesten® amongst others. 31 Jul 2018 (www.leo-pharma.com)

\* Acquisition: **Nabriva Therapeutics plc**, a clinical stage biopharmaceutical company engaged in the research and development of novel anti-infective agents to treat serious infections, acquired **Zavante Therapeutics**, a biopharmaceutical company focused on developing novel therapies to improve the outcomes of hospitalized patients, for upfront consideration of approximately 8.2 million of Nabriva Therapeutics' ordinary shares (which includes an indemnity holdback) to Zavante Therapeutics' former stockholders upon completion of the acquisition. In addition, Zavante Therapeutics' former stockholders are eligible to receive up to \$97.5 million upon the achievement of specified regulatory and commercial milestones, which subject to approval by Nabriva Therapeutics' shareholders and specified limitations, may be settled in Nabriva Therapeutics' ordinary shares. 24 Jul 2018 (www.nabriva.com)

\* Licensing: **Novartis** has entered into an exclusive license agreement with biotech companies **Galapagos NV**, Mechelen (Belgium) and **MorphoSys AG**, Planegg/Munich (Germany) regarding their compound MOR106. Under the agreement, Novartis acquires the exclusive global development and marketing rights to MOR106 for atopic dermatitis and all other potential indications. Novartis will make an upfront payment of EUR 95 million to Galapagos and MorphoSys, and additional payments, royalties

and fees pending achievement of agreed milestones. 19 Jul 2018 (www.novartis.com)

\* Acquisition: **NuPharm Group**, a leading European specialty pharma company focused on the treatment of central nervous system disorders, has completed the acquisition of the French specialty pharma company **Laboratoire Biodim** from **Pharma Omnium International**, a company owned by Weinberg Capital Partners since 2006. The terms of the transaction were not disclosed. 3 Jul 2018 (www.nupharm.com)

\* Acquisition: **Nutriband Inc.** completed the acquisition of Atlanta-based **4P Therapeutics Inc.** Pursuant to the previously announced acquisition agreement, on Aug 1, 2018, Nutriband completed the acquisition of 4P Therapeutics for 250,000 shares of Nutriband's common stock and cash of \$400,000. 4P Therapeutics is focused on the research and development of transdermal and novel drug delivery technologies and therapeutics. 1 Aug 2018 (nutriband.com)

\* Acquisition: **Otsuka Pharmaceutical Co., Ltd.** and **Visterra, Inc.** have entered into a definitive merger agreement pursuant to which Otsuka will acquire Visterra for approximately USD 430 million in an all-cash transaction. Visterra's Hierotope platform, comprised of novel computational and experimental technologies, enables the design and engineering of precision antibody-based therapies that specifically bind to, and modulate, disease targets that are not adequately addressed by current technologies in antibody therapeutics. Visterra's pipeline includes programs targeting IgA nephropathy and other kidney diseases, cancer, chronic pain and infectious diseases. 11 Jul 2018 (www.otsuka.co.jp)

\* Distribution Agreement:

**PharmaMar** signed an agreement with **Impilo Pharma**, a part of Immedica Group, for the exclusive promotion and distribution of its antitumour compound, Yondelis®, throughout the Nordic countries and Eastern Europe. This agreement will come into effect in six months. (www.pharmamar.com)

\* Acquisition: **PTC Therapeutics, Inc.** has entered into an agreement to acquire **Agilis Biotherapeutics, Inc.**, a biotechnology company advancing an innovative gene therapy platform for rare monogenic diseases that affect the central nervous system (CNS). The transaction was approved by the Boards of both companies. Under the terms of the merger agreement, PTC will pay an upfront consideration of \$50 million in cash and approximately \$150 million in PTC common stock, subject to an estimated maximum 9.34 million share limit (with any shortfall to be made whole with additional cash consideration). In addition to the upfront payments, potential future consideration includes \$60 million in development milestones to be paid over the next two years which includes the acceptance of a BLA. Additionally, the transaction includes up to \$535 million in success-based milestones in connection with regulatory approvals on the three most advanced programs and receipt of a priority review voucher, as well as tiered commercial milestones of \$150 million, and 2-6 % of annual net sales for Friedreich ataxia and Angelman syndrome. 19 Jul 2018 (www.ptcbio.com)

\* Acquisition: **Sangamo Bio-Sciences, Inc.** and **TxCel S.A.** have entered into a definitive agreement on July 20, 2018 pursuant to which Sangamo will, following the completion of the contemplated acquisition of a majority stake of TxCel, file a simplified cash tender offer for the purchase of all then outstanding ordinary shares of

TxCel, at a price of €2.58 per share in cash, or approximately €72 million, on a debt-free and cash-free basis. 23 Jul 2018 ([www.sangamo.com](http://www.sangamo.com))

\* Co-development: **Xbrane Biopharma AB** and **STADA Arzneimittel AG** have entered into a co-development agreement for Xlucane, a Lucentis® (ranibizumab) biosimilar. The companies will equally contribute to development expenses and share profits from commercialization in a 50/50 split. To enter into this agreement, STADA will make an upfront payment to Xbrane of EUR 7.5 million. 12 Jul 2018 ([www.stada.de](http://www.stada.de))

\* Acquisition: **Takeda Pharmaceutical Company Limited** has acquired all outstanding ordinary shares and warrants of **TiGenix** following the expiration of the squeeze-out period. 31 Jul 2018 ([www.takeda.co.jp](http://www.takeda.co.jp))

\* Partnership: **Ambys Medicines**, a biotechnology company focused on the discovery and develop-

ment of transformative therapies for people with serious liver disease, and **Takeda Pharmaceutical Company Limited** have entered into a partnership to support the advancement of the Ambys platform and pipeline. Ambys is pioneering the application of novel modalities, including cell and gene therapy and gain-of-function drug therapy, to meet the urgent need for treatments that restore liver function and prevent the progression to liver failure across multiple liver diseases that are untreatable or poorly treated today. 9 Aug 2018 ([www.takeda.co.jp](http://www.takeda.co.jp))

\* Distribution: **Tanner Pharma Group** signed a distribution agreement with **Nephcentric LLC**, a developer and marketer of evidence based therapeutic options for people with kidney disease and metabolic disorders. The agreement names Tanner as a distributor of ure-Na (Urea 15g) in areas outside of the United States, Canada, and the Middle East where the product is not yet

registered. ure-Na (Urea 15g) is a Medical Food for the management of hyponatremia. 7 Aug 2018 ([www.tannerpharma.com](http://www.tannerpharma.com))

\* Acquisition and name change: **Axe Exploration Inc** signed a letter of intent with the shareholders of **Terranueva Pharma Corporation** for the acquisition of all of Terranueva's outstanding shares. AXE will then change its name to Terranueva Corporation. 25 Jul 2018 ([www.terranueva.ca](http://www.terranueva.ca))

\* Licensing: **Theramex** and **Endoceutics** have entered into a definitive agreement granting Theramex the license to commercialise Intrarosa® (prasterone) across countries in Europe, Australia, Russia as well as select countries within the Commonwealth of Independent States (CIS). Intrarosa is a unique non-estrogen prescription therapy approved for the treatment of vulvar and vaginal atrophy (VVA) in postmenopausal women experiencing moderate to severe symptoms. VVA can lead to dryness,

irritation and dyspareunia (or pain during sexual activity). 19 Jul 2018 ([theramex.com](http://theramex.com))

## BD People on the Move

\* Disphar International B.V.: **Ingeborg Stuiver**, who has been Senior Global Licensing Manager, left the company as of 1st of June. (Pers Comm 29 Jun 2018)

\* Laboratoires SMB S.A.: **Frédéric Besançon**, who has been Director International Department, left the company. (Corp Comm 17 Jul 2018)

\* Oncolix, Inc.: **Andrew Scott** has been hired as Vice President of Corporate Development. (Press Release 5 Jul 2018)

\* Zeon Healthcare Limited: **Neil Bashforth**, who has been New Business Development Manager, left the company. (Corp Comm 29 Jun 2018).

# Insanely Effective Pharma Partnering

euroPLX is the world's most often held partnering conference for the pharma and biopharma industries.

Because of results delivered. Year-round.

Join the 68th International Partnering Conference for Pharma Business Development★

★euroPLX 68 Athens (Greece)

November 26 + 27, 2018, Hotel Grande Bretagne, Athens

Seeking and offering business opportunities in patented and generic (incl. biosimilars), prescription and OTC drugs, medical devices, and nutraceuticals - development, licensing, marketing, promotion, and distribution...

Each euroPLX Conference's actual collaboration interests are summarised and displayed on [www.europlx.com](http://www.europlx.com) as an hourly updated **Dynamic Partnering Focus**, as soon as sufficient data are submitted by registrants.

 **euroPLX**  
by RauCon

[www.europlx.com](http://www.europlx.com)  
[meetyou@europlx.com](mailto:meetyou@europlx.com)  
ph. ++49 (6221) 426296-0

The Original since 1995.  
Often copied. Never equaled.

Register online: [www.europlx.com](http://www.europlx.com)

