



Summer Break was by no Means a Break to M&A, Divestitures and Licensing

* Licensing: **Aucta Pharmaceuticals, Inc.**, a technology based company focusing on the development and commercialization of Branded Specialty Products, today announced that the Company has entered into an agreement with **Eton Pharmaceuticals, Inc.** to License U.S. marketing rights for AUC025. Aucta is seeking approval as an epilepsy treatment to be used as an adjunct therapy for partial seizures, primary generalized tonic-clonic seizures, and generalized seizures of Lennox-Gastaut syndrome in patients two years of age and older. 27 Jun 2019 (www.auctapharma.com)

* Acquisition: **Bayer AG** and **BlueRock Therapeutics** have agreed for Bayer to fully acquire BlueRock Therapeutics, a privately held US-headquartered biotechnology company focused on developing engineered cell therapies in the fields of neurology, cardiology and immunology, using a proprietary induced pluripotent stem cell (iPSC) platform. Bayer will acquire the remaining stake for approximately USD 240 million in cash to be paid upfront at closing and an additional USD 360 million payable upon achievement of pre-defined development milestones. With Bayer currently holding 40.8 percent stake, the investment corresponds to a

total company value of BlueRock Therapeutics of approximately USD 1 billion. The closing of the transaction is expected during the third quarter of 2019. 8 Aug 2019 (www.bayer.com)

* Divestiture: U.S.-based company **Elanco Animal Health** has entered into a definitive agreement to acquire **Bayer's** Animal Health business. The transaction is valued at 7.6 billion U.S. dollars consisting of 5.3 billion U.S. dollars in cash, subject to customary purchase price adjustments, and 2.3 billion U.S. dollars in Elanco stock based on the unaffected 30-day volume weighted average price as of August 6, 2019. 20 Aug 2019 (www.bayer.com)

* Name change: **BioTime, Inc.**, a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs, is launching a new corporate brand, including a change of its corporate name to **Lineage Cell Therapeutics, Inc.**, effective August 12, 2019. 31 Jul 2019 (www.biotimeinc.com)

* Acquisition: **Boston Scientific Corporation** completed its acquisition of **BTG plc**. BTG develops and commercializes products used in minimally-invasive procedures targeting cancer and vascular diseases, as well as specialty phar-

maceuticals. 19 Aug 2019 (www.bostonscientific.com)

* Divestment: **Bristol-Myers Squibb** announced that **Celgene Corporation**, in connection with its merger agreement with Bristol-Myers Squibb, has entered into an agreement with **Amgen** under which Amgen would acquire the global rights to OTEZLA® (apremilast) for \$13.4 billion in cash. 26 Aug 2019 (www.bms.com)

* Distribution: **Clinigen Group plc** and **CHEPLAPHARM Arzneimittel GmbH**, a family-owned pharmaceutical company based in Germany, have signed an exclusive distribution agreement for chemotherapy products Etopophos® and Vepesid® in Australia and New Zealand. Etopophos® and Vepesid® are currently approved for the treatment of Small Cell Lung Cancer, Hodgkin's Disease, Malignant (non-Hodgkin's) lymphomas, Acute non-lymphocytic leukaemia, testicular tumours. 2 Sep 2019 (www.clinigengroup.com)

* Acquisition: **Curaleaf Holdings, Inc.**, a leading vertically integrated cannabis operator in the United States, completed the acquisition of **Glendale Greenhouse**, a vertically integrated cannabis business in Arizona. 19 Aug 2019 ([\[curaleaf.com\]\(http://www.curaleaf.com\)\)](http://www.</p></div><div data-bbox=)

* Acquisition: **Fujifilm Corp.**, has completed the acquisition of **Biogen (Denmark) Manufacturing ApS**, a large-scale biologics manufacturing site located in Hillerød near Copenhagen, Denmark from Biogen. Fujifilm invested approximately US\$890 million in cash for the transaction. With the closing of this transaction, the Hillerød Manufacturing site is now the fourth biopharmaceutical manufacturing site of **FUJIFILM Diosynth Biotechnologies**, a subsidiary of Fujifilm and a leading Contract Development and Manufacturing Organization with expertise in the development and manufacture of biologics and advanced therapies. Hillerød Manufacturing will change its name to **FUJIFILM Diosynth Biotechnologies Denmark ApS** once all regulatory procedures are complete. 1 Aug 2019 (www.fujifilmusa.com)

* Acquisition: **Generex Biotechnology Corporation** has acquired an additional 38% of **Olaregen Therapeutix**, a regenerative medicine company, for a total Generex ownership of approximately 99%. 19 Aug 2019 (www.generex.com)

* Name Change: **HedgePath Pharmaceuticals** plans to change its name to **INHIBITOR**

Therapeutics. 19 Aug 2019 (www.hedgepathpharma.com)

* Co-Distribution: **Endo International plc** and **Helsinn Healthcare SA** announced that Endo International plc's subsidiary Endo Ventures Limited has entered into definitive agreements with Helsinn to register, commercialize, and distribute Pracinostat on an exclusive basis in Canada upon receipt of the required regulatory approval. Under the terms of the agreement, **Paladin Labs Inc.**, an operating company of Endo, will be responsible for the registration, distribution, sales, marketing, medical affairs, pricing and reimbursement activities in connection with Pracinostat in Canada. Helsinn will be responsible for supplying the drug to Paladin and will retain all international development rights, including clinical development activities. 31 Jul 2019 (www.helsinn.com)

* Licensing: **Helsinn**, together with **Blanver Farmoquímica e Farmacêutica S.A.**, and **Laboratorio Varifarma SA** have signed exclusive distribution and licensing agreements for Pracinostat in South America. São Paulo-based Blanver will register, promote, distribute and commercialize Pracinostat in Brazil, while Varifarma, located in Buenos Aires, will cover Argentina, Bolivia, Chile, Colombia, Ecuador, Paraguay, Peru, and Uruguay. Helsinn will retain all international development rights, including clinical development activities, and the supply of Pracinostat. 2 Sep 2019 (www.helsinn.com)

* Acquisition: **Hikma Pharmaceuticals PLC** has signed an asset purchase agreement with **Insys Therapeutics Inc.** to acquire a complementary manufacturing platform and two pipeline products. 9 Aug 2019 (www.hikma.com)

* Acquisition: **HotSpot Therapeutics, Inc.** a biotechnology company pioneering the discovery

of nature's regulatory sites to advance allosteric drug discovery, today announced the acquisition of **Macroceutics, Inc.**, a provider of DNA-encoded library (DEL) screening technologies. 23 Aug 2019 (www.hotspotthera.com)

* Acquisition: **Jazz Pharmaceuticals plc** announced the acquisition of **Cavion, Inc.** through a merger with a Jazz subsidiary. Under the terms of the agreement, the former Cavion shareholders receive an upfront payment of \$52.5 million and have the potential to receive additional payments of up to \$260.0 million upon the achievement of certain clinical, regulatory and commercial milestones, for a total potential consideration of \$312.5 million. 12 Aug 2019 (www.jazzpharma.com)

* Distribution: **Lannett Company, Inc.** has entered into an agreement with **Sinotherapeutics Inc.**, a China-based specialty pharmaceutical company, to be the exclusive U.S. distributor of Posaconazole Delayed-Release Tablets 100mg. Sinotherapeutics has received final approval from the U.S. Food and Drug Administration (FDA) of its Abbreviated New Drug Application (ANDA) for Posaconazole Delayed-Release Tablets 100mg, which is an AB-rated generic equivalent of Merck's Noxafil® Delayed-Release Tablets. 28 Aug 2019 (www.lannett.com)

* Acquisition: **LEO Pharma A/S** has acquired the exclusive rights to develop and market brodalumab (marketed as Kyntheum® in the European Union) for the treatment of moderate-to-severe psoriasis outside of Europe through a new sub-licensing agreement with **Bausch Health Ireland Limited.** The new agreement includes countries with significantly high unmet need, such as Australia, Brazil, Egypt, Mexico, Russia and Saudi Arabia. 13 Aug 2019 (www.leopharma.com)

* Name change: **Tedec-Meiji Farma, S.A.** changed its corporate name to **Meiji Pharma Spain, S.A.** effective September 2nd, 2019. 31 Jul 2019 (www.meiji.es)

* Restructuring: As a consequence of the failed Phase III IMPALA study **Mologen** will reduce staff numbers to around one third and bring down monthly burn rates to approximately EUR 0.8 million from roughly EUR 1.4 million at present. 23 Aug 2019 (www.mologen.com)

* Merger: **Mylan N.V.** and **Pfizer Inc.** agreed to combine Mylan with Upjohn, Pfizer's off-patent branded and generic established medicines business, creating a new global pharmaceutical company. Under the terms of the agreement, which is structured as an all-stock, Reverse Morris Trust transaction, each Mylan share would be converted into one share of the new company. Pfizer shareholders would own 57% of the combined new company, and Mylan shareholders would own 43%. The new company will transform and accelerate each businesses' ability to serve patients' needs and expand their capabilities across more than 165 markets by bringing together two highly complementary businesses. The new company is expected to have pro forma 2020 revenues of \$19 to \$20 billion. 29 Jul 2019 (www.mylan.com)

* Joint Venture: **Pfizer Inc.** is closing the joint venture with **GlaxoSmithKline plc** to combine the parties' respective consumer healthcare businesses to create the world's largest over-the-counter (OTC) business with robust iconic brands. Under the terms of the transaction, Pfizer owns a 32% equity stake in the joint venture and GSK owns 68%. The combined business, which will operate globally as GSK Consumer Healthcare, will be led by CEO Brian McNamara. The combined brand portfolio forms the world's

largest OTC business with leadership positions in pain relief, respiratory and vitamins, minerals and supplements, and therapeutic oral health. In addition, operating together, the two business will hold the number one OTC position in the U.S. and the number two OTC position in China – the two biggest OTC markets in the world. 1 Aug 2019 (www.pfizer.com)

* Investment: **Pfizer Inc.** invests US\$ 0.5 bn for the construction of its state-of-the-art gene therapy manufacturing facility in Sanford, North Carolina. This facility is anticipated to support Pfizer's continuing investment in gene therapy research and development, similar to Pfizer's Chapel Hill and Kit Creek, North Carolina research and development sites. This facility would expand the company's presence in North Carolina, where there are currently more than 3,600 Pfizer colleagues, including 650 in Sanford. The expanded facility is projected to add approximately 300 new jobs. In addition to its gene therapy operations, colleagues at Pfizer's Sanford facility also manufacture components for the company's vaccine portfolio, including Prevnaar 13 and several vaccines currently in Pfizer's research pipeline. 21 Aug 2019 (www.pfizer.com)

* Acquisition: **Sonnet BioTherapeutics, Inc.**, an oncology-focused biotechnology company developing innovative targeted biologic drugs, has entered into an agreement with **Relief Therapeutics Holding SA** to develop atexakin alfa through the acquisition of its subsidiary, Relief Therapeutics SA, via a share exchange transaction. 12 Aug 2019 (sonnetbio.com/)

* Co-promotion: **Takeda Pharmaceutical Company Limited** and **Pfizer Japan Inc.** terminated the co-promotion for the rheumatoid arthritis/juvenile idiopathic arthritis treatment "Enbrel®" (etanercept (rDNA), at the end of November

2019. Pfizer is the Marketing Authorization Holder (“MAH”) of Enbrel. 26 Jul 2019 (www.takeda.co.jp)

* Name change: **Velit Biopharmaceuticals GmbH** changed its name to **Velit Biopharma S.r.l.** 24 Jul 2019 (www.velitnb.com)

* Acquisition: **Vertex Pharmaceuticals Incorporated** has entered into a definitive agreement under which Vertex will acquire **Semma Therapeutics**, a privately held biotechnology company pioneering the use of stem cell-derived human islets as a potentially curative treatment for type 1 diabetes, for \$950 million in cash. 3 Sep 2019 (www.vrtx.com)

* Acquisition: **Zambon** is to acquire the respiratory company **Breath Therapeutics**. Zambon will pay €140m upfront to Breath Therapeutics BV, which is eligible to receive further €360m in milestones. 26 Jul 2019 (www.zambon.com)

* Acquisition: Rare disease specialist **Zogenix, Inc.** has entered into a definitive agreement to acquire **Modis Therapeutics, Inc.**, a privately held biopharmaceutical company focused on developing novel therapies for rare genetic diseases. Under the terms of the transaction, Modis will receive an upfront payment of \$250 million, comprised of \$175 million in cash and \$75 million in Zogenix common stock. Modis is also eligible to receive additional milestone payments of up to \$150 million. 26 Aug 2019 (www.zogenix.com)

BD People on the Move

* Alfa Wassermann SpA: Dr. **Giuseppe Colla**, who has been Director Corporate Pharma Marketing and an early and frequent euroPLX attendee, retired. (Pers Comm 24 Jul 2019)

* Bayer Pharma AG: **Marianne De**

Backer PhD, who spearheaded Business Development activities at Johnson & Johnson, has been appointed as the new Head of Business Development & Licensing of Bayer’s Pharmaceuticals Division. (Press Release 2 Sep 2019)

* Creo Pharma Limited: Frequent euroPLX attendee **Marc Hopley** who has been Senior Business Development Manager, left the company for a new position at Advanz Pharma. (Pers Comm 24 Jul 2019)

* Horizon Therapeutics plc: **Andy Pasternak**, coming from Bain & Company, Inc. has been appointed as executive vice president, chief business officer, and will lead business development, mergers and acquisitions, corporate strategy, commercial development and portfolio management. (Press Release 28 Aug 2019)

* Sopharma AD: **Ana Lichkova**, who has been Manager Contract Manufacturing and New Products, left the company. (Pers Comm 24 Jul 2019)

Newcomers to euroPLX 71 Lisbon - part 1

Since almost 25 years and more than 70 successfully held pharma partnering conferences euroPLX has managed to attract 15 to 20% newcomers to each single conference, i.e. companies that never attended euroPLX before:

Atnahs Pharma UK Ltd. (www.atnahs.com) is a British company with subsidiaries in Denmark, Australia, Dubai and India, focusing on the acquisition of “mature”, “established” or “tail” off-patent branded medicines divested by other firms. From these, the company develops new formulations for new territories and niche indications.

The German company **Biovariance GmbH** (www.biovariance.com/

en/) is a specialist for complex biomedical data analyses and individual software development in the field of personalised medicine and also offers an innovative mobile app as a solution for long-term therapy monitoring for patients with severe and/or chronic diseases. With this approach the company enables individualised, optimised treatments of patient.

Lugano, Switzerland based **Devintec** (www.devintecpharma.com) is a private and independent company, dedicated to research and development of medical devices and food supplements.

Based in Kaunas, **Lithuania**, **Edupharma Uab** (www.edupharma.lt) is a pharmaceutical wholesaler supplying medicines mostly for specialty care to pharmacies, hospitals and other pharmaceutical wholesalers.

Icon Group (www.iconocsgroup.com) is based in various countries of Europe and North and South America and is a specialist for commercialising medicines through multichannel strategies, innovative methodologies and using new technologies.

Nearmedic (www.nearmedic.ru) is a Russian pharmaceutical, biotechnological and medical company whose activities are focused on the development of new original medicines and their production and introduction into medical practice. The company also develops and manufactures of diagnostic test-systems and supplies laboratory equipment for medical laboratories.

Torbay Pharmaceuticals (www.torbaypharmaceuticals.nhs.uk) of Paignton, UK, is part of the National Health Service and as such not only the largest NHS manufacturer of sterile products in UK but also a supplier of products to all UK NHS hospitals with a portfolio of over 200 products.