

euroPLX



Business Developer

Vol. 14 # 5 | May | 2018

Mergers, Acquisitions, Licensing Agreements, and Management Changes

* Acquisition: **Altum Pharmaceuticals Inc** completed the acquisition of **Lexi Pharma Inc.**, a Canadian pharmaceutical company focused on the development of AP-002, a new chemical entity (NCE) small molecule with an active US FDA IND (Investigational New Drug application). AP-002, is a novel molecule, that selectively targets bone resorption while also demonstrating anti-tumor activity. 30 Apr 2018 (altumpharma.com)

* Acquisition: **ANI Pharmaceuticals, Inc.** has completed the acquisition of a portfolio of six generic products (Ezetimibe-Simvastatin tablets, Felbamate tablets and Desipramine tablets; approved ANDAs for Aspirin/Dipyridamole ER capsules and Methylphenidate ER tablets; option for Aspirin/Dipyridamole ER capsules; pipeline products Erythromycin IR tablets and Diclofenac-Misoprostol DR tablets), related manufacturing and supply agreements, and equipment and technical know-how from **Amneal Pharmaceuticals, LLC** and **Impax Laboratories, Inc.** for cash consideration of \$2.3 million. 7 May 2018 (www.anipharmaceuticals.com)

* Acquisition: **Cipher Pharmaceuticals Inc.** has completed the previously announced acquisition by Cipher Pharmaceuticals Inc. of

the Canadian business portfolio of **Cardiome Pharma Corp.** by way of the acquisition by Cipher of all of the issued and outstanding common shares of Cardiome. 16 May 2018 (www.cipherpharma.com)

* Acquisition: **Dipharma Francis S.r.l.**, a European manufacturer of Active Pharmaceutical Ingredients, has completed its previously announced acquisition of **Kalexsyn, Inc.**, a Contract Research Organisation (CRO) providing chemistry services to the biotech-

nology and pharmaceutical industry. Pursuant to an agreement dated March 19, 2018, Dipharma has acquired all of the issued and outstanding shares of Kalexsyn through its American subsidiary Dipharma, Inc. 17 May 2018 (www.dipharma.it)

* Name Change: **Eleven Biotherapeutics, Inc.**, a late-stage clinical company developing next-generation antibody-drug conjugate (ADC) therapies for the treatment

of cancer, announced that the company is changing its name to **Sesen Bio, Inc.** 16 May 2018 (www.sesenbio.com/)

* Acquisition: **Eli Lilly and Company** announced an agreement to acquire **AurKa Pharma, Inc.**, a company established by **TVM Capital Life Science** to develop oncology compound AK-01, an Aurora kinase A inhibitor that was originally discovered at Lilly. The compound is a potential first-in-class asset that AurKa Pharma is

studying in Phase 1 clinical trials in multiple types of solid tumors. Under the terms of the agreement, Lilly will acquire all shares of AurKa Pharma. In return, AurKa Pharma shareholders will receive an upfront payment of \$110 million. AurKa Pharma shareholders are also eligible to receive up to \$465 mn in regulatory and sales milestones should AK-01 gain approval in the U.S. and other markets, and achieve certain sales levels. 14 May 2018 (www.lilly.com)

* Acquisition: **Endo International plc** has reached definitive agreements to acquire **Somerset Therapeutics, LLC**, a New Jersey based specialty pharmaceutical company that develops and markets sterile injectable and ophthalmic drugs for the U.S. marketplace, and the business of its India based affiliate **Wintac Limited**, which operates as Somerset Therapeutics' contract developer and manufacturer. Endo is paying approximately \$190 million in total for Somerset Therapeutics and Wintac's business. Together, the acquisitions will secure for Endo's Par Sterile injectable business Somerset Therapeutics' commercial and pipeline products as well as Wintac's manufacturing capabilities for those products. 26 Apr 2018 (www.endo.com)

* Acquisition: **Novartis** has completed the acquisition of **AveXis, Inc.**, the US-based Nasdaq-listed clinical stage gene therapy company for USD 218 per share or a total of USD 8.7 billion in cash. The transaction was unanimously approved by the Boards of both companies. AveXis has several ongoing clinical studies for the treatment of SMA, an inherited neurodegenerative disease caused by a defect in a single gene, the survival motor neuron (SMN1). 17 May 2018 (www.novartis.com)

Advertisement - Position Offered

Hetero Europe: Business Development Manager

Hetero Europe is looking for an experienced Business Development Manager to strengthen its fast growing business. The candidate shall be responsible for out-licensing dossiers and selling pharmaceuticals in Europe. Job location is either at our Headquarters in Barcelona or in Germany. Apply on LinkedIn if you want to join us!

This is a free service to a euroPLX Community Member.

* Acquisition: **Shanghai Fosun Pharmaceutical (Group) Co. Ltd.** and **Dova Pharmaceuticals, Inc.** signed a distribution agreement, which provides Fosun Pharma Industrial the right to exclusively develop and commercialize and to assist Dova with the registration of Avatrombopag (trademark: Doptelet®) in China Mainland and Hong Kong. Avatrombopag is an orally administered drug candidate for the treatment of thrombocytopenia. 16 Mar 2018 (www.fosunpharma.com)

* Acquisition: **Takeda Pharmaceutical Company Limited** and **Shire plc** announced that they have reached an agreement on the terms of a recommended offer pursuant to which Takeda will acquire the entire issued and to be issued ordinary share capital of Shire. Under the terms of the acquisition, each Shire shareholder will be entitled to receive \$30.33 in cash for each Shire share and either 0.839 new Takeda shares or 1.678 Takeda ADSs. The transaction has been approved by both companies' boards of directors, and is expected to close in the first half of calendar year 2019. The equivalent value of £49.01 per Shire share values the entire issued and to be issued ordinary share capital of Shire at approximately £46 billion. 8 May 2018 (www.takeda.co.jp)

* Licensing: **Trevena, Inc.** and **Jiangsu Nhwa Pharmaceutical Co. Ltd.** have entered an exclusive license agreement for the development and commercialization of Trevena's investigational product oliceridine. Under the agreement, Trevena expects to receive near-term payments of \$5.5 million, including an upfront payment of \$2.5 million and a milestone payment of \$3.0 million upon regulatory approval of oliceridine in the United States, as well as additional approval and commercialization milestones and

10% royalties on all product sales in China. Oliceridine is currently under review by the U.S. Food and Drug Administration for potential approval in the United States for the management of moderate-to-severe acute pain. 1 May 2018 (www.trevena.com)

* Name change: **Valeant Pharmaceuticals International, Inc.** announced that the Company will change its name to **Bausch Health Companies Inc.**, effective in July 2018. As part of the name change, the Company will roll out a new corporate brand identity in July 2018, which will include new imagery and web site, and will trade under a new symbol, BHC. 8 May 2018 (www.valeant.com)

BD People on the Move

* ACell, Inc.: **Nino Pionati**, who was the Chief Strategy and Marketing Officer and a member of the executive management team has been appointed as Vice President, International and Business Development. (Press Release 8 May 2018)

* Aldeyra Therapeutics, Inc.: **David McMullin** who most recently served as Group Vice President at Shire, has been appointed to the newly created position of Senior Vice President, Corporate Development and Strategy. (Press Release 10 May 2018)

* Consilient Health Limited: **Simon Coates-Walker**, who has been Head of Pharmaceuticals left the company in order to pursue a new project. (Pers Comm 14 May 2018)

* DEMO S.A.: **Ioannis Dimitriou**, who has been Business Development Manager, left the company. (Pers Comm 14 May 2018)

* DSM Sinochem Pharmaceuticals: **Jolanta Liszewska**, who has been Licensing & Sales Manager, left the company. (Pers Comm 14 May

2018)

* Farmak JSC: **Mariia Dumanchuk**, who has been Head of Market Integration, left the company. (Corp Comm 14 May 2018)

* Generica Pharmaceuticals A.S.: **Dr. Yücel Iskender**, who has been Head of Business Development, left the company on 16 April. (Pers Comm 11 May 2018)

* Glenmark Pharmaceuticals Europe Limited: **Carlos del Moral**, who has been Business Development Manager, left the company effective 1 May. (Pers Comm 14 May 2018)

* PDL BioPharma, Inc.: **Jill M. Jene**, Ph.D., who was Senior Vice President, Business Development at twoXAR, has been appointed as Vice President, Business Development. (Press Release 21 May 2018)

* Rodin Therapeutics: **Anne M. Sullivan**, MBA, who led biopharma business development and corporate strategy at Sunovion Pharmaceuticals, has been hired as chief business officer. (Press Release 15 May 2018)

* Sinclair Research: **Mark Lane** has been appointed as director of business development. (Press Release 16 May 2018)

* Teva Pharmaceutical Industries Ltd.: **Gal Kaspi-Villeval**, who has been Commercial Operations Manager for the Generics Business Teva Israel, left the company. (Pers Comm 20 Apr 2018)

Newcomers to euroPLX 67 Noordwijk (part 2)

Since 23 years euroPLX has been attended by a large number of companies that have never had a delegate at any of the previous euroPLX Conference. For euroPLX 67 Noordwijk, 26 out of the 200 registered companies have never attended euroPLX before, an

astonishing number if the age of euroPLX and the 66 conferences are taken into account which have been held to date. Here is the second part of the companies that will attend euroPLX 67 Noordwijk:

ALMA is an Italian company based in Gorla Maggiore. The company develops, manufactures, submits registrations for, and licenses medical devices for topical use.

Extractumpharma Zrt. (www.expharma.hu) is a privately owned pharmaceutical company with headquarters in Budapest, Hungary. The company develops, manufactures and distributes own generic products, provides pharmaceutical services for other companies, and participates in the supply chain of IMPs for Clinical Trials.

Farmasierra (www.farmasierra.com) of Madrid, Spain, is comprised of three subsidiaries, Farmasierra Manufacturing S.L., Farmasierra Laboratorios S.L., and Farmasierra Distribución S.L who develop, manufacture and distribute pharmaceutical and food supplement products.

Hisun Pharmaceutical Co., Ltd. (www.hisunpharm.com) is a speciality pharmaceutical company based in Taizhou, Zhejiang, China. It ranks among the top 10 Chinese pharmaceutical companies with two branches in Beijing and three branches in Shanghai. Hisun is a fully integrated company, covering indications such as anticancer, cardiovascular, anti-infective, anti-parasitics, immunosuppressant, among others.

Based in Geleen, the Netherlands, **Interdos** (www.interdos.nl) is part of the Basic Pharma Group, focusing on regulatory affairs, clinical studies, pharmacovigilance and quality services.

Neo Health (OTC) Pty Ltd (www.neohealth.com.au) is based in Castle Hill, NSW, Australia. As a

full-service pharmaceutical company Neo Health develops and in-licenses OTC, complementary, medical device, niche and innovative products for the Australia and New Zealand markets.

Based in Pretoria, South Africa, **Novagen Pharma** (www.novagen-pharma.co.za) is an autonomously operating part of the Clinigen SA group of companies. Novagen , serving specialists, general practitioners and pharmacies through a national footprint of wholesalers.

Optimus Pharma Private Limited (www.optimuspharma.com) is an API and Advance Intermediates manufacturer based in Hyderabad, India. Starting in 2004 as a development lab, the company has evolved into to a commercial scale Intermediates /APIs /Finished dosages manufacturing company.

Based in Madrid, Spain, **OtCEM Pharmaceuticals SL** (www.otcem-pharma.com) focuses on the development and manufacturing of Consumer Healthcare products, offering licenses for innovative and niche OTC products in different therapeutic areas.

Perrigo Consumer Healthcare International is the consumer products branch of Perrigo (perrigo.com), the world's largest manufacturer of over-the-counter healthcare products and supplier of infant formulas for the store brand market. The company develops, manufactures, markets, and distributes well-known European OTC brands in the natural health and vitamins, cough, cold and allergy, smoking cessation, personal care and derma-therapeutics and lifestyle categories.

Pharma Line S.r.l. (www.pharmaline.org) is engaged in research, development and marketing of original formulations for a large number of therapeutic areas as well as food supplements, medical devices, and dermo-cosmetics. The

company is based in Milan, Italy, and is in operation since 30 years.

Pharmaxima Srl (www.pharmaxima.it) is a Milan, Italy, based Contract Manufacturing Organisation with a focus on raw materials, active ingredients, vitamins, mineral salts, prebiotic fibres, probiotics, standardized vegetable extracts supported by clinical evidence.

As one of the fastest growing pharmaceutical firms in Greece, Athens based **Pharmazac** (www.pharmazac.com) operates in-house the development, regulatory, medical promotion, manufacturing and logistics of medicinal, herbal, food supplement and healthcare products, with currently a portfolio of more than 100 licensed brands in Greece.

Being a subsidiary of Pharmex SA, Switzerland, **Pharmex Advanced Laboratories S.L.** (www.pharmex.swiss) is a Spanish pharmaceutical company, based in Cordoba. The company manufactures oral solids, suppositories, semi-solids, liquids and cosmetics, and develops and markets Rx, OTC and Medical Devices in Spain, MENA, and LatAm. It has also an Infant Nutrition unit highly focused in high quality and specialized Infant formula and cereals.

PMV Life Science Pvt. Ltd. (www.pmvlifescience.com) is based in Mumbai. The company offers and markets pharmaceutical dossiers and formulations.

Based in Ahmedad, Gujarat, India, **Sushen Medicamentos Pvt. Ltd.** (www.sushenmed.com) is an international formulation & development company with capabilities to develop oral solid tablet (IR / SR / MR, effervescent tablets, bi layer tablet) and capsules dosage forms, as well as ready to compress granules, pre mix powder and ready to fill coated pallets.

Tolmar International Ltd is based

in Dublin, Ireland, and a global leader in the manufacture of extended release LHRH injectable therapies. The company is committed to the ongoing research and development of specialty branded and generic products in the areas of urology, oncology, men's health, pediatric endocrinology and dermatology.

Ydl Ventures Ltd. (www.ydlventures.com) of Kiryat Tiv'on, Israel, is a pharmaceutical company, working with the entire national pharmaceutical value-chain: local distributors, pharmaceutical companies, HMOs, hospitals, pharmacies, etc.

Zenvision Pharma (www.zenvisionpharma.com) is a Contract Research & Development Organisation, offering a full range of custom designed formulation development services for Generic and Speciality pharmaceuticals. The company ist based in Mumbai, India, and offers product development for highly regulated markets (US, Europe) as well as Semi-regulated markets.