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## Outsourcing: A Year in Review

In a productive year, 2017 was filled with acquisitions, facility expansions, and new biopharma technology.

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By [Susan Haigney](#) (1)

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Outsourcing in the bio/pharmaceutical industry had a productive 2017. A flurry of acquisitions, an expansion of biotechnology needs, and a growth in new facilities and services offered were seen. The following are some of the highlights.

### Mergers and acquisitions

Acquisitions were robust in 2017, with more than 25 companies making moves to gain new facilities and services. The following are some of the notable mergers and acquisitions of 2017.

Recipharm completed the acquisition of Kemwell's pharmaceutical businesses located in Bengaluru, India in February 2017. As part of the transaction, Recipharm also has a right of first negotiation to acquire Kemwell's Indian biopharma business, which was not included in the transaction and will continue to be retained by the sellers.

The acquired business, Recipharm Pharmservices Private Ltd, offers development services and commercial manufacturing of solid, semi-solid, liquid, and topical products. The development business provides formulation development, small-scale manufacturing for clinical trials, and analytical services (1).

In April 2017, Sartorius Stedim Biotech (SSB) acquired Umetrics, a specialized provider of data analytics software for development and manufacturing processes headquartered in Malmö, Sweden. SSB has been a cooperation partner of Umetrics since the end of 2012, distributing and co-marketing their software to players in the biopharmaceutical industry. Umetrics' software has applications in critical process steps of biopharmaceutical manufacture and development, including cell culture processes and specific purification steps (2).

Lonza announced in August 2017 that it acquired Micro-Macinazione (Switzerland), a contract manufacturer providing micronization of active ingredients for the pharmaceutical and fine chemical industries, from Cross Equity, a Swiss private equity firm. The acquisition boosts Lonza's micronization services at its existing micronization clinical and commercial manufacturing site in Quakertown, PA, which Lonza gained through its previous US\$5.5-billion acquisition of Capsugel (US) in early July 2017 (3).

In September 2017, Roquette completed its acquisition of Itacel, an excipient division of Blanver, a Brazilian multinational company specializing in the development, manufacture, and commercialization of raw materials and drugs. The acquisition is part of a series of investments made by Roquette to position itself globally, according to the company (4).

PCI Pharma Services (PCI) acquired Millmount Healthcare, a pharmaceutical and healthcare contract packaging services provider, in October. Millmount provides services in blister packaging, bottling, and tub filling, as well as in late-stage customization and cold chain packaging services. The acquisition supports PCI's efforts to expand its clinical trial service offerings. The addition of Millmount, based near Dublin, Ireland, will be PCI's fourth acquisition outside of the United States in four years (5).

### Partnerships

Sanofi and Lonza announced on 27 Feb. 2017 that they have entered into a strategic partnership to build and operate a large-scale mammalian cell culture facility for monoclonal antibody production in Visp, Switzerland. The strategic partnership enables Sanofi to react quickly to fluctuations in demand in a short timeframe, reinforcing their capability to launch biologic medicines and ensure consistent access for patients. It also provides Lonza with needed capacities to respond to growing manufacturing demands for large-scale mammalian cell culture-based therapeutic proteins (6).

Vetter and medical-device company Microdermics entered into a strategic cooperation agreement to develop innovative microneedle drug-delivery systems in May 2017. The companies have joined forces to enable the progress of the microneedle technology to late-stage process development and device manufacture on a commercial scale. Vetter's primary role will be in the fill/finish aspect, but the it will also jointly conduct proof-of-concept studies on selected drugs and drug classes. Vetter will jointly design devices for testing, including how to integrate the microneedle technology into injection devices (7).

In June 2017, Rentschler Biotechnologie GmbH and Rentschler Fill Solutions GmbH announced a strategic partnership to provide new fill/finish facilities and solutions for biopharmaceutical products. Under the terms of the agreement, Rentschler Fill Solutions will serve as the exclusive partner for the fill/finish services of Rentschler Biotechnologie's manufacturing projects. Rentschler Fill Solutions is owned by the Rentschler family and will begin operations in mid-2018. In addition to servicing

Rentschler Biotechnologie's clients, Rentschler Fill Solutions will offer its fill/finish services on a clinical as well as commercial scale to its own client base. The company will employ advanced aseptic filling technology at the Rentschler Fill Solutions facility in Austria (8).

Recipharm announced on 20 Sep. 2017 a long-term manufacturing pact with Roche. The pact will add €35 million to Recipharm's annual sales, matching more than 6% of the company's current sales. Under the agreement, Recipharm will acquire a manufacturing facility located in Leganés, Spain, from Roche. The pact will also extend a collaborative opportunity to Recipharm's nearby facility in Parets, Spain (9). In September 2017, Recipharm also signed a contract with Kancera for the development and manufacture of drug candidate KAND567 as a capsule formulation for oral administration. Recipharm will develop the preparation required for effective release of KAND567 from the capsules, as well as manufacturing the pharmaceutical product. The work will be performed at Recipharm's development facility in Solna, Sweden (10).

SGS announced on 12 Oct. 2017 that it has entered into a collaboration with biotech company Bavarian Nordic A/S to develop a new respiratory syncytial virus (RSV) challenge strain. The collaboration will assist with the advancement of a universal vaccine candidate designed to induce protective immune responses against both subtypes (A and B) of RSV. The project will build upon the results of Phase II trials conducted by Bavarian Nordic, and will include a human challenge study, which will be carried out at the SGS Clinical Pharmacology Unit in Antwerp, Belgium, using the new RSV challenge strain, once it has been fully developed and validated (11).

## New facilities

MilliporeSigma announced in January 2017 the opening of a facility in Mollet des Vallès, Spain dedicated to the manufacture of meglumine, a US Food and Drug Administration (FDA)-approved excipient for pharmaceuticals and a component of medical imaging contrast media. The FDA-validated facility in Spain is solely dedicated to the production of meglumine, an amino sugar derived from glucose (12).

On 26 Jan. 2017, Almac Group announced that as part of its ongoing global expansion, the company has secured a new facility in Dundalk, County Louth, Ireland. The new facility will be located at IDA Business Park. The new facility will increase the group's European footprint by 32,000 ft<sup>2</sup> (13).

In February 2017, Novasep announced the opening of its new €11-million bioconjugation unit in the company's Le Mans site in France. The 2000-m<sup>2</sup> facility includes two flexible GMP production suites equipped with 10-L to 400-L vessels to support both clinical and commercial manufacturing of antibody-drug conjugates. The stand-alone facility is purpose-built and offers R&D services, quality control, and scale-up laboratories (14). Eurofins Scientific announced on 20 Mar. 2017 that it will be establishing a pharmaceutical chemistry and microbiology facility in Livingston, Scotland. The announcement follows Eurofins' acquisition of Exova's pharmaceutical, food, and water testing business in the United Kingdom and Ireland in July 2016, and the subsequent purchase of ILS's pharmaceutical business in October 2016 (15).

FUJIFILM Diosynth Biotechnologies announced in September 2017 the opening of its new 10,000-ft<sup>2</sup> cell culture Process Development Laboratories in Wilton Centre, Teesside in the United Kingdom. The laboratories were built through a JPY 1-billion (US\$9-million) investment, part of a greater JPY 14-billion (US\$130-million) expansion. The new laboratories will be dedicated to supporting activities in the Saturn mAb Platform (16).

Sartorius announced on 13 Sept. 2017 the official opening of its new facility for the manufacture of laboratory instruments in the Sartorius Campus in the industrial zone of Grone in Goettingen, Germany. Approximately €42 million has been invested into the 25,000-m<sup>2</sup> building, representing the largest single investment of the Sartorius Campus (17).

Sartorius Stedim Cellca is building a new €30-million Cell Culture Technology Centre at Science Park III in Eselsberg, situated at the northwestern scientific hub in Ulm, Germany, the company announced on 28 Sep. 2017. The new laboratory and office complex will approximately double the company's space and is scheduled to be completed by the end of 2019 (18).

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