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Manager of Company Announcements Australian Stock Exchange Limited Level 6, 20 Bridge Street NSW 2000 By E-Lodgement

# Unilife and sanofi-aventis Sign Industrialisation Agreement

Industrialisation Program for Unilife Ready-to-Fill Syringe (RTFS) Ahead Of Schedule

Sanofi-aventis Funding Unilife's A\$30.4m (€17m) Industrialisation Program

Unilife Retains Right to Supply RTFS to Other Pharmaceutical Groups

Unilife to Centralise Manufacturing in Pennsylvania

Unilife Medical Solutions Limited ("Unilife" or "the Company") (ASX: UNI) is pleased to announce that on June 30, 2009, it entered into an Industrialisation Agreement with Sanofi Winthrop Industrie, a wholly-owned subsidiary of sanofi-aventis ("sanofi-aventis"), for the commercialisation of the Unilife Ready-to-Fill Syringe (RTFS).

Under an exclusive agreement entered into by both parties on July 1, 2008 ("Exclusive Agreement"), sanofi-aventis paid to Unilife A\$16.4 million (€10 million) for the exclusive right to negotiate for the purchase of the RTFS (also known as the Unilife Prefilled Syringe) and to bear the costs of its industrialisation subject to the signing of the Industrialisation Agreement and the completion of agreed quarterly milestones.

The Industrialisation Agreement together with the Exclusive Agreement (as amended) ("the Agreements) set forth the terms of the on-going relationship of the parties, including sanofi-aventis' commitment to complete the funding of the A\$30.4 million (€17 million) RTFS industrialisation program commenced by Unilife one year ago. Furthermore, the Agreements outline the agreed pricing structure under which sanofi-aventis will purchase the RTFS, subject to the signing of a Supply Agreement, and provide to Unilife the right to supply the RTFS to other pharmaceutical companies in certain therapeutic drug classes (Unilife Therapeutic Drug Classes).

## **Key terms of the Agreements include:**

- Period of Exclusivity: Both parties have agreed to extend the period in which sanofi-aventis has the exclusive right to negotiate for the purchase of the RTFS by one year. This period of exclusivity for the RTFS will now expire on June 30, 2014 ("Period of Exclusivity") subject to extensions of up to ten years for specific products for which sanofi-aventis has placed orders (as described below).
- Exclusivity List: Within 120 days from the signing of this Agreement, sanofi-aventis will provide to Unilife a specific list of therapeutic drug classes ("Exclusivity List") where it intends to market injectable drug products, which are either currently available from them or in their development pipeline. Should the parties agree to the contents of this Exclusivity List within 60 days of its initial receipt, sanofi-aventis will retain the exclusive right to negotiate for the purchase of the RTFS for use with injectable drug products which are marketed in these therapeutic classes for the full Period of Exclusivity. If the parties are unable to agree to the Exclusivity List within 60 days of receipt of the list, sanofi-aventis will retain full exclusivity to the RTFS across all therapeutic classes; however the Period of Exclusivity will be reduced and will then expire on July 1, 2012. If the Period of Exclusivity expires on July 1, 2012, Unilife will be free to sell the RTFS to any pharmaceutical company across all therapeutic classes.
- Supply to Other Pharmaceutical Companies: Unilife has retained the right to enter into agreements with other pharmaceutical companies which may seek to use the RTFS with injectable drug products marketed in Unilife Therapeutic Drug Classes. Sanofi-aventis will receive a 5% royalty on revenue generated from sales of the RTFS to other pharmaceutical companies. Royalty payments to sanofi-aventis will cease when Unilife's total revenues from these other pharmaceutical companies reaches \$A600 million (€340 million).

- Therapeutic Exclusivity and other Pharmaceutical Companies: Unilife has the right to seek an Access Fee ("Access Fee") from other pharmaceutical companies for the right to negotiate for the purchase of the RTFS for use with a Unilife Therapeutic Drug Class. Unilife shall pay sanofi-aventis 70% of any Access Fees received until such time as total Access Fee revenue exceeds €14.286 million or June 30, 2014, whichever comes earlier. Thereafter, if not already expired, sanofi-aventis will receive 30% of Access Fee revenue generated by Unilife during the remainder of the Period of Exclusivity.
- Supply Agreement: Sanofi-aventis will receive a ten year extension of its exclusive right to purchase the RTFS for use for a designated therapeutic class should both parties sign a Supply Agreement prior to July 1, 2014 ("Supply Agreement"). This extension will be reduced to five years in the event that sanofi-aventis does not sell a minimum of 20 million units of the RTFS for use with an injectable drug product to be marketed for this therapeutic class in at least one of the first five years of the Supply Agreement. Each therapeutic class on the Exclusivity List will be treated separately for this purpose.
- Access to Production Capacities: Unilife is not required to commit more than 30% of its annual
  production capacity of the RTFS to sanofi-aventis, thereby allowing adequate capacity for
  other RTFS customers. Sanofi-aventis must provide Unilife with orders twenty-four months in
  advance to receive a greater portion of Unilife's annual capacity.

## **Update on Industrialisation Program**

Unilife is pleased to provide the following update with regard to the industrialisation of the RTFS.

- Period of Industrialisation Program: The Industrialisation Program was originally intended to be completed by the end of 2011. As the Industrialisation Program is proceeding ahead of schedule, both parties have agreed to bring its scheduled completion date forward to the end of 2010
- Payment of March Quarterly Milestone: Following the completion of designated milestones during the quarter ending March 30, 2009, Unilife received an industrialisation milestone payment of A\$3.5 million (€2 million). Unilife has now received a total of A\$9.5 million (€5 million) in quarterly milestone payments since the commencement of the RTFS industrialisation program. With the industrialisation program proceeding as scheduled, Unilife has issued to sanofi-aventis an invoice for the delivery of milestones attained during the quarter ended June 30, 2009.
- Selection of Automated Assembly Supplier: Unilife has completed due diligence on potential qualified international suppliers for the development of the high-volume automated assembly system to be used in the production of the RTFS. The quality of design concepts contained within the proposals validates Unilife's decision to outsource the development of automated assembly systems for the RTFS to an established industry specialist. The announcement of a preferred supply partner for the high-volume automated assembly system will be made upon the signing of an agreement with the selected company.
- Scheduled Production Capacities: Unilife is scheduled to commence supply of the RTFS by the end of 2010. Initial supply of the RTFS by Unilife will utilize a fully automated assembly system that will have a targeted annual capacity of more than 40 million units. The design and assembly process strategy developed for this first automated assembly line will enable Unilife to meet its production requirements under the Industrialisation Program. The design of this first line will also be used to develop a higher-volume automated assembly system scheduled to be completed by the end of 2011. This high-volume automated assembly system is anticipated to have an annual production capacity greater than 100 million units. The significant annual capacity of this high-volume line, and its modular design platform, will enable Unilife to increase production capacities at a much faster and more cost-effective rate than originally envisioned. Unilife's target production plan for the RTFS remains at approximately 400 million units per year beyond 2014.
- RTFS Production Facility: Unilife has conducted a review of opportunities within Europe for the establishment of a manufacturing facility suitable for the high-volume production of the RTFS. Following a review of these potential European sites, the expanded production capacities of Unilife's assembly lines and the ability for Unilife under the Industrialisation Agreement to sell to pharmaceutical companies other than sanofi-aventis, Unilife has decided to instead centralise its manufacturing activities within Pennsylvania. The centralisation of RTFS production activities within Pennsylvania is expected to reduce Unilife's operational costs,

further optimise its supply chain activities and place Unilife in a more favourable international location to supply the RTFS to all of its anticipated customers.

## **Comments by Unilife**

Unilife CEO Alan Shortall stated that "The signing of this agreement with sanofi-aventis puts Unilife in a strong position to complete the industrialisation of the RTFS, and become a global leader in the fast-growing pharmaceutical market for prefilled safety syringes."

"Whilst sanofi-aventis is the world's largest consumer of prefilled syringes, Unilife has also received significant levels of interest in the RTFS from many other major pharmaceutical companies. With the signing of this agreement, Unilife can now move forward in its discussions with these other potential customers which are all major prefilled syringe consumers in their own right."

"Unilife has allocated significant resources in the past year towards the industrialisation of the RTFS and the development of a world-class management team. It is this management team, in combination with our projected equipment suppliers, that has allowed Unilife to develop a more effective and efficient production strategy for the RTFS. We will continue to work towards the high-volume production of the RTFS in Pennsylvania, and the continued expansion of commercial relationships with pharmaceutical industry leaders."

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## Shareholder / Analyst Enquiries:

Australia Jeff Carter Phone: + 61 2 8346 6500 United States Stuart Fine Phone: + 1 908 469 1788

**Media Enquiries:** 

Australia Michael Mullane Phone: +61 2 8284 9990 United States Sharon O'Shea Phone: +1 610 659 9091

### **About Unilife**

Unilife Medical Solutions Ltd is an ISO 13485 certified company that designs, develops and supplies innovative safety medical devices. Listed on the Australian Securities Exchange (ASX: UNI) since 2002, Unilife has FDA-registered manufacturing facilities in the US State of Pennsylvania and a proprietary portfolio of clinical and prefilled safety syringes designed for use within healthcare and pharmaceutical markets.

#### **Unilife RTFS**

The Unilife Ready-to-Fill Syringe (RTFS) is a prefilled syringe with fully integrated safety features. It is designed to be compatible with the injectable drug filling and packaging systems of pharmaceutical customers to minimize production and supply chain costs associated with their compliance with needlestick prevention laws introduced within the US and other international regions. Like other proprietary Unilife syringes, the RTFS features a passive (automatic) needle retraction mechanism which allows operators to control the speed of needle withdrawal directly from the body to protect those at risk of needlestick injury. Initial pilot production of the RTFS commenced in 2008 at Unilife's US facilities. Initial supply of the RTFS to pharmaceutical customers is scheduled to commence in late-2010.

#### **About Sanofi-aventis**

Sanofi-aventis is one of the world leaders in the pharmaceutical industry, ranking number one in Europe and number four worldwide. Backed by a world-class R&D organisation, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine and vaccines. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).