

## **UNILIFE MEDICAL SOLUTIONS LIMITED**

### **QUARTERLY REPORT**

### **For the Period Ending 30 June, 2009**

The Board of Unilife Medical Solutions Limited ("Unilife") (ASX: UNI / OTCPK: UNIFF) is pleased to make the following statement to shareholders in regards to the Fourth Quarter Report for the period ending 30 June, 2009.

#### **Industrialisation Agreement**

Unilife entered into an Industrialisation Agreement with Sanofi Winthrop Industrie, a wholly-owned subsidiary of sanofi-aventis (pharmaceutical partner), for the commercialisation of the Unilife Ready-to-Fill Syringe (RTFS) on June 30, 2009. The pharmaceutical partner is now committed to complete its funding of the A\$30.4 million (€17 million) industrialisation program for the RTFS which Unilife commenced one year ago. Combined with the A\$16.4 (€10m) Exclusivity Fee paid to Unilife in 2008, this commitment to fund the industrialisation program for the RTFS by the pharmaceutical partner represents a total investment in Unilife of approximately A\$47 million. Under the Industrialisation Agreement, Unilife also retained the right to supply the RTFS to other pharmaceutical companies in certain therapeutic drug classes to be negotiated between the parties.

#### **Industrialisation Program for the Unilife Ready-to-Fill Syringe (RTFS)**

The Industrialisation Program for the RTFS is proceeding ahead of schedule, with its scheduled completion date having been brought forward from the end of 2011 to the end of 2010. 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). With the industrialisation program proceeding according to the revised schedule, Unilife has issued to sanofi-aventis an invoice for the delivery of milestones attained during the quarter ended June 30, 2009. During the period, Unilife 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.

#### **Agreement with the Commonwealth of Pennsylvania**

On April 2, 2009, Unilife completed the relocation of key commercial and operational functions from Sydney, Australia to its Lewisberry facility in the US State of Pennsylvania with the name change of its wholly-owned US subsidiary Integrated BioSciences Inc (IBS) to Unilife Medical Solutions, Inc. The Office of the Governor of the Commonwealth of Pennsylvania announced on the same day that Unilife would be provided with a A\$2.15 million (US\$1.775 million) funding program which included an A\$736,000 (US\$600,000) Infrastructure and Facilities Improvement Grant, a A\$122,000 (US\$100,000) Opportunity Grant, a A\$1.2 million (US\$1 million) loan from the Machinery and Equipment Loan Fund and a A\$92,000 (US\$75,000) grant for Job Training Assistance.

#### **Review of Unilife Facility Requirements**

During the period, Unilife completed 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 and the necessary operational and supply-chain resources required to support key projects such as the RTFS, the Company elected to centralise its manufacturing activities within Pennsylvania. Unilife has subsequently commenced a review of facility options within Pennsylvania.

## **US Production of Unित्रact 1mL Syringes**

During the quarter, Unilife made significant progress in its preparations for US production of its Unित्रact range of 1mL safety syringes at its Lewisberry facility in Pennsylvania.

## **Appointment of Senior Management**

During this quarter, Unilife appointed the following members to its senior management team:

### *Tom Westbye B.Sc., Director of Product Development*

Mr. Westbye has more than 30 years executive experience in all aspects of medical device manufacturing. Between 2000 and 2009, he was Vice President of Product Development and then Vice President of Technology Integration at Safety Syringes, Inc (SSI) of California. In these roles at SSI, he led dedicated design teams to develop current market-leading passive safety devices used in prefilled glass syringes, co-developed the first re-usable auto-injector, and managed the development of product specific automation for a number of major pharmaceutical companies. During this time, he lodged a significant number of patents covering passive safety devices, tamper evident devices, reconstitution devices and dental safety syringes. Prior to his time at SSI, Mr. Westbye worked with an eye care solutions company where he managed the construction and validation of a major new production facility and the FDA certification of several products. He was also Director of Manufacturing Support for a San Diego-based infusion therapy device manufacturer in managing the development, selection and procurement of molding, product mixing and Water for Injection (WFI) process equipment. Mr. Westbye has a Bachelor of Science in Polymer Engineering from Chalmers University in Sweden.

### *Tim Spang, B.Sc., MBA, Director of Manufacturing*

Mr. Spang has extensive operations experience with an almost 20 year background in high-tech manufacturing in the medical device and related industries of Europe and the U.S. Mr. Spang was previously Executive Director of New Product Development for pharmaceutical injection system company MEDRAD. He has also held roles as Director of Global Operations for Ariba, Inc. and as Managing Director-Europe for The JPM Company where he was responsible for driving the development and overall management of electro-mechanical manufacturing facilities in Germany and the Czech Republic. Mr Spang has experience in LEAN manufacturing, Six Sigma, demand flow manufacturing and e-sourcing operations globally. He has an MBA from Carnegie Mellon University's Tepper School of Business and a Bachelor's Degree in Industrial Engineering from Pennsylvania State University.

### *Alan Connor, B.Sc., MBA, Director of Supply Chain*

Mr. Connor is a highly experienced executive within the medical device supply chain industry who came to Unilife from pharmaceutical injection system company MEDRAD. He has also supported healthcare and pharmaceutical companies in areas including marketing, product commercialisation, manufacturing and project management. Prior to joining MEDRAD, he was a senior consultant in supply chain logistics at Arthur Anderson Business Consulting. Mr. Connor has an MBA from the University of Pittsburgh and a Bachelor of Science in Industrial Engineering from Penn State University.

### *Gary Reynolds, B.Sc., Senior Automation Engineer*

Mr. Reynolds is an experienced mechanical engineer specialising in developing manufacturing processes and designing automated equipment for production. He has over 25 years of diverse experience in a wide range of fields that include medical devices, consumer products, printing and military contracts. Mr. Reynolds holds 17 patents, is a Six Sigma Green Belt and a highly proficient consulting engineer. Prior to joining Unilife, Mr Reynolds had an 18 year career with Kimberly-Clark Corporation where he worked in both their Health Care and Baby Care Sectors. He holds a Bachelor of Science degree in Mechanical Engineering from Texas A&M University.

*Ralph Varrato, Facilities Manager*

Mr. Varrato has almost 20 years of experience in the management of manufacturing facilities for the aeronautical, pharmaceutical, biotech and medical device industries. In particular, he has extensive experience with Water for Injection (WFI) and clean rooms, as well as other facilities and equipment activities relating to the manufacture of pharmaceutical and medical device products. He has held senior leadership roles at Gensia Labs, Schein Pharmaceuticals, Teva Pharmaceuticals, and Boston Scientific. At Boston Scientific, he was Facilities Manager for five medical device manufacturing sites in California totalling 210,000 square foot in size where he was responsible for the development of several clean room and black room installations. As the Associate Director of Maintenance and Building Services at Teva Pharmaceuticals between 2000 and 2007, he managed more than 100 people across 13 manufacturing facilities in California.

*Bruce Randles, BA, MMM, Quality Engineer*

Mr. Randles has 20 years of multi-industry experience in the management of manufacturing quality systems in areas such as process analysis, quality control and product improvement. Prior to joining Unilife, Mr Randles was a Quality Engineer at global production materials leader Saint Gobain. Between 2000 and 2007, he was a Senior Quality Engineer at Boston Scientific where he was a charter member of the Six Sigma Council and led medical device and cardiology projects to deliver savings in areas such as injection moulding, facility management and data storage. Mr. Randles is a certified in Six Sigma (Black Belt) and has a Masters Degree in Manufacturing Management from Kettering University in Michigan, as well as a Bachelor of Science in Cytotechnology and a Bachelor of Arts in Biology.

**Cash Reserves**

During the quarter, receipts from customers of Unilife and its US subsidiary were \$5.4 million. Net operating cash outflow for Unilife and its US subsidiary was \$0.5 million. Unilife invested approximately \$2.0 million in research and development and the purchase of plant and equipment. Unilife had cash reserves of \$4.7 million as at 30 June 2009.

Details of Unilife's cash flow are set out in the attached Appendix 4C.

# Appendix 4C

## Quarterly report for entities admitted on the basis of commitments

Introduced 31/3/2000. Amended 30/9/2001

Name of entity

**UNILIFE MEDICAL SOLUTIONS LIMITED**

ABN

14 008 071 403

Quarter ended ("current quarter")

30 June 2009

### Consolidated statement of cash flows

Cash flows related to operating activities	Current quarter \$A'000	Year to date (12 months) \$A'000
1.1 Receipts from customers	5,355	33,338
1.2 Payments for		
(a) staff costs	(2,835)	(10,327)
(b) advertising and marketing	(43)	(176)
(c) research and development (refer to item 1.13)	-	-
(d) leased assets	(159)	(911)
(e) other working capital	(2,968)	(13,143)
1.3 Dividends received	-	-
1.4 Interest and other items of a similar nature received	38	482
1.5 Interest and other costs of finance paid	80	(245)
1.6 Income taxes paid	-	-
1.7 Other		
- Grants Received	61	61
<b>Net operating cash flows</b>	<b>(471)</b>	<b>9,079</b>

+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

	Current quarter	Year to date (12 months)
	\$A'000	\$A'000
1.8 Net operating cash flows (carried forward)	(471)	9,079
<b>Cash flows related to investing activities</b>		
1.9 Payment for acquisition of:		
(a) businesses (item 5)	-	-
(b) equity investments	-	-
(c) intellectual property	-	-
(d) physical non-current assets	(1,947)	(3,500)
(e) other non-current assets	-	-
1.10 Proceeds from disposal of:		
(a) businesses (item 5)	-	-
(b) equity investments	-	-
(c) intellectual property	-	-
(d) physical non-current assets	-	17
(e) other non-current assets	-	-
1.11 Loans to other entities	-	-
1.12 Loans repaid by other entities	-	-
1.13 Other – cash on acquisition of subsidiaries		
Other – payments for research and development	(54)	(247)
<b>Net investing cash flows</b>	(2,001)	(3,730)
<b>1.14 Total operating and investing cash flows</b>	(2,472)	5,349
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, etc	715	835
1.16 Proceeds from sale of forfeited shares	-	-
1.17 Proceeds from borrowings	-	127
1.18 Repayment of borrowings	(759)	(4,617)
1.19 Dividends paid	-	-
1.20 Other – share issue (costs) / refunds	-	-
<b>Net financing cash flows</b>	(44)	(3,655)
<b>Net increase (decrease) in cash held</b>	(2,515)	1,694
1.21 Cash at beginning of quarter/year to date	7,211	3,002
1.22 Exchange rate adjustments	-	-
1.23 <b>Cash at end of quarter (note 1)</b>	4,696	4,696

+ See chapter 19 for defined terms.

**Payments to directors of the entity and associates of the directors**

**Payments to related entities of the entity and associates of the related entities**

		Current quarter \$A'000
1.24	Aggregate amount of payments to the parties included in item 1.2	500
1.25	Aggregate amount of loans to the parties included in item 1.11	-
1.26	Explanation necessary for an understanding of the transactions	
	<p>Included in the above is directors' fees and executive director's remuneration (\$374K). A company associated with a director is now providing company secretarial, accounting and administrative services for compliance with Australian regulations (\$126K).</p>	

**Non-cash financing and investing activities**

- 2.1 Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows  
Nil during the quarter
- 2.2 Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest  
Nil during the quarter

**Financing facilities available**

*Add notes as necessary for an understanding of the position. (See AASB 1026 paragraph 12.2).*

		Amount available \$A'000	Amount used \$A'000
3.1	Loan facilities	3,893	3,893
3.2	Credit standby arrangements	-	-

+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

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**Reconciliation of cash**

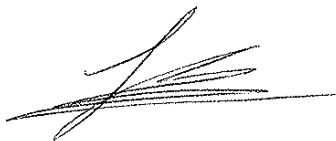
Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.	Current quarter \$A'000	Previous quarter \$A'000
4.1 Cash on hand and at bank	4,092	3,597
4.2 Deposits at call	604	3,614
4.3 Bank overdraft	-	-
4.4 Other (Term Deposit)	-	-
<b>Total: cash at end of quarter</b> (item 1.22)	<b>4,696</b>	<b>7,211</b>

**Acquisitions and disposals of business entities**

	Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
5.1 Name of entity		-
5.2 Place of incorporation or registration		-
5.3 Consideration for acquisition or disposal		-
5.4 Total net assets		-
5.5 Nature of business		-

**Compliance statement**

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement gives a true and fair view of the matters disclosed.



Sign here: ..... Date: 31 July 2009  
 (Director)

Print name: Jeff Carter

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+ See chapter 19 for defined terms.

## Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
2. The definitions in, and provisions of, *AASB 1026: Statement of Cash Flows* apply to this report except for the paragraphs of the Standard set out below.
  - 6.2 - reconciliation of cash flows arising from operating activities to operating profit or loss
  - 9.2 - itemised disclosure relating to acquisitions
  - 9.4 - itemised disclosure relating to disposals
  - 12.1(a) - policy for classification of cash items
  - 12.3 - disclosure of restrictions on use of cash
  - 13.1 - comparative information
3. **Accounting Standards.** ASX will accept, for example, the use of International Accounting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

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