



## **UNILIFE MEDICAL SOLUTIONS LIMITED**

**ABN 14 008 071 403**

**Appendix 4E – Preliminary Final Report  
Year ended 30 June 2009**

**Results for announcement to market**

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**UNILIFE MEDICAL SOLUTIONS LIMITED HIGHLIGHTS**

**Summary Results to 30 June 2009**

				<b>Year ended 30 June 2009 \$</b>	<b>Year ended 30 June 2008 \$</b>
Revenue from operating activities	UP	869%	to	40,413,706	4,170,166
Profit/(Loss) before interest, tax, depreciation and amortisation	UP	239%	to	10,371,211	(7,469,907)
Profit/(Loss) before tax	UP	237%	to	11,826,453	(8,660,853)
Net Profit/(Loss) for the period attributable to members	UP	249%	to	12,806,494	(8,617,238)

***Earnings Result***

Group Revenue for Unilife Medical Solutions Limited ("Unilife") increased by 869% from \$4,170,166 (2008) to \$40,413,706 (2009). The increase in revenue was primarily due to payments received from the pharmaceutical partner.

The Net Profit after tax for the year ended 30 June 2009 was \$12,806,494 representing a 249% increase in the Net Profit as compared with the previous corresponding year.

The Directors do not recommend that a dividend relating to the year ended 30 June 2009 be paid. As such, there is no applicable record date.

***Cash Flow***

During the year ended 30 June 2009, the net cash provided by operating activities was \$8,961,562 (2008: net cash out flow (\$7,980,916)).

An amount of \$246,666 was invested in research and development (2008: \$562,929) and \$3,572,645 was invested in plant, property and equipment (2008: \$895,433 ).

## **Review of Activities**

### ***Agreements with Major Pharmaceutical Partner***

On July 1, 2008, Unilife entered into a Global Agreement with its major pharmaceutical partner (pharmaceutical partner) under which the partner paid Unilife a non-refundable fee of \$16.4 million (€10 million) for the exclusive right to negotiate for the purchase of the Unilife Ready-to-Fill Syringe. On June 30, 2009, Unilife signed an Industrialisation Agreement with its pharmaceutical partner for the Unilife Ready-to-Fill Syringe under which its partner committed to complete the funding of the \$30.4 million (€17 million) industrialisation program.

Combined with the \$16.4 million (€10m) non-refundable Exclusivity Fee paid to Unilife in 2008, this commitment to fund the industrialisation program will represent a total expenditure by the pharmaceutical partner of approximately \$47 million between July 2008 and the end of 2010. Between now and the end of 2009, both parties will negotiate therapeutic drug class areas where the pharmaceutical partner would have the exclusive right to use the Unilife Ready-to-Fill Syringe. Under the Industrialisation Agreement, Unilife has also retained the right to enter into agreements with other pharmaceutical companies which may seek to use the Unilife Ready-to-Fill Syringe with injectable drug products marketed in other therapeutic drug classes.

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

The Industrialisation Program for the Unilife Ready-to-Fill Syringe commenced on July 1, 2008. The original project plan targeted the scheduled completion of the Industrialisation Program in the fourth quarter of 2011. As the program is approximately one-year ahead of schedule, both parties recognise that it is now expected to be completed by the end of 2010. Unilife has now completed due diligence on potential qualified international suppliers for the development and supply of the high-volume automated assembly system to be used in the production of the Unilife Ready-to-Fill Syringe. A final selection of the supplier will be made during the current quarter.

### ***FDA Clearance of Unitract 1mL Syringes***

Unilife secured U.S Food and Drug Administration ("FDA") clearance of the Unitract 1mL Insulin Syringe in October 2008. FDA clearance of the 510(k) submission for the Unitract 1mL Insulin Syringe gave Unilife permission to market the Unitract 1mL Insulin Syringe within the US.

### ***U.S Production of Unitract 1mL Syringes***

In August 2009, Unilife commenced U.S production of the Unitract™ 1mL Insulin Syringe ("Unitract 1mL Syringes") at its FDA-registered manufacturing facility in Pennsylvania. Prior to the successful transfer of the automated assembly system for the Unitract 1mL Syringes into its designated clean room in June 2009, Unilife had completed a series of key activities and operational tests. Prior to final installation in the clean room, Unilife had also successfully tested other related manufacturing systems including an automated barrel printer and an automated packaging system. The automated assembly system has been rated at up to 90% of efficiency, with Unilife now continuing to work towards achieving the optimum productivity rate for this assembly system of approximately 40 million units per annum. Commercial release of the Unitract 1mL Syringes is expected to occur during the fourth quarter of 2009 upon completion of product ageing studies, which are a standard requirement for the qualification of manufacturing processes at a new production site. A video of the automated assembly system developed by Unilife to manufacture the Unitract 1mL Syringes is available for viewing at [www.unilife.com](http://www.unilife.com).

### ***Transition of Key Commercial and Operational Functions to US Facility***

During the period, Unilife transitioned key commercial and operational functions from Australia to its FDA-registered U.S manufacturing facility. In the period from September 2008 to now, Unilife has recruited or relocated more than 35 management and senior professional staff that are now situated at this facility. These US-based roles include the appointment of a Chief Financial Officer, a Senior Vice-President of Operations, a Vice-President of Quality Systems and Regulatory Affairs and Director-level positions for Manufacturing, Supply Chain, Engineering, Product Development and Sales and Marketing.

The current Unilife management team has on average more than 20 year's experience. The majority of the members of this management team have a strong background in the medical device and pharmaceutical markets, having worked for multinational companies such as Baxter, Medtronic, Teva, Safety Syringes, Resmed, MEDRAD, Biotronik, Tyco, Dentsply, Boston Scientific and Kimberley Clark. In April 2009, Unilife announced the change of name of its U.S subsidiary from Integrated BioSciences Inc to Unilife Medical Solutions Inc.

During the period, Unilife also completed a review of opportunities within Europe for the establishment of a manufacturing facility suitable for the high-volume production of the Unilife Ready-to-Fill Syringe. Following a review of these potential European sites and the necessary operational and supply-chain resources required to support key projects such as the Unilife Ready-to-Fill Syringe, the Company elected to centralise its manufacturing activities within Pennsylvania. Unilife has subsequently commenced a review of facility options within Pennsylvania.

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

In April 2009, the Office of the Governor of the Commonwealth of Pennsylvania announced that Unilife would be provided with a \$2.15 million (US\$1.775 million) funding program which included an \$736,000 (US\$600,000) Infrastructure and Facilities Improvement Grant, a \$122,000 (US\$100,000) Opportunity Grant, a \$1.2 million (US\$1 million) loan from the Machinery and Equipment Loan Fund and a \$92,000 (US\$75,000) grant for Job Training Assistance.

#### **Preparations for Listing on U.S Exchange**

During the period, Unilife declared its intention to seek a listing on a recognised U.S stock exchange as part of its strategy to consolidate commercial and operational activities within the U.S. The Company has made significant progress in regards to its schedule for listing on a U.S exchange. To support awareness of Unilife and its business activities within U.S financial markets, an Executive Informational Overview® report on the Company was released by U.S-based research group Crystal Research Associates, LLC in January 2009.


In August 2009, U.S investment banking firm Griffin Securities Inc initiated independent research coverage on the Company. A copy of this report is available for viewing at [www.unilife.com](http://www.unilife.com) or [www.griffinsecurities.com](http://www.griffinsecurities.com).

This independent report was prepared by Keith Markey, Scientific Director of Griffin Securities. Mr Markey has been an equities analyst for more than 20 years, specializing in the biotechnology, pharmaceutical, and medical device sectors. Much of his career has been with Value Line, Inc., where he held various managerial positions in the Research Department for the world's leading investment advisory newsletter, the Value Line Investment Survey. He was responsible for initiating coverage of stocks in all industries and created Value Line Select, a premium advisory publication. Keith began his career as a biochemist, working in the fields of endocrinology and neuroscience at New York University Medical School and Cornell Medical College. His research, which resulted in more than 30 scientific publications, contributed to our understanding of regulatory biochemistry and stem cell plasticity. Keith has lectured on scientific and financial subjects, and is a contributing editor to HUM-MOLGEN, a news service for the scientific research community. He is also a member of the New York Academy of Sciences and the National Association of Science Writers. Keith earned a Ph.D. in Neurochemistry from the University of Connecticut and an M.B.A. in Finance from the Leonard N. Stern School of Business at New York University.

**Annual Report and Annual General Meeting**

Unilife expects to mail its Annual Report and Notice of Annual General Meeting to shareholders in the final week of October 2009. Unilife expects to hold its 2009 Annual General Meeting in Sydney on 30 November 2009.

Please find attached the Company's Preliminary Final Report for the year ended 30 June, 2009, together with relevant commentary thereto.



JIM BOSNJAK OAM  
Chairman  
31 August 2009

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**Income Statement**  
**Year ended 30 June 2009**

	Note	Year ended 30 June 2009 \$	Year ended 30 June 2008 \$
Other income	3	40,413,706	4,170,166
Cost of goods sold		(5,732,353)	(3,098,651)
Employee expense		(5,844,643)	(3,250,097)
Depreciation and amortisation expenses	4a	(1,210,022)	(803,881)
Other expenses	4b	(10,503,988)	(4,485,808)
Loss on sale of non-current assets		(6,692)	-
Finance costs	4a	(245,220)	(387,065)
Expense associated with issue of convertible note		(87,148)	(124,300)
Share based payments		(4,957,187)	(681,217)
<b>Profit/(Loss) before income tax expense</b>		11,826,453	(8,660,853)
Income tax benefit/(expense)		980,041	43,615
<b>Profit/(Loss) from continuing operations</b>		12,806,494	(8,617,238)
<b>Overall Operations</b>			
Basic earnings per share (cents per share)	5	6.2	(4.4)

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**Balance Sheet**  
**Year ended 30 June 2009**

	Note	Year ended 30 June 2009 \$	Year ended 30 June 2008 \$
<b>Current Assets</b>			
Cash and cash equivalents	6	4,506,684	3,002,277
Trade and other receivables		9,771,104	1,069,942
Inventories		1,362,851	1,107,515
Other current assets		182,591	36,286
<b>Total Current Assets</b>		<b>15,823,230</b>	<b>5,216,020</b>
<b>Non-Current Assets</b>			
Financial assets		-	-
Property, plant and equipment		11,352,786	8,111,437
Intangible assets		7,327,986	6,849,797
Other non-current assets		8,609,332	7,108,866
<b>Total Non-Current Assets</b>		<b>27,290,104</b>	<b>22,070,100</b>
<b>Total Assets</b>		<b>43,113,334</b>	<b>27,286,120</b>
<b>Current Liabilities</b>			
Trade and other payables		2,941,875	1,912,742
Short-term borrowings		503,361	4,333,621
<b>Total Current Liabilities</b>		<b>3,445,236</b>	<b>6,246,363</b>
<b>Non-Current Liabilities</b>			
Long-term borrowings		3,390,133	3,162,656
<b>Total Non-Current Liabilities</b>		<b>3,390,133</b>	<b>3,162,656</b>
<b>Total Liabilities</b>		<b>6,835,369</b>	<b>9,409,019</b>
<b>Net Assets</b>		<b>36,277,965</b>	<b>17,877,101</b>
<b>Equity</b>			
Issued capital	7	75,458,648	72,254,862
Reserves		4,994,881	2,604,297
Retained earnings		(44,175,564)	(56,982,058)
<b>Total Equity</b>		<b>36,277,965</b>	<b>17,877,101</b>

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**Statement of Changes in Equity**  
**Year ended 30 June 2009**

	Share Capital Ordinary	Retained Earnings	Share Based Payment Reserve	Foreign Exchange Unrealised Reserve	Total
	\$	\$	\$	\$	\$
<b>Balance at 1 July 2007</b>	66,783,726	(48,364,820)	1,748,972	5,489	20,173,367
Shares issued during the year	5,751,991	-	-	-	5,751,991
Transaction costs	(280,855)	-	-	-	(280,855)
Profit/(loss) attributable to members of parent entity	-	(8,617,238)	-	-	(8,617,238)
Transfers to and from reserve					
- equity compensation reserve	-	-	807,971	-	807,971
- foreign exchange unrealised reserve	-	-	-	41,865	41,865
<b>Balance at 30 June 2008</b>	<b>72,254,862</b>	<b>(56,982,058)</b>	<b>2,556,943</b>	<b>47,354</b>	<b>17,877,101</b>
Shares issued during the year	3,203,786	-	-	-	3,203,786
Transaction cost	-	-	-	-	-
Profit/(loss) attributable to members of parent entity	-	12,806,494	-	-	12,806,494
Transfers to and from reserve					
- equity compensation reserve	-	-	3,062,196	-	3,062,196
- foreign exchange unrealised reserve	-	-	-	(671,612)	(671,612)
<b>Balance at 30 June 2009</b>	<b>75,458,648</b>	<b>(44,175,564)</b>	<b>5,619,139</b>	<b>(624,258)</b>	<b>36,277,965</b>

**Cash Flow Statement**  
**Year ended 30 June 2009**

	Notes	Year ending 30 June 2009 \$	Year ending 30 June 2008 \$
<b>Cash flows from operating activities</b>			
Receipts from customers		4,621,318	3,616,539
Other revenue		26,891,156	-
Payments to suppliers and employees		(22,849,323)	(11,635,294)
Interest received		482,639	226,516
Finance costs		(245,220)	(277,861)
Government grants received		60,992	89,184
<b>Net cash provided by (used in) operating activities</b>	8	<u>8,961,562</u>	<u>(7,980,916)</u>
<b>Cash flows from investing activities</b>			
Proceeds from sale of property, plant and equipment		17,374	292,000
Purchase of property, plant and equipment		(3,572,645)	(895,433)
Payment for research and development		(246,666)	(562,929)
<b>Net cash provided by (used in) investing activities</b>		<u>(3,801,937)</u>	<u>(1,166,362)</u>
<b>Cash flows from financing activities</b>			
Proceeds from issues of shares		834,795	5,751,991
Proceeds from borrowings		127,407	5,437,813
Payments for borrowings		(4,617,420)	(2,961,279)
Payments for share issue expenses		-	(304,101)
<b>Net cash (used in)/provided by financing activities</b>		<u>(3,655,218)</u>	<u>7,924,424</u>
<b>Net increase/(decrease) in cash held</b>		1,504,407	(1,222,854)
<b>Cash at beginning of financial year</b>		3,002,277	4,225,131
<b>Cash at the end of financial year</b>		<u>4,506,684</u>	<u>3,002,277</u>

## Notes to the Consolidated Financial Statements

### 1. Basis of the Preparation of the Preliminary Final Report

The preliminary final report has been prepared in accordance with the ASX Listing rule 4.3A and the disclosure requirements of ASX Appendix 4E.

This report has been prepared in accordance with Australian Accounting Standards, Urgent Issues Group Interpretations, other authoritative pronouncements of the Australian Accounting Standards Board and The Corporations Act 2001. The accounting policies have been consistently applied, unless otherwise stated.

### 2. Dividends:

The Directors do not recommend that a dividend relating to the year ended 30 June 2009 be paid. As such, there is no applicable record date.

### 3. Revenue:

	Year ended 30 June 2009	Year ended 30 June 2008
	\$	\$
<i>Operating activities</i>		
Sale of goods revenue	4,154,474	3,482,139
Interest from:		
Other persons/corporations	482,638	226,516
Realised gain on foreign exchange transactions	-	-
<i>From outside operating activities</i>		
Gross proceeds from sale of non-current assets	-	-
Government grants	60,992	89,184
Other income	35,715,602	372,327
Total other revenue from ordinary activities	<u>40,413,706</u>	<u>4,170,166</u>
<b>Total revenue</b>	<b><u>40,413,706</u></b>	<b><u>4,170,166</u></b>

### 4. Profit for the year

#### (a) Expenses:

Depreciation of plant and equipment	513,884	749,545
Amortisation of leasehold improvements	696,138	54,336
Total depreciation and amortisation	<u>1,210,022</u>	<u>803,881</u>
Finance costs:		
Interest expense	245,220	387,065
Net loss on disposal of plant & equipment	6,692	-

#### (b) Other expenses

The following expense items are the major items in this category:

Corporate, regulatory and related advisory expenses	2,804,774	868,277
Legal fees	1,172,006	192,025
Occupancy expenses	917,093	650,333
Travel costs	1,458,787	912,850
Marketing and public relations	189,235	91,154
Foreign exchange	461,549	(21,059)

<b>5. Earnings per Share (EPS):</b>	<b>Year ended 30 June 2009</b>	<b>Year ended 30 June 2008</b>
(a) Earnings used to calculate basic EPS	(12,806,494)	(8,617,238)
(b) Weighted average number of ordinary shares outstanding during the year used in calculating basic EPS	206,558,116	197,630,860
Weighted average number of options outstanding	33,858,747	52,570,895
<b>6. Cash and Cash Equivalents</b>	<b>Year ended 30 June 2009</b>	<b>Year ended 30 June 2008</b>
	<b>\$</b>	<b>\$</b>
Cash	3,939,441	2,670,336
Short term deposits	567,243	331,941
Total Cash at 30 June	<u>4,506,684</u>	<u>3,002,277</u>
<b>7. Issued Capital</b>	<b>Year Ended 30 June 2009</b>	<b>Year Ended 30 June 2008</b>
219,754,809 (2008 : 205,774,310) fully paid ordinary shares	<u>75,458,648</u>	<u>72,254,862</u>
	<u>75,458,648</u>	<u>72,254,862</u>
<b>(a) Ordinary Shares</b>	<b>2009 No.</b>	<b>2008 No.</b>
At the beginning of year	205,774,310	182,226,860
Shares issued during year		
- 9 July 2007		1,250
- 20 July 2007		14,000,000
- October to December 2007 (Conversion of notes)		2,775,000
- 14 December 2007		500,000
- April to May 2008		1,259,000
- 27 June 08 (Exempt employee share plan)		132,200
- June 2008 (Conversion of notes)		4,880,000
- 3 July 2008 (Exercise of options)	83,689	
- 4 July 2008 (Exercise of options)	1,500	
- 7 July 2008 (Conversion of notes)	240,000	
- 22 September 2008 (Conversion of notes)	80,000	
- 24 December 2008 (Exercise of options)	500,000	
- 29 December 2008 (CEO shares)	10,000,000	
- 1 February 2009 (Exempt employee share plan)	275,310	
- 29 May 2009 (Conversion of notes)	2,800,000	
As at 30 June	<u>219,754,809</u>	<u>205,774,310</u>

(b) **Share Options**

During the year 23,100,000 (2008:14,250,000) options were issued and 585,189 (2008:1,762,250) options were exercised. Also during 2009, 31,600,930 (2008:6,407,000) unlisted options were cancelled and 9,612,857 (2008: nil) listed options were cancelled. At 30 June 2009 there were 37,935,000 (2008: 46,991,119) unlisted options on issue and nil (2008: 9,642,857) listed options on issue.

8. **Notes to Statement of Cash Flow**

<b>Reconciliation of loss from ordinary activities after income tax to net cash used in operating activities</b>	<b>2009</b>	<b>2008</b>
	<b>\$</b>	<b>\$</b>
Profit/(Loss) from ordinary activities after income tax	12,806,494	(8,617,238)
Non-cash flows in profit from ordinary activities:		
Depreciation	513,884	749,545
Amortisation	696,138	54,336
Loss on sale of plant and equipment	6,692	-
Profit on sale of plant and equipment	-	-
Provision for non-recovery of inter-entity loan	-	-
Convertible Note	-	-
Share based payment	4,957,187	681,217
Impairment of property, plant & equipment	-	-
Adjustment of goodwill	-	-
Changes in assets and liabilities, net of effects of purchase and disposal of subsidiaries:		
Increase/(decrease) in accrued expenses/employee entitlements	397,270	46,197
Increase/(decrease) in trade creditors	795,747	(510,744)
Increase/(decrease) in rent in advance	-	-
Increase/(decrease) in other creditors	(181,832)	156,231
Increase/(decrease) in income taxes payable	-	-
(Increase)/decrease in accounts receivable	(8,337,407)	83,510
(Increase)/decrease in other debtors	(20,195)	(29,438)
(Increase)/decrease in interest receivable	(544)	(1,158)
(Increase)/decrease in prepaid expenses	(490,408)	61,032
(Increase)/decrease in inventories	(255,336)	(620,896)
(Increase)/decrease in deferred tax benefit	(1,254,516)	(33,510)
(Increase)/decrease in unrealised foreign exchange	(671,612)	-
Cash flow from operations	<u>8,961,562</u>	<u>(7,980,916)</u>

**9. Events Subsequent To Balance Date**

In 2002 the Company acquired Unitract Syringe Pty Ltd (Unitract). Under this acquisition agreement (Agreement) and as further approved by the shareholders on 28 November 2008, the Company agreed to issue 10 million shares to certain former shareholders of Unitract if the Company earned net profit after tax of \$6.5 million (as confirmed by its auditors) in any financial year in the years following completion of the Agreement and a further 10 million shares if the Company earned net profit after tax (as confirmed by its auditors) of \$12 million in any financial year in the years following the Agreement. It is noted that the net profit after tax for the year ended 30 June 2009 exceeded \$12 million and accordingly 20 million shares, subject to shareholder approval (if required) and confirmation by the Auditors, will be issued to former shareholders of Unitract.

On 1 July 2009, the Company announced that it entered into an Industrialisation Agreement with pharmaceutical partner for the commercialisation of the Unilife Ready-to-Fill Syringe.

**10. Net Tangible Asset (NTA) Backing per Share**

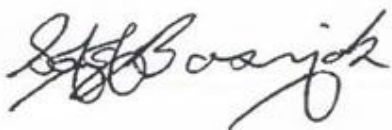
	Year Ended 30 June 2009	Year Ended 30 June 2008
Net assets backing per share (cents per share)	13.2	5.4

**11. Compliance Statement**

1. This report is based on the financial statements to which one of the following applies:

<input type="checkbox"/>	The financial statements have been audited.	<input type="checkbox"/>	The financial statements have been supplied to review.
<input checked="" type="checkbox"/>	The financial statements are in the process of being audited or subject to review.	<input type="checkbox"/>	The financial statements have not yet been audited or reviewed.

2. The entity has a formally constituted audit and committee.



**JIM BOSNJAK**  
Chairman

**Date: 31 August 2009**

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