

JS 44 (Rev. 12/12)

## CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

## I. (a) PLAINTIFFS

Talbot Smith

(b) County of Residence of First Listed Plaintiff Somerset  
(EXCEPT IN U.S. PLAINTIFF CASES)(c) Attorneys (Firm Name, Address, and Telephone Number)  
Virginia L. Harduck, Esq., Harduck Collier, LLC  
179 N. Broad St., Doylestown, Pa. 18942 (215) 230-9412

## DEFENDANTS

Unilife Corp., Alan Shortall  
and Ramin Mojdeh  
County of Residence of First Listed Defendant York, Chester  
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

## II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

## III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- |   | PTF                        | DEF                        |   | PTF                        | DEF                        |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State                   | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State     | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State                | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation  | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

## IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	<b>PERSONAL INJURY</b> <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input checked="" type="checkbox"/> 850 Securities/Commodities/Exchange <input checked="" type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	<b>PRISONER PETITIONS</b> <b>Habeas Corpus:</b> <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <b>Other:</b> <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

## V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District (specify)
- ☐ 6 Multidistrict Litigation

## VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

18 USC § 1514A; 15 U.S.C. § 78u-6

Brief description of cause:

Sarbanes Oxley; Dodd-Frank

## VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$

in excess of \$150,000

CHECK YES only if demanded in complaint:

JURY DEMAND: ☐ Yes ☒ No

## VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE

8/28/13

SIGNATURE OF ATTORNEY OF RECORD

Virginia L. Harduck

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE

## UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 54 Peoples Line Road, Somerset, NJ  
 Address of Defendant: 250 Cross Lane Farm, York, PA; 150 N. Radnor Chester Rd, Shafford, PA  
 Place of Accident, Incident or Transaction: Pennsylvania  
 (Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a))

Yes ☐ No ☐

Does this case involve multidistrict litigation possibilities?

Yes ☐ No ☒

RELATED CASE, IF ANY:

Case Number: \_\_\_\_\_ Judge \_\_\_\_\_ Date Terminated: \_\_\_\_\_

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?  
 Yes ☐ No ☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?  
 Yes ☐ No ☒
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court?  
 Yes ☐ No ☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?  
 Yes ☐ No ☒

CIVIL: (Place ☒ in ONE CATEGORY ONLY)

A. Federal Question Cases:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☒ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases  
 (Please specify) \_\_\_\_\_

B. Diversity Jurisdiction Cases:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☐ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases  
 (Please specify) \_\_\_\_\_

ARBITRATION CERTIFICATION

(Check Appropriate Category)

I, Virginia L. Hardwick, counsel of record do hereby certify:  
☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs;  
☐ Relief other than monetary damages is sought.

DATE: 8/28/13

Virginia L. Hardwick  
 Attorney-at-Law

202649

Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 8/28/13

Virginia L. Hardwick  
 Attorney-at-Law

202649

Attorney I.D.#

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 54 Peoples Line Road, Somerset, NJ  
Address of Defendant: 250 Cross Lane Farm, York, PA; 150 N. Radnor Chester Rd., Shadford PA  
Place of Accident, Incident or Transaction: Pennsylvania  
(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a))

Yes ☐ No ☐

Does this case involve multidistrict litigation possibilities?

Yes ☐ No ☒

RELATED CASE, IF ANY:

Case Number: \_\_\_\_\_ Judge \_\_\_\_\_ Date Terminated: \_\_\_\_\_

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?  
Yes ☐ No ☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?  
Yes ☐ No ☒
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court?  
Yes ☐ No ☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?  
Yes ☐ No ☒

CIVIL: (Place ☒ in ONE CATEGORY ONLY)

A. Federal Question Cases:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☒ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases  
(Please specify) \_\_\_\_\_

B. Diversity Jurisdiction Cases:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify) \_\_\_\_\_
7. ☐ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases

(Please specify) \_\_\_\_\_

ARBITRATION CERTIFICATION

(Check Appropriate Category)

- I, Virginia L. Hardwick, counsel of record do hereby certify:
- ☒ Pursuant to Local Civil Rule 53.2, Section 3(e)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs;
- ☐ Relief other than monetary damages is sought.

DATE: 8/28/13

Virginia L. Hardwick  
Attorney-at-Law

202649  
Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 8/28/13

Virginia L. Hardwick  
Attorney-at-Law

202649  
Attorney I.D.#

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**CASE MANAGEMENT TRACK DESIGNATION FORM**

Talbot Smith

CIVIL ACTION

Unilife Corporation, Alan  
Shortall, and Ramin Mojdeh

NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

**SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:**

- (a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) ( )
- (f) Standard Management – Cases that do not fall into any one of the other tracks. (✓)

8/28/13  
Date

Virginia L. Hardwick  
Attorney-at-law

Plaintiff  
Attorney for

(215) 230-1912

(215) 230-1913

vhardwick@hardwickcollier.com  
E-Mail Address  
wfreym@hardwickcollier.com

Telephone

FAX Number

E-Mail Address

United States District Court  
Eastern District Of Pennsylvania  
United States Courthouse  
Independence Mall West  
601 Market Street  
Philadelphia, PA 19106-1797

*Chambers of  
James T. Giles  
Chief Judge*

*Michael E. Kunz  
Clerk of Court*

*Clerk's Office  
Room 2609  
Telephone  
(215)597-7704*

NOTICE OF RIGHT TO CONSENT TO EXERCISE OF JURISDICTION  
BY A UNITED STATES MAGISTRATE JUDGE

The district judges of this Court have found that the United States magistrate judges are experienced judicial officers who have regularly handled the disposition of hundreds of civil cases through motions and trials and are fully qualified to try any civil cases arising before this Court.

In accordance with the provisions of 28 U.S.C. §636(c), you are hereby notified that pursuant to Local Rules 72.1(h), the United States magistrate judges of this district, in addition to their other duties, may, upon the consent of all the parties in a civil case, conduct any or all proceedings in a civil case, including a jury or non-jury trial, and order the entry of a final judgement. Appropriate consent forms for this purpose are available from the clerk of court.

Your decision to consent, or not to consent, to the referral of your case to a United States magistrate judge for disposition is entirely voluntary and should be communicated solely to the clerk of the district court. Only if all the parties in the case consent to the reference to a magistrate judge will either the judge or magistrate judge be informed of your decision. If you decide to consent, your case will receive a date certain for trial.

No action eligible for arbitration will be referred by consent of the parties until the arbitration has been concluded and trial *de novo* demanded pursuant to Local Rules 53.2, Paragraph 7. The Court may, for good cause shown, or on its own motion, or under extraordinary circumstances shown by any party, vacate a reference of a civil matter to a magistrate judge.

When a case is referred to a magistrate judge for all further proceedings, including the entry of final judgement, the final judgement shall be appealed directly to the Court of Appeals for the Third Circuit in the same manner as an appeal from any other judgement of a district court.

Nothing herein shall be construed to be a limitation of any party's right to seek review by the Supreme Court of the United States.

JAMES T. GILES  
CHIEF JUDGE

MICHAEL E. KUNZ  
CLERK OF COURT

**HARDWICK COLLIER, LLC**

**BY: VIRGINIA HARDWICK, ESQ. (Attorney I.D. No. 202649)**

**JOYCE L. COLLIER, ESQ. (Attorney I.D. No. 54324)**

**TIFFANIE C. BENFER, ESQ. (Attorney I.D. No. 202096)**

179 North Broad Street

Doylestown, PA. 18901

Attorneys for Plaintiff

---

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

---

**TALBOT (TODD) SMITH**

No. \_\_\_\_\_

Plaintiff,

v.

**UNILIFE CORPORATION,  
UNILIFE MEDICAL SOLUTIONS, INC.,  
ALAN SHORTALL, and RAMIN MOJDEH**

Defendants.

---

**COMPLAINT**

**I. INTRODUCTION AND NATURE OF CLAIMS**

1. Plaintiff Talbot (Todd) Smith ("Smith" or "Plaintiff") by his attorneys, Hardwick Collier LLC, brings this action for equitable, monetary, and other relief to redress intentional violations by defendants Unilife Corporation and Unilife Medical Solutions, Inc. (collectively, "Unilife"), and Unilife executives, Alan Shortall ("Shortall") and Ramin Mojdeh ("Mojdeh") pursuant to the Sarbanes-Oxley Act of 2002, 18 U.S.C. § 1514A; the Dodd-Frank Wall Street Reform & Consumer Protection Act, 15 U.S.C. § 78u – 6; and related state common law claims.

2. This action arises out of defendants' discriminatory and retaliatory termination of plaintiff Smith because of his opposition to and protected disclosures

relating to shareholder fraud and Unilife's failure to comply with the requirements of the Food and Drug Administration ("FDA").

## **II. JURISDICTION AND VENUE**

3. This action is brought pursuant to the Sarbanes-Oxley Act of 2002, 18 U.S.C. § 1514A ("Sarbanes-Oxley" or "SOX").

4. A Sarbanes-Oxley Complaint was filed and received by the U.S. Department of Labor/OSHA on or about November 15, 2012.

5. The Secretary of Labor did not make a final determination in this matter after 180 days of a timely filed Complaint pursuant to 18 U.S.C. § 1541A(b)(1)(B), although sufficient prima facie evidence was found to begin an investigation.

6. On August 12, 2013, Plaintiff filed a notice of his intention to file a complaint. Accordingly, under the provisions of 29 C.F.R. 1980.114, Smith now has the right to bring this claim in federal court.

7. This action is also brought pursuant to the Dodd-Frank Wall Street Reform & Consumer Protection Act, 15 U.S.C. § 78u – 6 ("Dodd-Frank").

8. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 since this matter is founded on the existence of a federal question.

9. This Court also has pendent jurisdiction over related state law claims under 28 U.S.C. § 1367(a).

10. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claims occurred in this district. Venue is also proper in this District pursuant to 28 U.S.C. § 1391(b), (c) and (d) because one or more defendants is a resident of this District.



### **III. PARTIES**

11. Plaintiff, Talbot (“Todd”) Smith (“Plaintiff” or “Smith”) is an adult who currently resides at 54 Peoples Line Road, Somerset, New Jersey. Smith was hired by Unilife in September 2011 as Vice President, Integrated Supply Chain, and was thus an employee of Unilife.

12. Smith is a 1987 graduate of Stanford University with a B.S. in Industrial Engineering and a 1988 graduate with an M.S. degree in Operations Research.

13. Smith is highly respected in his field, with substantial experience in supply chain consulting, inventory management, and supply chain management.

14. Smith’s educational and professional background affords him the opportunity to reasonably believe, both subjectively and objectively, what constitutes mail fraud, wire fraud, bank fraud, securities fraud, fraud against shareholders and/or SEC rules and regulation violations.

15. During the time of Smith’s employment, he never received a negative performance evaluation, or any indication that there was any performance-based rationale for the termination of his employment.

16. Smith’s employment was terminated in August 2012, after he made whistleblowing complaints about violations of the law that had occurred or were about to occur, and after he provided information relating to a violation of the securities laws to the Securities and Exchange Commission (“SEC”).

17. Smith was discharged from his employment because he engaged in lawful acts that were protected by SOX.



18. Defendants retaliated against Smith in contravention of SOX and in contravention of Dodd-Frank after he made disclosures that were required or protected under SOX.

19. Defendant Unilife Corporation is corporation organized under the laws of Delaware.

20. Defendant Unilife Medical Solutions, Inc. is the operating division of Unilife Corporation.

21. Unilife is a company covered by Section 806 of SOX having a class of securities registered under Section 12 of the Securities Exchange Act and/or required to file reports under Section 15(d) of that Act.

22. Unilife is a public traded company (NASDAQ:UNIS/ASX:UNS) and describes itself as a “U.S.-based developer, manufacturer and supplier of advanced drug delivery systems . . . .”

23. Unilife’s products include the Unifill and Unitract product lines of safety (retractable) syringes.

24. Unilife’s corporate headquarters and principal place of business is located at 250 Cross Farm Lane, York, Pennsylvania 17406. Unilife also maintains an office at 150 N. Radnor Chester Road, Strafford, Pennsylvania 19087.

25. In October 2009, Unilife accepted a \$5.45 million offer of assistance from the Commonwealth of Pennsylvania.

26. Defendant Alan Shortall (“Shortall”) is the founder and Chief Executive Officer of Unilife.

27. Ramin Mojdeh ("Mojdeh") has been the Chief Operating Officer of Unilife since early 2011. Mojdeh was Smith's direct supervisor.

28. The individual defendants were officers and/or employees of Unilife.

29. The individual defendants had supervisory authority over Smith, and/or had the authority to investigate, discover, or terminate misconduct.

#### **IV. STATEMENT OF FACTS**

30. Unilife extended an employment offer to Smith in August 2011 after an interview process that began in July 2011.

31. Smith was induced to accept employment at Unilife by false representations of Chief Executive Officer Alan Shortall and others – and by press releases issued in July 2011 – that the Unifill product had been validated as required by FDA regulations and that commercial shipments had been made to Sanofi, and that with these accomplishments the company was poised for growth.

32. Smith's employment at Unilife began on September 19, 2011.

33. The terms of Unilife's employment of Smith included an annual salary of \$230,000; a \$10,000 sign on bonus; an annual 30% incentive bonus; stock options; and a restricted stock grant.

##### **A. July 2011 Press Releases**

34. The false or misleading representations that induced Smith to accept employment had been previously made in press releases to shareholders on July 13 and July 19, 2011.

35. On July 13, 2011, Unilife issued a press release to shareholders. Unilife stated that "it has commenced the initial supply of validated product of the Unifill®

syringe to Sanofi” and “Unilife is now in a position to also commence initial sales of the Unifill syringe to other pharmaceutical companies.” (Exhibit A)

36. On July 19, 2011, Unilife issued a press release stating that Unilife “today announced it has commenced the initial sale of the Unifill® ready-to-fill syringe to a U.S.-based global pharmaceutical company.” (Exhibit B)

37. Notwithstanding its statements to investors that it was supplying “validated” product in July 2011, the validation activities and the associated documentation required by the Food and Drug Administration (“FDA”) were not completed and signed off until March 30, 2012.

38. The FDA validation process is a three-part process including (a) proving the manufacturing line can produce the product to specifications; (b) preparing design documentation; and (c) validating the raw materials provided by suppliers.

39. Despite the claims made in the July 2011 press releases, Smith learned after he commenced employment that the company was not supplying “validated” product in July 2011 as claimed in the press releases. When Smith commenced employment, none of the required documentation was available and raw materials had not been validated by the supplier.

40. After he began employment with Unilife, Smith reached the reasonable belief that the July 13 and July 19, 2011 press releases were false and/or misleading.

41. If Unilife was providing product to customers, as Unilife stated in the July press releases, it was providing the product before it was validated (thus violating FDA regulations). Alternatively, if Unilife was providing only samples, it was not making

commercial sales as indicated in its July 2011 press releases. In either case the press releases were false and/or misleading.

42. The false reports made by Unilife in the July 2011 press releases have not been corrected.

43. The July 2011 press releases have been reported as accurate by Unilife through the U.S. Mail and by wire communications such as the Internet, thus constituting mail and wire fraud.

**B. Unilife's FY 2011 SEC 10-K**

44. Unilife made similar false or misleading claims concerning the shipment of validated and/or commercial product in its Fiscal Year 2011 SEC 10-K filing, which was published in September 2011. (Exhibit C)

45. The statements in the 10-K were false or misleading because no sales revenue had been collected from "commercial sales" of the Unifill product.

46. After beginning employment, Smith also learned that, contrary to claims made in the 2011 SEC 10-K filing, the Unifill production line was only partially installed.

47. The Unifill production line was to consist of four large production machines and numerous feeder machines. Only two of the production machines were installed when Smith began work on September 19, 2011; the other two machines were still in Denver, Colorado, and had not yet undergone the required "factory acceptance test" (which is usually required before equipment is shipped) or the "site acceptance test," (which is required once the equipment is installed).

48. The false reports made by Unilife in the 2011 SEC 10-K filing have not been corrected and have been reported as accurate by Unilife through the U.S. Mail and by wire communications such as the Internet, thus constituting mail and wire fraud.

**C. Unilife's Failure to Comply with FDA Requirements and Smith's Complaints About that Failure**

49. Unilife was required to meet validation standards established by the FDA.

50. If Unilife failed to meet FDA regulatory requirements, that failure would harm Unilife's business, and that failure would be significant information for Unilife shareholders.

51. The importance of FDA regulatory requirements was acknowledged by Unilife in its 2011 10-K. Exhibit C at 29 - 31.

52. The three components of FDA validation required for the Unifill product were not completed until about the end of March 2012, despite the fact that Unilife had represented to shareholders since July 2011 that it was shipping validated product.

53. During the time that Smith and others at Unilife were working on meeting the FDA validation requirements, Mojdeh (Smith's supervisor) on more than one occasion expressed frustration to Smith that Smith was following the rules and procedures established by the FDA too closely, and that the careful following of the FDA rules and procedures was causing production delays.

54. During the course of his employment, Smith became highly concerned with Unilife's failure to comply with FDA requirements.

55. Smith voiced these concerns to Mojdeh, his supervisor.

56. Smith also voiced these concerns to Melissa Dehass (Director, Regulatory) and Mark Iampietro (VP Quality Control and Regulatory).

57. Iampietro told Shortall (CEO) about the concerns voiced by Smith.

58. Smith refused to sign documentation relating to the Unifill validation, including the Device Master Record (DMR), a record that is required by the FDA.

59. Smith's refusal to sign was based on a reasonable belief that documents and test results had been falsified to complete the validation.

60. Smith reasonably believed that signing the documentation as requested would have violated the law.

61. In fact, signing the documentation would have been a violation of the law.

62. Smith refused to violate the law.

63. Mojdeh was angry with Smith for his refusal to sign the FDA documentation.

64. Mojdeh signed the FDA documentation in Smith's place.

65. In April 2012, two Corrective Actions/Preventive Actions ("CAPA's") were opened at Smith's request because of non-conformances Smith identified.

66. CAPA is a critical process for addressing non-conformances and failure to open a CAPA when there has been a non-conformance would be a violation of FDA requirements.

67. Specifically, in one instance, unreleased product was shipped to an external laboratory for testing without following proper procedure or keeping required records.

68. In another instance, product from the same lot had been sterilized and then used in validation testing without following procedure or keeping records.

69. The fact that Smith had two CAPA's opened was communicated to Ann Otzenberger (Quality Assurance Manager). Otzenberger communicated this to Iampietro, who communicated it to Shortall.

70. Smith opened an additional CAPA when Mojdeh and Jyoti Gupta entered the production area and violated numerous clean room procedure.

71. Mojdeh expressed his displeasure to Smith about the CAPA arising from the violation of clean room procedures.

72. In another example of violation or potential violation of FDA regulatory requirements, the Material Specification for the Unifill device was changed in order to achieve a passing result after the first process qualification (PQ) run failed in February 2012.

73. Smith voiced objections to Mojdeh and Gupta about this change, telling them that it could be a violation of FDA regulatory requirements.

74. Mojdeh attempted to transfer a key quality control process to Gupta, with the stated objective that quality issues would no longer be reported through the CAPA process.

75. The transfer of the process to Gupta and the failure to report quality issues would be reasonably likely to result in a violation of FDA rules and regulations.

76. Smith reasonably believed that the transfer of the process to Gupta to avoid quality control reports was likely to result in a violation of FDA rules and regulations.

77. Smith reported his concern about this likely violation of FDA rules and regulations to Dehass. Dehass brought the issue to Iampietro. Iampietro informed Shortall.



78. Mojdeh then complained to Smith that Smith had “stirred up trouble” by raising this issue.

79. In about late May 2012, Smith emailed Mojdeh and Gupta to alert them to a violation of FDA guidance for testing. Smith advised them that the suggested procedure would be likely to raise concerns with customers and regulatory body auditors, and that there was a high risk that the suggested procedure would not have reproducible results.

80. The following day, Mojdeh told Smith to come to his office. Mojdeh instructed Smith that he should not put any concerns into emails because they could be used against the company in future legal action.

**D. Unilife Actions to Mislead Investors about Customer Demand and Manufacturing Capacity; Smith’s Complaints About those Actions**

81. Unilife also took actions to mislead investors about its customer demand and manufacturing capacity.

82. To this end, Mojdeh directed Smith to have his team purchase 1,000,000 Unifill components per month in spite of the fact that there was no customer demand or manufacturing capacity to justify this level of purchasing.

83. Mojdeh told Smith that the objective of the purchases was to make suppliers believe that Unilife was manufacturing at this volume, with the hope that the information would leak to financial markets.

84. Smith repeatedly objected to the inflated purchasing objectives, knowing that this action would leave investors with the impression that Unilife was producing product when it was not. Smith also objected to the inflated purchasing because it wasted the company’s available cash.

85. Another action that Unilife took to mislead investors was to run fake production when investors or customers were visiting the facility.

86. On more than one occasion, scrap was run through the machines to make it appear that Unilife was making product when it was not. Product was placed on skids by the warehouse doors to give the false appearance that product was being packaged and sent to customers when it was not.

**E. Other Material Information Withheld from Investors**

87. On or about February 1, 2012, Smith attended a meeting with Shortall (CEO), Jack Kelly (VP, Business Development), Michael Rattigan (VP, Business Development), and Dennis Piers (VP, Finance).

88. At that meeting, Smith reported that an analysis by Manufacturing stated that the likely unit cost for Unifill at an annual volume of 50 million units was about 90 cents.

89. At that time, the expected pricing of the Unifill product to Sanofi was about 50 to 55 cents per unit.

90. The participants in the meeting were told that Shortall expected the cost to be approximately 40 cents per unit. The meeting participants were instructed by CEO Shortall to suppress the results of the analysis that projected a cost of 90 cents per unit.

91. Subsequently, Smith met with Gupta to review a Unifill costing model that indicated a cost of approximately 53 cents per unit. That costing model failed to account for production yields and other factors that would add about 10% to the number. This analysis, therefore, also indicated that Unifill would not be profitable at the price that Sanofi was expected to be willing to pay.

92. Smith told Mojdeh about his concerns.

93. Mojdeh directed that Finance exclude certain product overhead expenses to create the appearance of a more favorable gross margin.

94. Smith was concerned that Mojdeh's suggestion could be deemed shareholder fraud. He questioned R. Richard Wieland (CFO) and Dennis Piers (Vice President, Finance) about whether Mojdeh's directions were permissible.

95. Later, Shortall made comments that were posted on the Yahoo! Finance message board on July 10<sup>th</sup>, 2012 indicating that Unitract was profitable with a 20% gross margin, when Unilife was in fact losing approximately \$1 per unit.

**F. Smith Reports Concerns About Press Releases and 10K**

96. Unilife's senior management was aware of or complicit in the violations and potential violations of FDA regulatory requirements, as alleged in Section C above.

97. Nevertheless, Unilife did not disclose the violations or potential violations of FDA regulatory requirements to its shareholders.

98. In fact, in the 2011 SEC 10-K filing, Unilife falsely communicated to investors that Unilife had a compliant quality system. (Exh. C at 5, 16). The importance of FDA compliance is recognized by Unilife in the 2011 SEC 10-K. (Exh. C at 29 – 31).

99. The investor communications in the 2011 SEC 10-K concerning compliance are directly contradicted by the issues raised by Smith concerning FDA compliance and quality assurance.

100. Management commentary on Unilife's financial statements, the statements made in press releases, and other statements made to investors were not discussed in the quarterly management meeting attended by Smith.

101. Smith reported or discussed his concerns about the statements in the press releases and 10-K to Mojdeh, who had supervisory authority over Smith.

102. Smith also reported or discussed his concerns about the statements in the press releases and 10-K to Mark Iampietro (Vice President of Quality Control and Regulatory) and Melissa Dehass (Director, Regulatory), both of whom had authority to investigate, discover, or terminate misconduct.

103. In conversations with Iampietro in early 2012, Smith told Iampietro about his concerns that the press releases were not accurate. Smith told Iampietro that Smith believed those press releases were misrepresentations to the investor community.

104. Iampietro took the position that the press releases were accurate because the product shipped were “engineering samples.”

105. Smith explained to Iampietro that if the product shipped were “engineering samples,” then it could not be “commercial sales.” Moreover, Iampietro’s argument did not address the misstatement in the press release concerning the sale of “validated product.”

106. The complaints that Smith voiced about false or misleading statements in the July 2011 press releases and in the 2011 SEC 10-K were complaints about violations of the law concerning mail fraud, wire fraud, and/or violations of rules or regulations of the Securities and Exchange Commission or federal laws concerning fraud against shareholders.

107. Even if Smith was mistaken in his belief that the complaints referenced in the paragraph above were about violations of the law, Smith had a reasonable belief that there had been a legal violation.

**G. Smith Complains on Ethics Hotline**

108. During the spring of 2012, Smith was aware that there would be a reduction in the manufacturing workforce because of a lack of customer demand for Unilife products.

109. On June 14 and 15, 2012, numerous Unilife employees were fired as a result of a reduction in force ("RIF").

110. Smith observed that many of those chosen for termination were employees who had complained about or refused to participate in unlawful activities.

111. On June 14, Smith was told to take the rest of the week off, and was told that his position would be changing. Smith was not told that he would be terminated.

112. On June 19, 2012, Smith made an anonymous report of numerous concerns to the Unilife Board of Directors, using the company's ethics reporting website. (Exhibit D). That ethics report included information about numerous activities that Smith reasonably believed constituted a violation of federal law relating to fraud against shareholders, including:

- a. Stock fraud, based on false statements in press releases;
- b. Stock fraud and/or misuse of company resources, based on unnecessary purchases made with the intention of manipulating financial markets;
- c. Suppression of negative information, based on Shortall's direction to employees to suppress information that Unifill would not be profitable or would barely be so, and based on Unilife's failure to disclose design and manufacturing issues;

- d. Compromise of the Quality System, based on numerous violations with respect to FDA regulation and product quality in general, all of which Smith reasonably believed should be reported to shareholders under the law; and
- e. Retaliation against Whistleblowers, based on the selection of individuals for the reduction in force who had expressed reservations about the other violations.

113. That ethics report also raised concerns about the treatment of Massoud Samandi (VP, Research and Development), whose employment had been terminated on June 14.

114. When Smith made the ethics complaint on June 19, he believed he was an employee of Unilife, and he was in fact an employee of Unilife.

115. When Smith made the ethics complaint on June 19, he was not aware that his employment would be terminated.

116. He made the ethics complaint because the events of the week of June 14 were so troubling to him that he could not keep silent any longer.

117. Smith also made the ethics complaint because he came to believe that it would not be effective to continue to complain to Unilife management, because the issues raised in the ethics complaint were well known to upper management.

118. The ethics website assured employees that reports naming senior management would be kept confidential and would not be provided to the managers named until after the investigation was complete.

119. However, the ethics report was not kept confidential.

120. When Smith returned to the office on June 21, Mojdeh had a copy of the ethics report.

121. Mojdeh told Smith that Mojdeh believed that Smith was the author of the ethics complaint. He later told Smith that Shortall also believed that Smith was the author.

122. Mojdeh repeatedly asked Smith about the complaint saying things along the lines of, "It must have been you who did this," and "you were the only one that had this information."

123. Smith did not confirm or deny to Mojdeh that he was the author of the ethics complaint.

124. Mojdeh told Smith on June 21 that the Board had already "dismissed" the June 19 ethics complaint, but that Mojdeh would be providing documentation to the Board so they could close it out.

125. Smith was never interviewed about the ethics complaint.

126. It is believed and therefore averred that the Unilife Board made no investigation of the ethics complaint, other than the accusations of Mojdeh to Smith.

127. It is believed and therefore averred that Unilife's counsel was not informed of the ethics complaint.

**H. Despite Outstanding Performance, Unilife Retaliates Against Smith**

128. Smith's job performance was excellent. He received performance bonuses in February and March of 2012.

129. Smith was never told of any respects in which his job performance was not satisfactory.



130. Smith was asked to participate in the planning of the June 2012 reduction in force.

131. On June 13, after a discussion with Iampietro, Smith sent an email to a number of managers concerning a fact-finding meeting to investigate a problem with the Unitract plunger.

132. That email concerned a significant problem that affected ten batches of assembled syringes, including one that was in distribution.

133. Before the meeting, Mojdeh scolded Smith for putting a quality concern into an email.

134. During the meeting, the participants concluded that there was a quality issue and the need for a potential product recall.

135. In the midst of the meeting on June 13, Smith was called to Mojdeh's office and told that he would be moved to a different job.

136. In the following days, Smith wrote the ethics report and filed it on June 19 as alleged in Section G above.

137. On June 21, Smith returned to the office. As alleged in Section G above, Mojdeh accused Smith of being the author of the ethics complaint.

138. On June 21, Smith was informed that he would be moved to a different office, away from the people with whom he had previously worked.

139. Smith was given the title Vice President of Strategic Planning, but was given no duties other than the preparation of a "strategic plan" for manufacturing to identify steps needed to scale up production.

140. During the days following June 21, Mojdeh told Smith that Smith was not permitted to talk to other employees or to walk through the manufacturing areas that Smith had previously managed. These walkthroughs of the manufacturing areas would also be required to allow Smith to complete his new job assignments.

141. Mojdeh told other employees that they were not to speak to Smith.

142. Unilife and Mojdeh took these steps to isolate Smith to retaliate against him for filing the ethics complaint.

**I. Smith Reports to SEC**

143. On or about July 16, 2012, Smith provided information relating to Unilife's violation of the securities law to the SEC in a manner established by the SEC.

144. On or about August 6, 2012, Smith was interviewed by the SEC.

**J. Unilife further Retaliates Against Smith and Terminates His Employment.**

145. On July 26, 2012, Mojdeh told Smith that Unilife would not have a role for Smith in the company after all.

146. Smith began to interview for other positions.

147. Mojdeh told Smith on August 14, 2012 that Smith's employment would be terminated effective August 31, 2012.

148. Smith's employment was terminated because of his numerous complaints and reports, including complaints and reports about Unilife's violations of the law and of FDA rules and regulations; complaints and reports about shareholder fraud; and Smith's ethics report to the Unilife Board of Directors.

149. After Unilife learned of Smith's whistleblowing claims against it, Unilife continued to retaliate against Smith.

150. Unilife claimed for the first time that Smith's performance was terminated for "performance" reasons, thus damaging Smith's reputation.

151. Unilife also retaliated against Smith by refusing to pay severance

152. Unilife also retaliated against Smith by not properly processing Smith's COBRA paperwork.

153. Unilife, through its counsel, also made a retaliatory threat to Smith, through Smith's counsel, threatening that Unilife or its key employees would sue Smith for defamation unless Smith walked away from his whistleblowing claims.

### **COUNT I**

#### **PLAINTIFF'S CLAIM UNDER SARBANES-OXLEY** **18 U.S.C. § 1514A** **AGAINST ALL DEFENDANTS**

154. Plaintiff incorporates by reference the preceding paragraphs of this Complaint.

155. At all times relevant hereto, Smith was an employee of Unilife.

156. Unilife and the individually named officers and employees of Unilife demoted, suspended, threatened, harassed, discharged, and otherwise discriminated against Smith because Smith took action protected by SOX.

157. Smith provided information concerning conduct which Smith reasonably believed to constitute a violation of section 1341, 1343, 1344, or 1348, any rule or regulation of the Securities and Exchange Commission, or any provision of Federal law relating to fraud against shareholders.

158. Smith provided the aforementioned information to persons with supervisory authority over Smith and/or persons working for Unilife who had the authority to investigate, discover, or terminate misconduct.

159. Unilife is also vicariously liable for the actions of its employees and agents as described above.

160. Defendants terminated Smith's employment and took other discriminatory and retaliatory actions against Smith, motivated in whole or in part by Smith's reports, which were protected by SOX.

161. Because of defendants' actions, Smith suffered damages including loss of income including annual bonus; loss of benefits including 401k, pension, contributions to Social Security and health insurance; loss of restricted stock; compensatory damages; damage to reputation; damage to his career; consequential damages; litigation costs; expert witness fees; and reasonable attorneys' fees.

WHEREFORE, plaintiff, Talbott (Todd) Smith, respectfully requests judgment in his favor and against defendants in an amount exceeding One Hundred and Fifty Thousand Dollars (\$150,000) for compensatory and consequential damages, plus costs of this action, reinstatement, reimbursement of back pay with interest, front pay, attorneys' fees, and such other relief as the Court may deem just, proper and appropriate in the circumstances of this case.

**COUNT II**

**PLAINTIFF'S CLAIM UNDER DODD-FRANK**

**15 U.S.C. § 78u – 6**

**AGAINST ALL DEFENDANTS**

162. Plaintiff incorporates by reference the preceding paragraphs of this Complaint.

163. By informing Unilife Management, the Unilife Board of Directors, and the SEC of Unilife's violations of law, Plaintiff engaged in activity protected under the Dodd-Frank.

164. Defendants were aware of Smith's protected activity in making statements and reports to Unilife Management and the Unilife Board of Directors.

165. After Smith's protected activities, Defendants terminated Smith's employment and took other discriminatory and retaliatory actions against Smith, motivated in whole or in part by Smith's protected activities.

166. Because of defendants' actions, Smith suffered damages including loss of income including annual bonus; loss of benefits including 401k, pension, contributions to Social Security and health insurance; loss of restricted stock; compensatory damages; damage to reputation; damage to his career; consequential damages; litigation costs; expert witness fees; and reasonable attorneys' fees.

WHEREFORE, plaintiff, Talbot (Todd) Smith, respectfully requests judgment in his favor and against defendants in an amount exceeding One Hundred and Fifty Thousand Dollars (\$150,000) for compensatory, and consequential damages, costs of this action, reinstatement, double back pay with interest, front pay, attorneys' fees, and such

other relief as the Court may deem just, proper and appropriate in the circumstances of this case.

**COUNT III**

**PLAINTIFF'S COMMON LAW CLAIM**  
**WRONGFUL TERMINATION**  
**AGAINST DEFENDANT UNILIFE (CORPORATE DEFENDANTS)**

167. Plaintiff incorporates by reference the preceding paragraphs of this Complaint.

168. Smith was required by law to make the reports detailed above of actions by Unilife that violated the law or the regulations and rules of the FDA.

169. As detailed above, Smith refused to participate in or cooperate with actions that would violate Smith's or Unilife's responsibilities under the law.

170. As detailed above, Smith refused to engage in illegal activity.

171. Defendant Unilife terminated Smith's employment and took other retaliatory action against Smith because of Smith's refusal to violate the law and/or because Smith was complying with a legally imposed duty.

172. It is a violation of Pennsylvania public policy to terminate the employment of an employee because of that employee's refusal to violate the law.

173. Pennsylvania also has a public policy interest in the actions of Unilife because Unilife accepted a \$5.45 million offer of assistance from the Commonwealth of Pennsylvania.

174. Unilife's discriminatory and retaliatory actions toward Smith constitute wrongful discharge, in violation of Pennsylvania common law.

WHEREFORE, plaintiff, Talbot (Todd) Smith, respectfully requests judgment in his favor and against defendants in an amount exceeding One Hundred and Fifty Thousand Dollars (\$150,000) for compensatory, consequential, and punitive damages, plus costs of this action, reimbursement of back pay with interest, front pay, and such other relief as the Court may deem just, proper and appropriate in the circumstances of this case.

**HARDWICK COLLIER, LLC**

BY: 

\_\_\_\_\_  
Virginia L. Hardwick, Esquire  
Attorneys for Plaintiff

Dated: August 30, 2013



**EXHIBIT A**



« Previous Release | Next Release »

July 13, 2011

## Unilife Commences Initial Supply of the Unifill® Syringe to Sanofi

YORK, Pa., July 13, 2011 /PRNewswire/ -- Unilife Corporation ("Unilife" or the "Company") (NASDAQ: UNIS; ASX: UNS) today announced it has commenced the initial supply of validated product of the Unifill® syringe to Sanofi, as per the terms of the industrialization agreement between both parties.

Since signing the Exclusive Agreement in July 2008, Sanofi has paid Unilife a total of approximately \$40 million, comprising a \$16 million (euro 10 million) fee in exchange for the exclusive right to negotiate the purchase of the Unifill syringe, and to help fund the Industrialization Program for the device up to a maximum of \$24 million (euro 17 million). Sanofi has secured exclusivity for the Unifill syringe within the full therapeutic classes of antithrombotic agents and vaccines, plus an additional four smaller sub-groups, until June 30, 2014.

Unilife is now in a position to also commence initial sales of the Unifill syringe to other pharmaceutical companies. Upon the receipt of the Unifill syringe, these pharmaceutical customers will typically conduct drug compatibility and stability studies that will test the device in combination with their injectable drugs. The resulting data is then filed as the last step in completing the regulatory process for the drug-device combination product.

Mr. Alan Shortall, CEO of Unilife, said, "The start of initial sales of the Unifill syringe is arguably the most significant achievement in our company's history. We very much appreciate the support of Sanofi since 2003, when they had the initiative and vision to approach us to develop a new generation of prefilled syringes that can help to improve patient care, while also enhancing and saving the lives of healthcare workers.

"The Unifill syringe is generating strong interest from an increasing number of pharmaceutical companies for use in therapeutic classes outside of those retained by Sanofi. These pharmaceutical companies recognize the significant potential of the Unifill syringe to help generate powerful brand differentiation for their injectable drugs within competitive therapeutic drug classes."

Dr. Ramin Mojdeh, COO of Unilife, said, "The integration of safety features within the glass barrel of a prefilled syringe was a challenge that many within the device and pharmaceutical industries thought to be impossible. Yet, through our operational expertise, core technology platform and innovative spirit, we have successfully overcome a number of technical obstacles to commercialize a game-changing device that is now poised to revolutionize the \$2.7 billion market for prefilled syringes.

"The Unifill syringe sits at the leading edge of a rich and diverse platform of advanced drug delivery devices that we are now developing in collaboration with a number of pharmaceutical partners. Having recognized our capacity for device innovation with the Unifill syringe, these top tier pharmaceutical companies are selecting Unilife as their partner to develop other innovative, differentiated and proprietary devices that are customized to address the specific and unmet needs of their biological drugs. These partnerships will enable us to build upon the success of the Unifill syringe and expand our horizons across several additional high-value market sectors for injectable drug delivery devices."

### About Unilife Corporation

Unilife Corporation (NASDAQ: UNIS / ASX: UNS) is a U.S. based developer, manufacturer and supplier of advanced drug delivery systems with state-of-the-art facilities in Pennsylvania. Established in 2002, Unilife works with pharmaceutical and biotechnology companies seeking innovative devices for use with their parenteral drugs and vaccines. Unilife has developed a broad, differentiated proprietary portfolio of its own injectable drug delivery products, including the Unifill® and Unitract® product lines of safety syringes with automatic, operator controlled needle retraction. Unifill represents the world's first prefilled syringe technology integrating safety within the primary drug container. The products are ideally positioned to help pharmaceutical companies maximize the lifecycle of their injectable drugs and enhance patient care. Unifill syringes, together with other devices that are part of the Unilife technology platform, can either be supplied to pharmaceutical customers ready for use, or customized to address the specific requirements of targeted novel drugs.

For more information on Unilife, please visit [www.unilife.com](http://www.unilife.com).

This press release contains forward-looking statements. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements. These forward-looking statements are based on management's beliefs and assumptions and on information currently available to our management. Our management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on any such forward-looking statements because such statements speak only as of the date when made. We do not undertake any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. In addition, forward-looking statements are subject to certain risks and uncertainties that could cause actual results, events and developments to differ materially from our historical experience and our present expectations or projections. These risks and uncertainties include, but are not limited to, those described in "Item 1A. Risk Factors" and elsewhere in our Annual Report on Form 10-K and those described from time to time in other reports which we file with the Securities and Exchange Commission.

General: UNIS-G

Investor Contacts (US):

Investor Contacts (Australia)

Todd Fromer / Gerth Russell     Stuart Fine     Jeff Carter  
KCSA Strategic Communications Carpe DM Inc     Unilife Corporation  
P: + 1 212-682-6300     P: + 1 908 469 1788 P: + 61 2 8346 6500

SOURCE Unilife Corporation

News Provided by Acquire Media

[Close window](#) | [Back to top](#)

Copyright 2012 Unilife Corporation

**EXHIBIT B**



« Previous Release | Next Release »

July 19, 2011

## Unilife Starts Unifill Syringe Sales to Another Pharmaceutical Customer

YORK, Pa., July 19, 2011 /PRNewswire/ -- Unilife Corporation ("Unilife" or the "Company") (NASDAQ: UNIS; ASX: UNS) today announced it has commenced the initial sale of the Unifill® ready-to-fill syringe to a U.S.-based global pharmaceutical company.

The commencement of Unifill sales to this new customer, whose identity remains confidential at this time, follows the initial shipment of the device to Sanofi last week. Unilife continues to expand its customer pipeline as an increasing number of pharmaceutical companies seek access to Unifill for the delivery of their prefilled injectable drugs.

Unilife expects this new U.S.-based pharmaceutical customer to conduct drug compatibility and stability tests with their injectable drugs in combination with Unifill as per standard industry practices for drug-device combination products. The resulting data is then filed to regulatory agencies as a final step before approval.

Mr. Alan Shortall, CEO of Unilife, said, "Unilife is pleased to have commenced initial sales of the Unifill syringe to another global pharmaceutical company. We expect to continue supplying the Unifill syringe to this customer over the coming months to support their drug compatibility and stability tests with a number of target molecules.

"The Unifill syringe is the world's first and only known prefilled syringe with safety features fully integrated within the glass barrel. The Unifill syringe is essentially a primary drug container, a safety device and a sharps disposal unit all rolled into one. It is strongly positioned to help improve patient care and better protect healthcare workers at risk of contracting infectious diseases, such as HIV via needlestick injuries and other potential transmission modes.

"We are pleased with the strong level of interest in the Unifill syringe from a significant number of pharmaceutical and biotechnology companies that recognize its potential to optimize the lifecycles of their injectable drugs and generate powerful brand differentiation within competitive therapeutic classes. We look forward to entering into agreements with a number of additional pharmaceutical partners over the coming months."

### About Unilife Corporation

Unilife Corporation (NASDAQ: UNIS / ASX: UNS) is a U.S. based developer, manufacturer and supplier of advanced drug delivery systems with state-of-the-art facilities in Pennsylvania. Established in 2002, Unilife works with pharmaceutical and biotechnology companies seeking innovative devices for use with their parenteral drugs and vaccines. Unilife has developed a broad, differentiated proprietary portfolio of its own injectable drug delivery products, including the Unifill® and Unitract® product lines of safety syringes with automatic, operator controlled needle retraction. Unifill represents the world's first prefilled syringe technology integrating safety within the primary drug container. The products are ideally positioned to help pharmaceutical companies maximize the lifecycle of their injectable drugs and enhance patient care. Unifill syringes, together with other devices that are part of the Unilife technology platform, can either be supplied to pharmaceutical customers ready for use, or customized to address the specific requirements of targeted novel drugs. For more information on Unilife, please visit [www.unilife.com](http://www.unilife.com).

This press release contains forward-looking statements. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements. These forward-looking statements are based on management's beliefs and assumptions and on information currently available to our management. Our management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on any such forward-looking statements because such statements speak only as of the date when made. We do not undertake any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. In addition, forward-looking statements are subject to certain risks and uncertainties that could cause actual results, events and developments to differ materially from our historical experience and our present expectations or projections. These risks and uncertainties include, but are not limited to, those described in "Item 1A. Risk Factors" and elsewhere in our Annual Report on Form 10-K and those described from time to time in other reports which we file with the Securities and Exchange Commission.

General: UNIS-G

#### **Investor Contacts (US):**

Todd Fromer / Garth Russell     Stuart Fine  
KCSA Strategic Communications     Carpe DM Inc  
P: + 1 212-682-8300

#### **Investor Contacts (Australia)**

Jeff Carter  
Unilife Corporation  
P: + 61 2 8346 6500

SOURCE Unilife Corporation

News Provided by Acquire Media

Copyright 2012 Unilife Corporation

**EXHIBIT C**



# UNILIFE CORP

## FORM 10-K (Annual Report)

Filed 09/13/11 for the Period Ending 06/30/11

Address	633 LOWTHER ROAD LEWISBERRY, PA 17339
Telephone	717 938 9323
CIK	0001476170
Symbol	UNIS
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment & Supplies
Sector	Healthcare
Fiscal Year	06/30

Powered By **EDGAR**Online  
<http://www.edgar-online.com>

© Copyright 2011, EDGAR Online, Inc. All Rights Reserved.

Distribution and use of this document restricted under EDGAR Online, Inc. Terms of Use.



UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Form 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934

For the Fiscal Year Ended June 30, 2011

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number 001-34540

UNILIFE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

27-1049354

(I.R.S. Employer  
Identification No.)

250 Cross Farm Lane, York, Pennsylvania

(Address of principal executive offices)

17406

(Zip Code)

Registrant's telephone number, including area code (717) 384-3400

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value \$0.01 per share	The Nasdaq Stock Market, LLC

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ Smaller reporting company ☐  
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the common equity held by non-affiliates of the registrant as of December 31, 2010, the last business day of the registrant's most recently completed second fiscal quarter was \$310.4 million, computed by reference to the closing sale price of the Company's common stock. For purposes of the foregoing calculation only, the registrant has assumed that all officers and directors of the registrant are affiliates.

As of September 1, 2011, there were 64,058,508 shares of registrant's common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's Definitive Proxy Statement to be filed with the Commission pursuant to Regulation 14A in connection with the registrant's 2011 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this Report. Such Definitive Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days after the conclusion of the registrant's fiscal year ended June 30, 2011.

---

---

**UNILIFE CORPORATION**  
**FORM 10-K**  
**FOR THE YEAR ENDED JUNE 30, 2011**

**TABLE OF CONTENTS**

	<u>Page</u>
<b>PART I</b>	
Item 1. Business	4
Item 1A. Risk Factors	26
Item 1B. Unresolved Staff Comments	34
Item 2. Properties	35
Item 3. Legal Proceedings	35
Item 4. Removed and Reserved	35
<b>PART II</b>	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	35
Item 6. Selected Financial Data	36
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	37
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	44
Item 8. Financial Statements and Supplementary Data	45
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	75
Item 9A. Controls and Procedures	75
Item 9B. Other Information	75
<b>PART III</b>	
Item 10. Directors, Executive Officers and Corporate Governance	75
Item 11. Executive Compensation	75
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	75
Item 13. Certain Relationships and Related Transactions, and Director Independence	84
Item 14. Principal Accountant Fees and Services	84
<b>PART IV</b>	
Item 15. Exhibits and Financial Statement Schedules	84
EX-12.1	
EX-21	
EX-23.1	
EX-23.2	
EX-31.1	
EX-31.2	
EX-32.1	
EX-32.2	

**Presentation of Information**

Unilife Corporation was incorporated in the State of Delaware on July 2, 2009. On January 27, 2010, Unilife Medical Solutions Limited, an Australian corporation ("UMSL"), completed a redomiciliation from Australia to the State of Delaware pursuant to which stockholders and option holders of UMSL exchanged their interests in UMSL for equivalent interests in Unilife Corporation, a Delaware corporation ("Unilife") and Unilife became the parent company of UMSL and its subsidiaries. The redomiciliation was conducted by way of schemes of arrangement under Australian law. The issuance of Unilife common stock and stock options under the schemes of arrangement was exempt from registration under Section 3(a)(10) of the Securities Act of 1933, as amended. The redomiciliation was approved by the Australian Federal Court, and approved by UMSL shareholders and option holders.

In connection with the redomiciliation, holders of UMSL ordinary shares or share options received one share of Unilife common stock or an option to purchase one share of Unilife common stock, for every six UMSL ordinary shares or share options, respectively, held by such holders, unless the holder elected to receive in lieu of Unilife common stock, Chess Depositary Interests of Unilife, or CDIs (each representing one-sixth of one share of Unilife common stock), in which case such holder received one CDI for every UMSL ordinary share. All share and per share amounts in this Annual Report on Form 10-K have been restated to reflect the one for six share recapitalization effected in connection with the redomiciliation.

On February 16, 2010, Unilife's common stock began trading on the Nasdaq Global Market under the symbol "UNIS."

References to the "Company", "we", "our" or "us" include Unilife Corporation and its consolidated subsidiaries, including UMSL, unless the context otherwise requires. References to "Unilife" are references solely to Unilife Corporation.

**Trademarks, Trade Names and Service Marks**

Unilife®, Unitract® and Unifill® are registered trademarks of Unilife Corporation and its subsidiaries.

**Cantionary Note Regarding Forward-Looking Information**

This Annual Report on Form 10-K contains forward-looking statements. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations." In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements.

These forward-looking statements are based on management's beliefs and assumptions and on information currently available to our management. However, you should not place undue reliance on any such forward-looking statements because such statements speak only as of the date when made. We do not undertake any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. In addition, forward-looking statements are subject to certain risks and uncertainties that could cause actual results, events and developments to differ materially from our historical experience and our present expectations or projections. These risks and uncertainties include, but are not limited to, those described in "Item 1A. Risk Factors" and elsewhere in this Annual Report on Form 10-K and those described from time to time in our future reports which we will file with the Securities and Exchange Commission. You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to this Annual Report on Form 10-K completely.

**Currencies**

Unless indicated otherwise in this Annual Report on Form 10-K, all references to \$ or dollars refer to U.S. dollars. References to A\$ mean the lawful currency of the Commonwealth of Australia. References to € or euros are to the lawful currency of the European Union.

**PART I****Item 1. Business****Overview**

We are a U.S. based developer and commercial supplier of a diversified portfolio of advanced drug delivery systems. We collaborate with pharmaceutical and biotechnology companies seeking to optimize drug lifecycles and generate differentiation for their brand in competitive therapeutic markets through the use of innovative devices that can improve patient care, protect healthcare workers and prevent disease. We have developed a broad portfolio of drug delivery systems in direct response to unmet market needs for macromolecule injectable drugs including biologics.

Our Unifill<sup>®</sup> syringe, the world's first and only known, commercially available, ready-to-fill syringe with automatic, user-controlled safety features integrated within the glass barrel, sits at the leading edge of a proprietary platform of primary drug containers. The Unifill syringe is designed to be supplied to pharmaceutical manufacturers in a form that is ready for filling with an injectable drug or vaccine of up to 1mL in dose volume. As a primary drug container, the Unifill syringe has USP Class Six compatible materials within the drug fluid path. Following our supply of the Unifill syringe to the pharmaceutical company, they are primarily responsible for the filling, packaging, shipment, regulatory approval, clinical use and marketing of the drug-device combination product. The Unifill syringe is suitable for use by healthcare workers and by patients that self-administer prescription medication outside of healthcare facilities.

We have a strategic relationship with Sanofi, a large global pharmaceutical company, pursuant to which it has paid to us 10.0 million euros under an exclusive licensing agreement plus an additional 17.0 million euros during the industrialization program for the Unifill syringe. Together, these payments (equating to approximately \$40 million in total based upon currency rates at the time of payments) provide Sanofi with the exclusive right to negotiate for the purchase of the Unifill syringe within the main therapeutic classes of anti-thrombotic agents, vaccines and four smaller confidential sub-classes until June 30, 2014.

We commenced initial production and supply of the Unifill syringe to Sanofi and one other U.S. based pharmaceutical company in July 2011. We are also in discussions with other pharmaceutical companies regarding the supply of, and access to, the Unifill syringe, within therapeutic drug classes outside of those retained by Sanofi.

We expect that current and future customers will seek to utilize initial units of the Unifill syringe for required compatibility and stability studies with target injectable drugs and vaccines.

Our Unifill portfolio of ready-to-fill syringes with integrated safety features is now being expanded to support the delivery of other prefilled injectable drugs and vaccines. Our Unifill Select syringes are designed for the use of interchangeable needles of up to 1 1/2" in length. They can be prefilled either with liquid stable drugs for therapeutic classes such as vaccines where intramuscular injections are commonly required, or with a diluent for use with lyophilized drugs supplied in a vial for reconstitution at the point of delivery. We have also developed and filed provisional patent applications for the Unifill EZMix range of syringes with multiple chambers that contain the lyophilized drug and the diluent for reconstitution within the single delivery system.

Additional technology platforms that we have developed in response to the unmet device needs of pharmaceutical companies include patient self-administration systems including auto-injectors and wearable subcutaneous pump infusion systems for viscous, large-volume drugs, and other specialized devices for targeted organ delivery. We also supply our Unitract 1mL range of syringes to medical distributors for use within healthcare facilities and by patients that self-administer prescription medication.

These technology platforms may also facilitate the customization of each device to address the specific pharmaceutical, molecular and patient requirements of a target drug supplied in either a liquid stable form or lyophilized for reconstitution. As our devices can form an integral part of the drug-device combination product that is submitted to regulatory agencies for approval, our collaboration with pharmaceutical companies can begin during the early clinical development of a pipeline drug and potentially span its entire commercial lifecycle.

Our goal is to enter into commercial supply contracts with pharmaceutical companies, as well as to enter into development agreements under which a pharmaceutical company may fund the development or customization of a Unilife device for use with its drugs entering into scheduled clinical trials. Programs to develop products suitable for use in scheduled clinical trials are now ongoing with one pharmaceutical company.

We design and manufacture our devices out of a state-of-the-art global headquarters and production facility located in York, Pennsylvania. We opened the 165,000 square foot facility in December 2010 following a \$32 million one-year construction program. The facility includes a 100,000 square foot production center that contains eleven cleanrooms, a product development center, quality labs, machine shops and a fully segregated warehouse. Activities undertaken at the site include device design, rapid prototyping, pilot and commercial production, bio-analytical testing, packaging, quality assurance and supply chain. All activities are guided by business systems, such as SAP ERP, that complement those of pharmaceutical companies. Our Quality Management System is fully certified to ISO 13485 and operates in compliance with 21 CFR 210/211 for pharmaceuticals and 21 CFR 820 for medical devices.

## Market Opportunity

### *The Pharmaceutical Market for Pre-Filled Syringes*

A ready-to-fill or prefilled syringe serves as a primary drug container for an injectable drug or vaccine.

Prefilled syringes have a number of advantages over conventional plastic syringes that typically draw medication from vials or ampoules at the time of administration. First, prefilled syringes help pharmaceutical companies improve manufacturing efficiencies through the elimination of drug wastage commonly associated with the overfilling of multi-use vials. Second, healthcare workers often prefer prefilled syringes because they can facilitate a relatively fast, accurate and convenient administration of a drug. Furthermore, a pre-measured dose of an injectable drug in a prefilled syringe can help reduce the risk of dosing errors. Finally, the relative ease-of-use and accuracy of prefilled syringes can also make them suitable for patient self-administration of many types of prescription medication.

Prefilled syringes are supplied to a pharmaceutical company 'ready for filling' with an injectable drug or vaccine, before it is packaged and shipped for administration by either healthcare workers or by patients that self-administer prescription medication outside of healthcare facilities. Prefilled syringes are made of glass, with USP compliant materials within the fluid path to support the compatibility and stability of the target drug within the device for an average period of at least two years. The majority of prefilled syringes are used with drugs supplied in a liquid stable dose format of up to 1mL in volume, and targeted for administration either by subcutaneous or intramuscular injection. Some lyophilized drugs requiring reconstitution at the point of delivery are also supplied in a dual-chamber prefilled syringe where one container is filled with a drug and another chamber with diluent.

We are aware of more than 50 drugs and vaccines that are currently available in a prefilled syringe format from more than 20 pharmaceutical companies, and believe that a number of pipeline drugs are likely to be supplied in this format in the future. Greystone Associates, a medical and health care technology consulting firm, has estimated that approximately 2.54 billion prefilled syringes were used globally in 2010, and that this number will increase significantly in the coming years. Another market research firm, MarketsandMarkets, estimates that the market for prefilled syringes was valued at \$2.55 billion in 2010, and is projected to increase to \$4.806 billion in 2015, representing a compound average growth rate of 13.5%.

Drugs targeted for use across more than a dozen therapeutic classes that are currently supplied in a prefilled syringe format include anti-coagulants to prevent and treat thrombosis, anti-inflammatories to treat rheumatoid arthritis, anti-infectives to treat hepatitis B and C, hematological drugs to stimulate production of red or white blood cells to treat anemia or fight infection, and vaccines which seek to prevent a range of diseases. We expect that prefilled syringes will also be increasingly used in the coming years as a drug delivery device for other therapeutic drug classes including obstetrics, oncology, osteoporosis and human growth hormone treatment.



*Increased Focus on Prevention of Needlestick Injuries*

The World Health Organization estimates that 1.3 million people die each year as a result of unsafe injection practices, which can include syringe re-use and needlestick injuries. Unsafe injection practices result in the transmission of a number of blood-borne diseases such as HIV/AIDS and hepatitis C. The U.S. Centers for Disease Control and Prevention estimates that 385,000 needlestick and other sharps-related injuries are sustained by U.S. hospital-based healthcare personnel each year. The U.S. Occupational Safety and Health Administration, or OSHA, estimates that when other secondary healthcare settings are also taken into account, there are as many as 800,000 needlestick injuries to U.S. healthcare workers each year. To help minimize the transmission of blood-borne pathogens caused by unsafe injection practices, many international healthcare and pharmaceutical markets are transitioning to the mandatory use of safety syringes.

In many sophisticated healthcare markets, governments are focused on the mandatory use of safety devices within healthcare facilities to protect healthcare workers from the risk of acquiring blood-borne pathogens via needlestick injuries. The United States was the first nation to mandate the use of safety syringes and other safety-engineered medical devices within healthcare facilities, with the adoption of the Federal Needlestick Prevention Act in 2000, or FNSPA, and the subsequent revision to the Bloodborne Pathogens Standard (BPS).

The European Union has also introduced a directive in March 2010 requiring member countries to introduce laws within three years requiring the use of needlestick prevention products within healthcare facilities. Other countries such as Canada and Australia have also taken steps to encourage the use of safety syringes. As a result of this existing and proposed legislation, safety syringes are now commonly used within the healthcare facilities in a number of countries.

The United States represents the largest and most mature market for safety syringes, with a substantial majority of hypodermic syringes and needles used within acute-care facilities featuring some type of needlestick prevention device. Notwithstanding the increased use of safety syringes, we believe that current safety syringe technologies are in several respects inadequate to fully protect healthcare workers from infection risk caused by needlestick injuries or other potential transmission modes. First, most products currently available require operators to manually slide an external plastic guard or sheath over the needle after use, or retract the needle into the barrel at a rapid, uncontrolled rate. Second, healthcare workers may choose to remove or not activate the safety feature of some types of safety syringe products. Moreover, activation of the needle retraction mechanism in the open air for some retractable syringes, rather than inside the body of the patient, may create the potential risk of infection via needlestick injuries or aerosol (splatter).

OSHA differentiates safety features in two primary ways. First, it differentiates *passive* safety features which “remain in effect before, during and after use” from *active* devices which “require the worker to activate the safety mechanism.” Second, OSHA regulations state that products with an “integrated safety design that is an integral part of the device and cannot be removed” are usually preferred to those with an accessory safety device with safety features that are “external” and “dependent on employee compliance.” We believe the majority of safety syringe products used in U.S. healthcare facilities incorporate active safety features which are not fully integrated within the barrel of the syringe.

We are not aware of any prefilled syringe with passive safety features that are integrated within the glass barrel. To improve compliance with legislation such as the FNSPA, a number of pharmaceutical companies attach ancillary safety products onto standard prefilled syringes following dose filling and prior to packaging. We estimate that approximately half of the approved drugs currently available in a prefilled syringe format are supplied by the pharmaceutical manufacturer with some type of ancillary safety device. The majority of these ancillary safety products slide an external plastic sheath or guard over the needle once the injection has been completed.

It is costly for pharmaceutical companies to purchase these ancillary safety products and to operate the automated assembly systems required to attach them onto a standard prefilled syringe. The relatively large size of prefilled syringes supplied with an ancillary safety device can also significantly increase the shipping and packaging costs of pharmaceutical companies. Furthermore, some of these prefilled syringes supplied with an ancillary safety device require the removal of the device from the body prior to activation of the safety mechanism, creating the risk of infection via needlestick injury or aerosol (splatter). Thus, we believe that there is a significant

## Table of Contents

market opportunity for the Unifill syringe that has passive and integrated safety features and is compatible with pharmaceutical companies' drug filling systems.

We also believe there are significant market opportunities for the use of conventional and prefilled safety syringes outside of mainstream healthcare facilities. In addition to insulin, a range of other injectable drugs designed for the prevention and/or treatment of chronic or debilitating conditions such as arthritis, multiple sclerosis and osteoporosis and thrombosis are now available for self-administration. We believe the popularity of safety syringes among patients who self-administer prescription medication may increase due to their capacity to prevent needlestick injuries to family members and encourage safe, convenient disposal. When purchased with a prescription, a number of insurance providers in the U.S. now cover safety insulin syringes under the same tier level for reimbursement as standard insulin syringes.

#### *Increasing Pharmaceutical Investment in Large-Molecule Drugs*

The composition of clinical development pipelines is being increasingly dominated by large-molecule injectable drugs, such as biologics, with specific formulation and delivery requirements. Biological drugs are created by biologic processes, rather than being chemically synthesized. They are used in the treatment of many acute and chronic diseases such as cancer, rheumatoid arthritis, diabetes, multiple sclerosis and growth hormone deficiency. The market for biologics has grown from \$60.3 billion in 2004 to \$109.8 billion in 2010. The injectable drug delivery market is being increasingly driven by the increasing development and marketing of large-molecule drugs and vaccines such as biologics by a number of top tier pharmaceutical companies. According to MarketsandMarkets, the biologics market is expected to grow from \$109.8 billion in 2010 to \$180.9 billion in 2015, representing a compound annual growth rate of 10.5%. Based on available information, we believe that there are more than a thousand large-molecule drugs such as biologics now in the clinical and pre-clinical development pipeline. Biologics are expected to account for 17.5% of total projected global drug sales in 2015.

Due to the protein based structure of biologics, most are fragile in nature. As a result, the vast majority-of-biological drugs is injected into the body and supplied in either a liquid stable or lyophilized form for reconstitution. Due to the specific molecular, formulation and patient requirements of large-molecule drugs including biologics, pharmaceutical companies will often seek to enter into collaborative partnerships with device manufacturers to develop effective drug- device combination products that can enable and enhance their clinical use and commercialization.

In addition to the commercial supply of our devices for approved drugs, we believe there are significant opportunities for us to establish collaborative relationships with pharmaceutical companies whereby we can develop delivery devices in parallel with the clinical development of a target pipeline biological drug. Based upon legal reviews of FDA guidance, we believe that the development of devices that are designed or customized to address the specific requirements of the target molecule can generate unique claims for the drug-device combination product that may make it non-substitutable for biosimilar competitors. We are further aware of a number of biologics that are expected to lose patent protection between 2011 and 2015, which may create opportunities for us to collaborate with manufacturers of biologic or biosimilar drugs to develop innovative or differentiated devices that can potentially extend product lifecycles within increasingly competitive therapeutic drug classes.

#### *Patient-Self-Administration of Injectable Drugs*

Increased prevalence of chronic and debilitating diseases such as diabetes, rheumatoid arthritis, multiple sclerosis and cancer, along with increased life expectancies, has created increasing demand for ways to administer treatment outside of healthcare facilities. The self-administration of injectable medication by patients offers several significant benefits including reduced financial and operational constraints on healthcare facilities and improvements in patient care and overall quality of life. Self-injection devices such as prefilled syringes, auto-injectors, subcutaneous infusion systems and pens are among the device categories that enhance and enable the safe, simple and convenient administration of prescription medications. MarketsandMarkets projects the patient self-injection sector to increase to \$1.2 billion by 2015.

Drug delivery devices that are intuitive to use and have minimal steps of use can increase the overall value of the drug-device combination product. In particular, we believe such devices can help to enhance levels of patient

acceptance to improve adherence to therapy compliance. Such device-related factors can play a significant role in the selection of which drug a physician will prescribe for treatment and its reimbursement. As a result, innovative, patient-friendly devices can help to generate higher numbers of units sold, raise the average selling price per dose, increase levels of market share and generate brand differentiation within competitive therapeutic classes.

## **Our Solutions**

We have developed a diversified and highly innovative portfolio of advanced drug delivery systems in direct response to the unmet needs of pharmaceutical companies, healthcare workers and patients. We consider our devices to be differentiated by their market-driven design and capacity to be developed to address the specific molecular, formulation, clinical, regulatory, patient and marketing requirements of a target drug. By supporting pharmaceutical companies during the clinical development and commercial lifecycles of their drugs, our devices are designed to improve patient care, optimize product lifecycles and generate powerful brand differentiation within competitive therapeutic classes.

### ***Proprietary Technology Platforms***

Our broad platform of primary drug containers and other device technologies has been designed to support the administration of injectable drugs and vaccines, including biologics, supplied in a liquid stable or lyophilized form for reconstitution, across a wide range of therapeutic classes. In our opinion, this technology platform of prefilled syringes, patient-self-injection systems and novel target organ delivery systems represents one of the most diversified and customer-focused device portfolios on the market for use with drugs targeted for administration via common routes such as subcutaneous and intramuscular injection. Our technology platforms cover the following device categories:

#### ***Unifill: Prefilled Syringes (Primary Drug Containers) with Integrated Safety Features***

We have developed a full platform of Unifill ready-to-fill (prefilled) syringes that are designed for use with a broad range of liquid stable and lyophilized drugs and vaccines that are targeted for use in a prefilled format. All Unifill products within this proprietary platform utilize our unique automatic retraction safety mechanism enabling operators to control the speed of needle withdrawal directly from the body into the barrel of the syringe. This combination of automatic, operator-controlled needle retraction features fully integrated within the barrel is designed to minimize the risk of infection via potential transmission modes including needlestick injuries, device reuse or aerosolization (splatter). All components within the fluid path feature USP-compliant materials, with the devices designed to be supplied to customers for integration into their existing fill-finish systems.

The Unifill syringe (see below) sits at the leading edge of this proprietary platform. These devices are manufactured at our FDA-registered facility in York, PA, and available for supply to pharmaceutical companies. Other Unifill ready-to-fill syringes we have developed include primary and multi-container systems featuring either staked (fixed) or interchangeable needles.

Unifill Select syringes feature a primary drug container that can either be utilized as a ready-for injection prefilled delivery system for liquid stable drugs, or with a diluent for use with lyophilized drugs supplied in a vial format for reconstitution at the point of delivery. Interchangeable needles of up to 1.5 inches in length can be attached onto Unifill Select products. All Unifill syringes can be customized to address the specific customer, molecular component and patient requirements of a target drug.

#### ***Clinical (Hypodermic) Syringes***

We have developed a proprietary range of Unitract safety syringes for use with liquid stable drugs supplied in a vial or ampoule are targeted for common administration routes including subcutaneous and intramuscular injection. All Unitract syringes feature a unique combination of automatic and fully integrated safety features that help to enable intuitive use and convenient disposal by either healthcare workers or patients that self-administer prescription medication. An audible, tactile click signals the automatic (passive) activation of the needle retraction mechanism upon the full injection of the dose. Operators can control the speed at which the needle is withdrawn

directly from the body into the barrel of the syringe by relieving thumb or finger pressure on the plunger. The plunger is then locked to prevent needle re-exposure, product tampering or device reuse.

At the leading edge of this platform is the Unitract range of 1mL safety syringes. Product variants including the Unitract Insulin and Tuberculin syringes are approved and available for use within a number of international markets including the U.S., Canada and the European Union. These devices are manufactured at our FDA-registered facility in York, PA.

We have also developed an extended range of Unitract syringes from 3mL in size designed for the intramuscular injection of drugs and vaccines that require the attachment of needles up to 1.5 inches in length

### ***Self-Injection Systems***

#### **Auto-Injectors**

Our Unifill Auto-Injector platform is designed for the self-administration of injectable drugs by patients outside of healthcare facilities. Designed for use with the Unifill ready-to-fill syringes, Unifill Auto-Injectors have been developed in single-use disposable and re-usable configurations, and can be customized to support a range of drug viscosities and patient dexterity requirements.

Due to the integrated safety features of the Unifill syringe, Unifill Auto-Injectors are highly compact in size compared to comparable devices to provide easier portability, compact handling and convenient disposal. We believe that because of its utilization with the Unifill syringe, Unifill Auto-Injectors also offer the first true end-of-dose indicator for the patient self-administration of injectable drugs in an auto-injector format. An audible, tactile click signals the injection of the full dose and the automatic activation of the safety mechanism in the Unifill syringe, which retracts the needle directly from the body into the cylinder. This true end-of-dose indicator ensures the operator is able to intuitively and accurately deliver the full volume of prescribed medication to optimize therapy compliance.

Unifill Auto-Injectors also utilize fewer components than many comparable devices over an equivalent standard prefilled syringe due to its provision with the Unifill syringe.

#### **Auto-Infusors**

We have developed and filed a patent application for what we consider to be a unique technology platform of single-use wearable subcutaneous infusion pump systems enabling patients to self-administer large-molecule injectable drugs between 3mL and 10mL in volume. Unifill Auto-Infusors are designed to serve as a patient-centric delivery system for a number of emerging therapies including biologics that require higher dose volumes, less frequent dosing regimens, and the formulation of more complex injectable molecules. Our range of Auto-Infusors is designed to be worn by the patient for preset infusion times that can span between minutes and hours in duration based upon the requirements of the pharmaceutical company. After the application of the device on or near the injection site and the pushing of a button by the patient, the delivery of the medication commences. Upon the completion of dose delivery, the patient can remove the system from the body for convenient disposal.

Auto-Infusors consist of a primary drug container, the standard fluid path and a drive mechanism that are all modular in design to enable customization to address the specific molecular, viscosity and patient requirements of the target drug. For clinical trial use, our Auto-Infusors can be filled at time of use to eliminate the need for drug compatibility studies. We expect the device will be used in clinical drug trials by pharmaceutical companies scheduled to occur during the 2012 calendar year.

#### **Novel Devices for Targeted Organ Delivery**

We have started working with pharmaceutical companies to develop specialized drug delivery systems to administer biologics and other macro-molecule drugs that require high-precision administration to target organs of the human body. For these projects, this collaboration with the pharmaceutical company can occur early in the clinical development phase. These close relationships that we build with pharmaceutical companies can help to



## Table of Contents

create unique drug-device combination products that can contain and administer the dose to the target organ with high-precision and reliability.

By addressing the specific device innovation needs in parallel with the development of the target pipeline drug, the specialized organ delivery systems that we develop can help to support successful clinical trial outcomes and the filing of regulatory applications with strong claims for the combination product. As a result, our proprietary organ delivery systems may help to generate powerful brand differentiation for the target drug, to create a competitive advantage of over drugs offered by other manufacturers of branded drugs or biosimilar or generic competitors.

### Business Strategy

Our goal is to become established as a preferred partner to pharmaceutical and biotechnology companies in the development and commercial supply of innovative, differentiated delivery systems for the administration of injectable drugs and vaccines. In the near-term, our primary focus is to supply our lead product, the Unifill syringe to pharmaceutical companies in order for them to commence stability and compatibility studies with target drugs.

Over the medium to long-term, we will seek to commercialize a diversified portfolio of advanced drug delivery systems that can help to enable the clinical development and, or enhance the commercial lifecycles of branded, biosimilar and generic drugs across a multitude of therapeutic drug classes. Unlike conventional commodity products marketed by incumbent device manufacturers, it is our goal to develop highly differentiated devices that can be customized to address the specific molecular and patient requirements of a drug and its target patient.

We do not intend to enter any market sectors with devices that have equivalent features as conventional products. Our focus is on innovative, high-value devices that will have unique value-adding features over equivalent products. We can also custom-design our devices, where required, to meet specific needs of pharmaceutical companies. Where our proprietary devices need to be developed or customized to meet the specific requirements of a target drug, we will typically enter into a development program with a pharmaceutical company under which they will provide funding before, subject to regulatory approval, entering into long-term contracts for commercial supply. Through this strategy, we hope to develop and commercially supply a diverse range of injectable drug delivery systems that can help to enhance patient care, improve therapy compliance, protect healthcare workers, prevent disease, reduce healthcare costs and generate powerful brand differentiation for brand-name, generic or biosimilar drugs marketed within competitive therapeutic classes.

We believe we are well positioned to achieve this goal due to a combination of factors that include:

- *Proprietary Safety Syringe Technology:* We have provisional or issued patents for an extensive portfolio of safety syringe technologies that can be applied for use with virtually all liquid-stable or lyophilized drugs and vaccines that are supplied in a vial, ampoule or prefilled format. We are not aware of any other technology platform that incorporates the following safety features that are fully integrated within the barrel of the syringe:
  - Automatic activation of the safety mechanism upon full dose delivery to virtually eliminate the risk of needlestick injuries;
  - The ability for operators to control the speed of needle retraction directly from the body into the barrel to minimize the risk of aerosol (splatter); and
  - The automatic locking of the plunger inside the barrel to prevent needle re-exposure, device reuse or product tampering.
- Patents for our safety syringe technology extend from 2018 to 2030 for core features of our Unifill range of prefilled syringes across multiple jurisdictions including the United States, Europe, Canada, Japan, China and Australia.
- *The Unifill Syringe:* The Unifill syringe is the world's first commercially available and only known, prefilled syringe with safety features that are fully integrated within the glass barrel. Designed to serve as a primary drug container for a range of prefilled drugs and vaccines, the Unifill syringe features USP compliant materials in the fluid path to support drug compatibility and is supplied for integration into fill-

finish lines currently used with conventional prefilled syringes. Unlike ancillary safety devices now utilized by pharmaceutical companies with their prefilled drugs to comply with needlestick prevention laws, the Unifill syringe can minimize the packaging, transport and storage costs of a pharmaceutical company. Sharing similar steps of use to equivalent standard prefilled syringes, the Unifill syringe is suitable for use either by healthcare workers or by patients that self-administer prescription medication.

- *Diversified Portfolio of Advanced Drug Delivery Systems:* The successful development and commercialization of the Unifill syringe has given us the operational capabilities, expertise and industry credibility to expand our research and development activities into a number of other high-value drug delivery sectors where we have identified unmet market needs for device innovation. In direct response to these unmet needs, we have developed a broad and differentiated portfolio of primary drug containers with integrated safety features, patient self-injection systems and novel organ delivery devices.
- *Full Development and Commercial Supply Partner:* We have established our operational capabilities to serve the device innovation requirements of pharmaceutical companies from the clinical development phase of pipeline drugs and then throughout their commercial lifecycles.

Our facilities in York, Pennsylvania have been designed to function as an integrated center for device innovation, pilot and commercial production and quality assurance. Activities undertaken at the site include device design, rapid prototyping, pilot and commercial production, bio-analytical testing, packaging, quality assurance and supply chain. All activities at Unilife are guided by advanced business systems, such as SAP ERP, that complement those of pharmaceutical companies. Our Quality Management System is fully certified to ISO 13485, and in compliance with 21 CFR 210/211 for pharmaceuticals and 21 CFR 820 for medical devices.

## Our Products

### *Unifill Syringe*

The Unifill ready-to-fill syringe is the world's first and only prefilled syringe with automatic safety features fully integrated within the glass barrel. Supplied and designed for integration into fill-finish systems currently used for equivalent conventional prefilled syringes, the Unifill syringe can streamline drug production systems and significantly reduce transport, packaging and storage costs associated with the attachment of ancillary safety products. The Unifill syringe has USP compliant materials within the drug fluid path that are sourced from established pharmaceutical suppliers.

The Unifill syringe is designed for safe, simple and convenient use by either healthcare workers or patients that self-administer prescription medication. Upon the injection of the full dose, an automatic safety mechanism is activated, whereby operators can control the speed of needle retraction directly from the body into the barrel of the syringe. The combination of automatic, operator-controlled retraction features within the Unifill syringe can help to virtually eliminate the risk of infection from needlestick injuries or other potential transmission modes such as aerosolization (splatter). The plunger is then automatically locked to prevent the re-use of the device, circumvent product tampering, and encourage its convenient and compact disposal. The Unifill syringe is now being produced at our production facilities in York, Pennsylvania.

The Unifill syringe is a primary drug container with automatic safety features that are fully integrated within the glass barrel. We believe it is the only ready-to-fill, or prefilled, syringe with such integrated safety features. Currently, many pharmaceutical companies marketing standard (non-safety) prefilled syringes into markets requiring mandatory compliance with needlestick prevention laws have two options. They can either supply the prefilled syringe without a needle into the market, whereby it becomes the responsibility of the healthcare facility to comply with legislation. More commonly, the pharmaceutical company will attach an ancillary safety product over the prefilled syringe before it is packaged and shipped for use. The Unifill syringe can eliminate the purchase of ancillary safety products and their associated cost to attachment it onto a standard prefilled syringe. The Unifill syringe is also similar in size to an equivalent prefilled syringe and significantly smaller than those with an attached ancillary safety product thereby reducing packaging and transportation costs and storage volumes.

As a primary container, all components within the fluid path utilize materials that are USP compliant and can be sourced from established pharmaceutical suppliers. The handling and administration of the Unifill syringe is the

same as injections undertaken with an ordinary prefilled syringe. Upon the delivery of a full dose using the Unifill, a passive retraction mechanism is activated, whereupon operators may control the speed of needle withdrawal directly from the body into the barrel of the syringe to virtually eliminate the risk of needlestick injury or aerosol (splatter). The plunger is then automatically disabled to prevent needle re-exposure, and to facilitate compact, convenient disposal.

The Unifill syringe has been designed in a staked (fixed) needle format for use with therapeutic drugs which are primarily administered via subcutaneous injection and targeted for use either by healthcare workers or patients that self-administer prescription medication outside of healthcare facilities.

The compact size, intuitive use, functionality and automatic safety features of the Unifill syringe compared to other prefilled syringes, including those supplied with an ancillary safety product, may also help pharmaceutical companies optimize product lifecycles, increase levels of market differentiation in competitive therapeutic areas, and expand the marketability of some drugs for convenient self-administration by patients outside of the healthcare setting.

We intend to file a Type III Drug Master File for the product with relevant regulatory authorities such as the FDA. It is the ultimate responsibility of the pharmaceutical company to obtain final approval of the combination drug-delivery device.

### ***Unitract 1mL Syringes***

The Unitract 1mL range of safety syringes is primarily designed for the subcutaneous injection of drugs within healthcare facilities and by patients who self-administer prescription medication such as insulin. In addition to insulin and tuberculin, or TB, variants, the Unitract 1mL range also includes the Unitract Safe Syringe which is custom-designed for use by governments that utilize harm reduction (needle exchange) programs to prevent the reuse, sharing and unsafe disposal practices of Injecting Drug Users (IDUs). Unlike the Unifill ready-to-fill syringe, the Unitract 1mL syringes require healthcare workers or patients to draw up the dose from a vial or ampoule immediately prior to the injection.

We have received regulatory certification for the marketing and sale of various Unitract 1mL syringe products in the United States, Australia and Canada and have received CE Mark approval in the European Union.

### ***Pipeline Products***

We have also developed additional pipeline products which we intend to commercialize in the future, either independently or in collaboration with pharmaceutical and biotechnology companies. These pipeline products include:

#### **Unifill Select**

The Unifill Select range of ready-to-fill syringes combines the benefits of automatic, fully integrated safety features with the ability to attach interchangeable needles of up to 1 and 1/2 inches in length. Unifill Select syringes facilitate the use of injectable drugs and vaccines between 0.2 and 1.5mL in volume that are supplied in either a liquid stable form or lyophilized for reconstitution. Unifill Select delivery systems are designed to be supplied for integration into fill-finish systems used for equivalent conventional 1mL standard, 1mL long or larger prefilled syringes. As primary drug containers with USP class 6 compliant materials within the drug fluid path, Unifill Select products are similar in size to equivalent prefilled syringes. They can be supplied ready-for-injection in a kit format with one or more needles for intuitive and convenient administration either directly into the patient or into an IV port.

The Unifill Select can either be pre-filled with a liquid stable drug or with a diluent for the reconstitution of lyophilized drugs supplied in a vial. In a liquid stable format, the Unifill Select may be selected for use with drugs and vaccines where it is recommended that the healthcare worker select the length and gauge of a needle based upon the age or size of the patient and other specific delivery requirements of the drug. Vaccines are one common therapeutic class where prefilled syringes are commonly supplied with attachable needles, to facilitate their intramuscular injection to the patient. In addition to its targeted use with drugs supplied in a liquid stable format, the

**Table of Contents**

Unifill Select can also be prefilled with a diluent and packaged with a vial adaptor for use with lyophilized drugs requiring reconstitution. As a unique delivery system for liquid stable drugs targeted for intramuscular injection, or other lyophilized drugs, Unifill Select syringes are ideally positioned to generate brand differentiation for drugs marketed within target competitive therapeutic classes to optimize product lifecycles.

**Unifill EZMix**

Unifill EZMix syringes have been developed in direct response to the unmet needs of pharmaceutical companies seeking an innovative and convenient delivery system for the reconstitution and administration of lyophilized drugs and vaccines. Unifill EZmix syringes feature two or more primary drug containers within a single delivery system to store a combination of liquid stable or lyophilized drugs along with up to 1mL of diluent for reconstitution.

In addition to being the world's first and only known dual or multi-chamber prefilled syringes with automatic (passive) safety features fully integrated within the delivery system, the Unifill EZMix syringe offers minimal steps of use for healthcare workers and patients alike. The end-user simply advances the plunger to mix the lyophilized powder with the diluent, before swirling the device to complete reconstitution. An audible, tactile click signals the injection of the full dose and the activation of a passive safety system that allows operators to control the speed of needle retraction directly from the body into the barrel. The Unifill EZMix syringe has been designed for development in either a fixed (staked) needle for drugs indicated for subcutaneous injections, or with attachable needles of up to 1 and 1/2 inches in length.

**Unifill Auto-Injectors**

The Unifill range of auto-injectors has been designed for the accurate, intuitive and convenient administration of injectable drugs by patients outside of healthcare facilities. Developed for use in conjunction with Unifill prefilled syringes, Unifill Auto-Injectors are highly compact in size, and enable patients to inject a measured dose of medication with the simple push of a button. Unlike conventional auto-injector technologies that are used with standard prefilled syringes, we believe the incorporation of the Unifill syringe with its integrated safety features gives Unifill Auto-Injectors several significant market advantages including a relatively small diameter and a true end-of-dose indicator.

The Unifill Auto-Injector platform has been designed to accommodate devices targeted for use in either single-use disposable or re-usable configurations for use across a wide spectrum of therapeutic drug classes. The devices can be custom-designed to support a range of drug viscosities and patient dexterity requirements. With the increasing standardization of many injectable drugs across a number of therapeutic classes in both a stand-alone prefilled syringe format and supplied with an auto-injector, the combination of the Unifill syringe and a compact, accurate auto-injector under one best-in-class technology platform can streamline the pathway to commercial launch and generate powerful brand differentiation during the product lifecycle.

We believe that because of its utilization with the Unifill syringe, Unifill Auto-Injectors also offer the first true end-of-dose indicator for the patient self-administration of injectable drugs in an auto-injector format. An audible, tactile click signals the injection of the full dose and the automatic activation of the safety mechanism in the Unifill syringe, which retracts the needle directly from the body into the cylinder. This true end-of-dose indicator ensures the operator is able to intuitively and accurately deliver the full volume of prescribed medication to optimize therapy compliance. Unifill Auto-Injectors also utilize fewer components than many comparable devices over an equivalent standard prefilled syringe due to its provision with the Unifill syringe.

**Auto-Infusors**

We have developed our proprietary range of single-use, disposable subcutaneous infusion systems for the patient self-injection of drugs between 3mL and 10mL in volume. Our Auto-Infusors are designed to serve as a wearable delivery system for a number of emerging therapies that require large dose volumes, less frequent dosing regimens, and the formulation of more complex injectable molecules. Our Auto-Infusors can be readily attached and conveniently worn by the patient for pre-set infusion times that may span either minutes or hours in duration.



depending upon the requirements of the target drug. After the application of the device onto the injection site and the pushing of a button by the patient, the measured delivery of the medication occurs over a designated period of time.

Our Auto-Infusers consist of a primary drug container, the standard fluid path and a drive mechanism that are all modular in design to enable customization to address the specific molecular, viscosity and patient requirements of the target drug. Upon administration of the full dose, the patient can conveniently dispose of the device. For clinical trial purposes, the AutoInfuser can either be filled at the time of use for the convenience of pharmaceutical companies, or supplied in a prefilled format.

#### **Unitract Clinical Range**

In addition to the commercially available Unitract 1mL syringes, we have developed other hypodermic variants with barrel sizes of 3mL or larger for use with drugs and vaccines supplied in a vial or ampoule and targeted for intramuscular injection. The technology platform behind the Unitract Clinical Range can be used with either a fixed (staked) needle configuration or with attachable needles up to 1 and  $\frac{1}{2}$  inches in length. A range of attachable needle configurations has been developed, including one Unitract variant suitable for use with standard luer slip or luer lock cannulas (needles).

As with all Unitract 1mL or Unifill prefilled syringes, the Unitract Clinical Range to be available in 3mL barrel sizes or larger will include automatic and fully integrated safety features. An audible-tactile click will signal the automatic activation of the safety mechanism and the delivery of the full dose. Operators can control the speed at which the needle is withdrawn directly from the body into the barrel of the syringe by relieving thumb or finger pressure on the plunger. Upon the full retraction of the needle into the barrel, the plunger is locked in place to enable convenient disposal and to prevent syringe reuse, product tampering or needle re-exposure.

#### **Novel Device for Targeted Organ Delivery**

Unilife has also developed its first novel, specialized device for the administration of a drug to a target organ. Unilife is collaborating with a pharmaceutical company to develop this device for use with a target drug scheduled to enter clinical trials during the 2012 fiscal year. Unilife may also develop other novel devices for targeted organ delivery in conjunction with pharmaceutical companies.

#### **Commercial Relationships**

##### ***Sanofi***

We started to collaborate with Sanofi in 2003 for the development of the Unifill syringe as a next-generation drug delivery safety device. Sanofi is a large, global pharmaceutical company, whose products span multiple therapeutic areas, including cardiovascular diseases, thrombosis, oncology, metabolic diseases, internal medicine and vaccines. We believe that Sanofi is currently the world's largest purchaser of prefilled syringes.

We have signed an exclusive licensing agreement with Sanofi. Under the exclusive licensing agreement, we have granted Sanofi an exclusive license to certain of our intellectual property in order and solely to develop, in collaboration with us, the Unifill syringe for use in and sale to the prefilled syringe market within those therapeutic areas agreed upon between us, and a non-exclusive license outside those therapeutic areas that are exclusive to Sanofi or after the expiration of the exclusive license with Sanofi.

We and Sanofi have agreed on a list of therapeutic drug classes that are exclusive to Sanofi. These areas include the full therapeutic classes of antithrombotic agents and vaccines and an additional four smaller subgroups that fall within other therapeutic classes that we believe represent new market opportunities in the pharmaceutical use of prefilled syringes. Sanofi will retain the exclusive right to negotiate to purchase the product within these designated therapeutic drug classes until June 30, 2014, subject to the extension described below.

Pursuant to the exclusive licensing agreement, Sanofi paid to us a 10.0 million euro upfront one-time fee in 2008. The exclusive license granted thereunder has an initial term expiring on June 30, 2014. If, during the term of the exclusive license, Sanofi has purchased the Unifill syringe for use with a particular drug product, Sanofi will receive a ten-year extension of the term of the exclusive license within the therapeutic sub-class in which that drug is

marketed. The extension will be reduced to five years if Sanofi does not sell a minimum of 20 million units of the product in any of the first five years of such ten-year extension period.

Under the exclusive licensing agreement, we are not precluded from using certain of our intellectual property to develop, license and sell any products in any market other than the ready-to-fill syringe market, or from entering into licensing or other business arrangements with other pharmaceutical companies for the ready-to-fill syringe market outside those therapeutic areas that are exclusive to Sanofi, or after the expiration of the exclusive license with Sanofi. If we grant a license to a third party in respect of the ready-to-fill syringe market, then we are required to pay Sanofi 70% of any access, license or other upfront fee received from such third party for access to purchase the products until our payments to Sanofi have totaled 10.0 million euros, following which we are required to pay 30% of such fees we receive through the end of the initial exclusivity period. We are also required to pay Sanofi an annual royalty payment of 5% of the revenue generated from any sale of the Unifill syringe to third parties, up to a maximum amount of 17.0 million euros in such royalty payments.

On June 30, 2009, we signed an industrialization agreement with Sanofi. The industrialization agreement sets forth the terms for the collaboration between the parties to design, develop, scale up and industrialize the Unifill syringe, including the timetable and milestones for the industrialization program. Under the industrialization agreement, Sanofi agreed to make payments of 17.0 million euros to us based on milestones we achieved in our industrialization program. The industrialization program began in July 2008 and was completed in June 2011, with the initial supply of the Unifill syringe to Sanofi in July 2011.

The supply agreement, if completed, will provide that Sanofi and its affiliates will purchase the final product exclusively from us, and the industrialization agreement provides that we are not required to commit more than 30% of our expected installed production capacity to Sanofi and its affiliates for the 12 months following the receipt of a purchase order. Orders from Sanofi, that will exceed the 30% capacity limit will require up to a maximum of 24 months lead time before we are required to commence delivery of that order.

Pursuant to the industrialization agreement, if we agree to, or propose to agree to, a change of control with a third party, we must give written notice to Sanofi, who will be entitled, within five business days, to make an offer on at least equivalent terms. In the absence of an improved change of control proposal, we must accept the matching offer of Sanofi subject to shareholder approval. If we receive an improved change of control offer from the third party, then we must give further notice to Sanofi for it to make a further matching offer. In addition, if during the term of the industrialization agreement, a change of control that does not involve Sanofi, or its affiliates, obtaining control of the company (i) is not recommended by our board of directors, (ii) will cause harm to Sanofi, as defined in the agreement or (iii) under which Mr. Alan Shortall, our CEO and director, is not to continue in such capacities for at least two years after the change of control, then Sanofi will have the right to terminate the industrialization agreement within ten business days after receiving a notice from us, or after it otherwise becomes aware of the change of control. Pursuant to the industrialization agreement, a change of control means, in general terms, a change in the ownership of 50% or more of our shares or the power to determine the majority composition of our board of directors or any other event that our board determines to be a change of control event.

#### *Other Pharmaceutical Relationships*

We are seeking to establish relationships with a number of pharmaceutical and biotechnology companies regarding the supply and use of the Unifill syringe with their injectable drugs outside of those therapeutic classes retained by Sanofi. These relationships may include the signing of commercial agreements relating to the sale of the Unifill syringe, or the provision of exclusive access to the device within designated therapeutic sub-classes in exchange for upfront fees or royalty payments.

We are also engaging in active discussions with many pharmaceutical and biotechnology companies regarding the development and use of other proprietary devices within our portfolio of advanced drug delivery systems. These devices include other primary drug containers within our Unifill family of ready-to-fill syringes, as well as other patient-self injection systems, drug reconstitution systems and target organ delivery devices. We expect to enter into development programs with some of these pharmaceutical companies to design, develop and supply devices for initial use in scheduled clinical trials for target pipeline drugs. Subject to the commercial approval of these drug-device combination products by regulatory agencies, we intend to enter into long-term supply agreements for the

## Table of Contents

production and sale of these devices to the pharmaceutical company. These partnerships may also include the payment of exclusivity or access fees to enable the pharmaceutical company to generate brand differentiation within a therapeutic drug class against other brand-name, generic or biosimilar competitors.

As of September 1, 2011, Unilife had commenced the supply of the Unifill syringe to one additional U.S. based pharmaceutical company. In addition, we have developed a novel device for targeted organ delivery that has already been selected by a large global pharmaceutical company for use in upcoming clinical trials in conjunction with a pipeline biologic.

### Manufacturing

Our center of operations is a state-of-the-art manufacturing facility located in York, Pennsylvania. This state-of-the-art facility serves as an integrated center for device innovation, bringing together the people, production systems, design expertise and quality processes necessary to design and develop best-in-class drug delivery systems. Designed by architects who have substantial experience in designing facilities used to develop, produce and supply medical devices, the FDA-registered site plays a key role in ensuring that we comply with stringent internal and industry standards for quality and reliability.

Our 165,000-square-foot site includes eleven Class 7 and Class 8 clean rooms totaling 40,000 square feet in size. Environmental factors, including temperature, moisture and particulates, are tightly controlled. Additional features include a 'Water for Injection' system, bio-analytical and quality laboratories, a product development center, a machine shop and a 20,000-square-foot warehouse. The facility gives us the capacity to meet the immediate requirements of our pharmaceutical companies, and to progressively expand in line with the development and commercial launch of a series of drug-device combination products.

Activities undertaken at the site include device design, rapid prototyping, pilot and commercial production, bio-analytical testing, packaging, quality assurance and supply chain. All activities at Unilife are guided by advanced business systems, such as SAP ERP, that complement those of pharmaceutical companies. Our Quality Management System is fully certified to ISO 13485 and operates in compliance with 21 CFR 210/211 for pharmaceuticals and 21 CFR 820 for medical devices.

We source the production of components and other raw materials utilized in the production of our proprietary devices under written contracts with a variety of suppliers, all of which specialize in the medical device and pharmaceutical sectors. These components are shipped to our York, Pennsylvania facility for quality review, assembly, qualification and packaging.

Due to an initial requirement for only limited production volumes of components which comprise the Unifill syringe, we currently receive a majority of components, such as rubber seals and glass barrels, from a single-source supplier. To support the industrialization program for this product and further strengthen our supply chain in the long-term, we intend to establish, wherever feasible, a dual-source strategy for the production of key components, raw materials and related services. The companies we expect to appoint for the production and supply of items and related services pertaining to the Unifill syringe all have an established presence in the international drug delivery market, with the majority having facilities in North America and/or Europe. It is our intention to utilize United States made components whenever possible.

All of our proprietary devices are assembled by us at our York, PA facility utilizing pilot or commercial assembly systems. The automated assembly system used to manufacture our Unifill syringes has an optimum capacity of up to 30 million units per year, and was fully designed, developed, built and qualified by our in-house team. The development of the automated assembly lines used to manufacture the Unifill syringe was outsourced to Mikron Assembly Technology, an established industry specialist. The automated assembly system supplied to us by Mikron and now located at our York, PA facility can support the commercial production of up to 60 million units per year of the Unifill syringe. Additional assembly lines, which will be ordered in line with customer demands, are targeted to have an annual manufacturing capacity of approximately 150 million units per year.

## Sales and Marketing

Our primary target customers are pharmaceutical and biotechnology companies which utilize our advanced drug delivery systems to contain injectable drugs and vaccines supplied in a liquid stable or lyophilized form for reconstitution at the point of delivery. These devices are targeted for use within healthcare facilities or by patients that self-administer prescription medication. We are at various stages of discussion with a number of pharmaceutical companies related to entering commercial contracts regarding the development, commercial supply and exclusive use of a variety of our devices.

For the Unifill syringe, we expect the supply of initial production batches to pharmaceutical companies, will be utilized for compatibility and stability studies with target drugs and vaccines. These compatibility and stability studies seek to determine that materials within the device fluid path are compatible with the designated drug to attain a shelf-life of two years or more. This data is utilized in the filing of regulatory applications by the pharmaceutical companies seeking approval of the drug-device combination product. We expect to enter into supply agreements with pharmaceutical companies relating to the use of the Unifill syringe with specific drugs and vaccines during the course of compatibility and stability studies to facilitate the building of product inventory in anticipation of commercial launch of the drug-device combination product.

For other pipeline drug delivery devices in our portfolio, we expect to enter into development agreements with a pharmaceutical company under which they will provide funding to support its industrialization or customization for use with a target drug or vaccine.

The majority of the pharmaceutical and biotechnology companies with whom we are in active discussions are multinational companies with headquarters located in the United States, Europe or Asia. In the majority of cases, these pharmaceutical and biotechnology companies are large multinational organizations which are ranked as being among the top twenty in the world. The majority of these pharmaceutical companies specialize in the development of novel (brand-name) drugs and vaccines. However we may also enter into relationships with pharmaceutical manufacturers of generic or biosimilar drugs, which also recognize the commercial opportunities of utilizing our proprietary devices to generate market differentiation against either the brand-name, other generic or biosimilar competition.

We expect the pharmaceutical company to be primarily responsible for the sale, marketing and clinical use of the combination drug-delivery device to target government agencies, healthcare facilities or patients who self-administer prescription medication within indicated therapeutic drug classes. We expect to support pharmaceutical companies in the development of documentation or marketing material pertaining to the recommended clinical use of the device with the contained drug or vaccine.

We may also enter into agreements for the supply of the Unitract 1mL syringes directly to pharmaceutical companies for use with injectable drug products which are supplied in a vial and marketed in a kit format. We also distribute our Unitract 1mL syringes within the United States via distributors which specialize in target markets such as long-term and acute care healthcare facilities. We are also examining opportunities to enter into relationships for our Unitract 1mL syringes with group purchasing organizations, or GPOs, which secure competitive pricing for items such as syringes on behalf of members such as acute-care hospitals. Over the past decade, many GPOs have introduced programs that encourage the expedient evaluation and selection of innovative products developed by smaller companies. However, we do not expect to fully penetrate the acute-care hospital market until we complete the line of Unitract Clinical Range of larger sizes and access a larger network of customer support representatives and sales agents.

Outside of the United States, we have distributors to sell our Unitract 1mL syringes in India, China, Japan and Taiwan where they are applying for regulatory approval. We also expect to appoint other distributors within other international healthcare markets such as Western Europe and the Asia-Pacific region. Furthermore, we intend to review opportunities to collaborate with governments seeking to examine the use of our Unitract 1mL syringes as a means of helping to prevent the re-use, sharing and unsafe disposal of non-sterile syringes by IDUs.

We have a small internal team focused on the commercial development, strategic marketing, clinical support and sale of our proprietary devices to pharmaceutical and biotechnology companies. Many members of this team have strong industry expertise and deep relationships within the pharmaceutical market, which are utilized to



## Table of Contents

generate and progress commercial discussions. In addition, we also receive direct enquiries or Request for Proposals from pharmaceutical companies regarding the potential use of our devices with their target drugs. In some instances, we expect to be approached by pharmaceutical companies with unmet needs for a drug delivery system, whereby we will develop and customize the device to address the specific molecular and patient requirement of the target drug. We also attend a number of industry events, trade shows and conferences, and advertise within selected industry media publications whereby we exhibit, network and promote our products and services to prospective customers.

### Intellectual Property

Patents, trademarks and other proprietary rights are very important to our business. We also rely on a combination of trade secrets and manufacturing know-how to protect our intellectual property. We hold numerous patents and patent applications covering our products and technologies. Our focus is to safeguard the intellectual property surrounding our devices, manufacturing processes and other related technologies to protect not only our position, but that of our strategic partners and customers.

As of July 2011, we had 45 issued patents relating to our safety syringe and primary drug container platforms across 19 countries including the United States and China. We have filed 66 patent applications in 23 jurisdictions, including Europe, where the applications are reviewed by the 30 countries that participate under the Madrid Protocol. We have filed a significant number of patent applications that are now pending in other countries covered under the Patent Cooperation Treaty.

Our patents relating to our safety syringe technologies expire at various dates between 2018 and 2030. Patents relating to the Unifill syringe are expected to expire by 2030. We also enter into non-disclosure agreements with certain vendors and customers. It is also our policy to have employees sign confidentiality, non-compete and intellectual property assignment agreements.

We classify our patents and patent applications as they relate to particular product categories including 1mL insulin and safe syringes with an attached needle; clinical syringes which include larger sizes and interchangeable luer needles; and our Unifill syringe. Many of the features claimed in the insulin and safe syringes patents, such as the mechanism allowing automatic and controlled needle retraction within an integrated medical device, also apply to our other safety syringe products, including the Unifill syringe. Some key patents covering countries such as Australia, the United States and Europe, as well as some of our international patent applications, are described below:

<u>Document</u>	<u>Patent Number</u>	<u>Application Number</u>	<u>Publication Number</u>	<u>Date</u>
<b>UNITRACT 1mL SYRINGE</b>				
Australia	PATENT 731159			22 September 2018
USA	PATENT 6,083,199			22 September 2018
IPA		PCT/AU2004/000354	WO 2004/082747	
Australia	PATENT 2004222676		AU2004222676	19 March 2024
Canada		2518360	CA2518360	
	PATENT ZL		CN1761497	
China	200480007595.8		CN100479876	19 March 2024
Europe		04721775.7	EP1608421	
India	PATENT 228410			19 March 2024
			JP2006520219 -	
Japan	PATENT 4652326		JP04652326	19 March 2024
USA		US 10/549,710	US-2006-0235354	
Taiwan	PATENT 253944		TWI253944	19 March 2024

## Table of Contents

<u>Document</u>	<u>Patent Number</u>	<u>Application Number</u>	<u>Publication Number</u>	<u>Date</u>
<b>UNTRACT 3mL and 5mL RETRACTABLE SYRINGE with INTERCHANGEABLE NEEDLE</b>				
<b>IPA</b>		<b>PCT/AU2005/000107</b>	<b>WO 2005/072801</b>	<b>(11.08.2005)</b>
Australia	PATENT 2005209014		AU2005209014	28 January 2025
Canada		2554196	CA2554196	
China	PATENT 731869		CN1929887A	28 January 2025
Europe		05700138.0	EP1708772	
USA		10/587,705	US20080255513	
Taiwan	PATENT I 290840		TWI290840	28 January 2025
<b>IPA</b>		<b>PCT/AU2006/000618</b>	<b>WO 2006/119570</b>	<b>(16-11-2006)</b>
Australia	PATENT 2006246309		AU2006246309	11 May 2026
Canada		2607836	CA2607836	
	PATENT ZL			
China	200680016383.5		CN101203258	10 May 2026
Europe		06721494.0	EP1879635 (23-01-2008)	
India		8880/DELNP/2007		
USA		11/914,092	20090221962	
<b>IPA</b>		<b>PCT/AU2010/001504</b>	<b>WO2011/057334</b>	
<u>Document</u>	<u>Patent Number</u>	<u>Application Number</u>	<u>Publication Number</u>	<u>Date</u>
<b>UNIFILL 1.0mL CONTROLLED RETRACTION READY-TO-FILL SYRINGE</b>				
<b>IPA</b>		<b>PCT/AU2006/000516</b>	<b>WO 2006/108243</b>	<b>(19.10.2006)</b>
Australia	PATENT 2006235224	2010210012	AU2006235224	18 April 2026
Canada		2604322	CA2604322	
			CN101203256A	
China		200680019140.7	(18-06-2008)	
Europe		06721397.5	EP1868669 (26.12.2007)	
India		4637/CHENP/2007		
			JP2008 535589	
Japan		2008-505695	(04-09-2008)	
USA		11/911,481	US2009093759	
<b>IPA</b>		<b>PCT/AU2008/000971</b>	<b>WO 2009/003234 A1</b>	<b>(08.01.2009)</b>
Australia		2008271920	AU2008271920	
Canada		CA 2,692,968		
			CN 101730558	
China		200880021389.0	(09-06-2010)	
Europe		08757038.8	EP2162173	
India		7710/CHENP/2009		
Israel		202736	IL202736	
			JP2010-531679	
Japan		2010-513584	(30.09.2010)	
			US20110015572-A1	
USA		12/666448	(20.01.2011)	
Taiwan		97124808		
<b>IPA</b>		<b>PCT/AU2010/001677</b>	<b>WO 2011/075760 A1</b>	<b>(30.06.2011)</b>
<b>IPA</b>		<b>PCT/AU2011/000515</b>		
<b>IPA</b>		<b>PCT/AU2010/001505</b>	<b>WO 2011/057335 A1</b>	

**Table of Contents**

We have registered trademarks including Unilife, Unitract and Unifill in a number of key countries and regions including the United States.

**Government Regulation**

The development, manufacture, sale and distribution of medical devices are subject to comprehensive government regulation. Our medical devices and manufacturing operations are subject to regulation under the Federal Food, Drug and Cosmetic Act, or the FDC Act, as implemented and enforced by the FDA and various other federal and state agencies and are also subject to regulation by foreign governmental agencies. These laws and regulations govern the development, testing, manufacturing, labeling, advertising, marketing and distribution and market surveillance of medical devices.

***FDA's Premarket Clearance and Approval Requirements***

Unless an exemption applies, each medical device we wish to distribute commercially in the United States will require either prior 510(k) clearance or premarket approval from the FDA. The FDA classifies medical devices intended for human use into three classes: Class I, Class II and Class III. Class I or Class II devices require the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Class III devices require premarket approval. Our clinical ranges of syringes, including our Unitract 1mL syringe, are Class II devices. Our Unifill syringe does not require 510(k) clearance because it will be sold to drug manufacturers in its component parts for use as a primary packaging container.

There is a different regulatory process that will apply to our Unifill syringe because it will not be distributed as a device. It will be used as a primary container by drug manufacturers to provide drugs in a prefilled format. In the case of the Unifill syringe, it is the responsibility of the pharmaceutical company who will use the Unifill syringe for its drug to obtain final product approvals, either by submitting a new drug application or abbreviated new drug application. In order to support the pharmaceutical company's application, we intend to create what is known as a Drug Master File ("DMF"). A DMF is a submission to the FDA that may be used to provide information about facilities, processes or articles used in the manufacturing, packaging and storing of one or more human drugs. The DMF will define the manufacturing and safety characteristics of the Unifill syringe while protecting proprietary information regarding its technical design.

***510(k) Clearance Pathway***

When applying for 510(k) clearance, we must submit a premarket notification demonstrating that our proposed device is substantially equivalent to another legally marketed product (i.e., that it has the same intended use and that it is as safe and effective as a legally marketed, or predicate device and does not raise different questions of safety or effectiveness than does a predicate device). According to FDA regulations, the FDA is required to clear or deny a 510(k) premarket notification within 90 days of submission of the application, or 30 days in the case of an abbreviated 510(k) application that may be filed for product line extensions. As a practical matter, 510(k) clearance often takes between three and twelve months.

We received 510(k) clearance for our Unitract 1mL insulin syringe in October 2008 that covered the production of the device by a contractor outside the United States. We received 510(k) clearance for the production of our Unitract 1mL insulin syringe at our Pennsylvania manufacturing facility in March 2010. We received 510(k) clearance for the production of our Unitract 1mL tuberculin syringe at our Pennsylvania manufacturing facility in September 2010.

***Premarket Approval Pathway***

A premarket approval application must be submitted to the FDA if the device cannot be cleared through the 510(k) process. A premarket approval application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. To the best of our knowledge, this process does not apply to our current range of products.



*Pervasive and Continuing Regulation*

After a device is placed on the market, numerous regulatory requirements apply. These include:

- quality system regulations, or QSR, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or “off label” uses;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to occur; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our manufacturing subcontractors.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any or all of the following sanctions:

- fines, injunctions, consent decrees and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspensions or total shutdown of production;
- refusing our requests for 510(k) clearance or premarket approval of new products or new intended uses;
- withdrawing 510(k) clearance or premarket approvals that are already granted; and
- criminal prosecution.

*Regulation in the European Union and Australia*

The European Union has adopted numerous directives regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of the relevant directive will be entitled to bear CE conformity marking, indicating that the device conforms with the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the member states of the European Union. The method of assessing conformity varies depending on the type and class of the product, but normally involves a combination of self-assessment by the manufacturer and a third party assessment by a “Notified Body” which is an independent and neutral institution appointed by a country to conduct the conformity assessment. This third-party assessment may consist of an audit of the manufacturer’s quality system and specific testing of the manufacturer’s device. An assessment by a Notified Body in one member state of the European Union is required in order for a manufacturer to commercially distribute the product throughout these countries. ISO 9001 and ISO 13845 are voluntary harmonized standards. Compliance establishes the presumption of conformity with the essential requirements for CE Marking. In July 2009, we received our ISO 13485:2003 quality system certification. Our certification includes the design, development, production and distribution of sterile syringes and insulin syringes.

We have successfully completed a Notified Body audit to allow our Unitract syringes to bear the CE mark resulting in CE certification for our Unitract insulin and tuberculin 1mL syringes.

In Australia, the Therapeutic Goods Administration, or TGA, is responsible for administering the Australian Therapeutic Goods Act. The Office of Devices, Blood and Tissues is the department within the TGA responsible for medical devices. The Australian Register of Therapeutic Goods, or ARTG, controls the legal supply of therapeutic goods in Australia. The ARTG is the register of information about therapeutic goods for human use that



**Table of Contents**

may be imported, supplied in, or exported from Australia. Any use of an unapproved medical device in humans, even in pilot trials, requires an exemption from the requirement for inclusion on the ARTG. US manufacturers seeking to market product in Australia must acquire CE certification and lodge manufacturer evidence, including the CE certificate and a Declaration of Conformity to Australian Requirements, with the TGA. The lodging of this information with the TGA is completed by an Australian sponsor, with the assistance/support of the manufacturer. Upon TGA acceptance of the manufacturer evidence, the Australian sponsor/manufacturer must create a medical device inclusion in the ARTG and only is then able to release USA-manufactured product in Australia. Our only product that is included on the ARTG is our Unitract 1mL syringe that was previously manufactured for us in China. During June 2010, we received our CE certification for U.S.-manufactured stock of this product. We are currently completing the necessary registration and listing documents for sale of this product in Australia.

With regard to the regulatory process in the European Union and Australia for the Unifill syringe, as in the case of the U.S., it is the responsibility of the pharmaceutical company who will use the Unifill syringe for its drug to obtain final product approvals.

***Other Regulations***

We are also subject to various federal, state and local laws and regulations, both in the United States and other international territories where we conduct business, relating to such matters as safe working conditions, laboratory and manufacturing practices and the use, handling and disposal of hazardous or potentially hazardous substances used in connection with our research and development work. Although we believe we are in compliance with these laws and regulations in all material respects, we cannot provide assurance that we will not be required to incur significant costs to comply with environmental laws or regulations in the future.

We are subject to various federal, state and local laws in the United States targeting fraud and abuse in the healthcare industry, which generally prohibit us from soliciting, offering, receiving or paying any remuneration in order to induce the ordering or purchasing of items or services that are in any way paid for by Medicare, Medicaid or other government-sponsored healthcare programs. Healthcare costs have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. The U.S. federal government continues to scrutinize potentially fraudulent practices affecting Medicare, Medicaid and other government healthcare programs. Payers have become more influential in the marketplace and increasingly are focused on drug and medical device pricing, appropriate drug and medical device utilization and the quality and costs of healthcare. Violations of fraud and abuse-related laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in healthcare programs such as Medicare and Medicaid and health programs outside the United States.

**Competition**

The healthcare equipment, pharmaceutical and medical device industry sectors in which we operate are highly competitive. We compete with many companies, both public and private, that range in size from small, highly focused businesses to large diversified multinational manufacturers of healthcare and pharmaceutical equipment, as more fully described below. Some of the large and established companies we are aware of which are active in the injectable drug delivery device market include Becton Dickinson ("BD"), SCHOTT forma vitrum AG ("Schott"), Baxter Biopharma, B. Braun, Gerresheimer Bünde GmbH ("Gerresheimer"), Terumo, West Pharma, Ypsomed and Owen Mumford. We believe that collectively, these companies represent the significant majority of total revenues for this market, with BD having the largest share. Most of these companies are larger and better-capitalized than we are and have an extensive base of pharmaceutical companies. However, we are aware of very few, if any, other companies, that have developed a broad and diversified portfolio of primary drug containers and other advanced drug delivery systems that are suitable for drugs and vaccines supplied in either a liquid stable or reconstitution form for injection as Unilife's.

***Ready-to-Fill (Prefilled Syringes)***

We do not believe there are any other companies that offer a ready-to-fill syringe with safety features which are fully integrated within the glass barrel. However there is a highly concentrated market for the production of standard

ready-to-fill syringes for supply to pharmaceutical manufacturers. We are aware of five companies which specialize in the production and supply of glass ready-to-fill syringes. These companies are BD, Gerresheimer, MGLAS AG, Schott and Nuova Ompi. We estimate the market concentration rate for these five companies to be approximately 95%. We believe BD's market share to be in excess of 50%, as it has supply relationships with most pharmaceutical companies and contract manufacturing organizations. Of these five aforementioned companies, we believe that BD is the only one which also markets and supplies ancillary safety products for attachment onto standard prefilled syringes to assist pharmaceutical companies in their compliance with needle stick prevention laws. We are aware of another specialist supplier of ancillary safety products, Safety Syringes Inc, which has contracts with a number of pharmaceutical manufacturers.

#### *Hypodermic Clinical Syringes Used with Vials*

The global market for hypodermic clinical (non-pre-filled) syringes is highly competitive, with at least 50 manufacturers located across North America, Europe and the Asia-Pacific. The market for clinical safety syringes is relatively less competitive, yet highly concentrated. We believe BD is the largest global supplier of clinical safety syringes. Other companies which compete in this market sector include Retractable Technologies, Inc, Covidien and Smiths Medical. All of these companies offer a full range of clinical safety syringes, operate a strong sales, distribution and customer support network, and have existing supply relationships with major healthcare buying groups.

#### *Auto-Injectors*

The global market for patient self-injection devices such as auto-injectors is relatively consolidated, with BD and a handful of other companies including Ypsomed, Owen Mumford and SHL Group holding the majority of market share.

#### *Subcutaneous Pump Infusion Systems*

The global market for subcutaneous drug infusion systems targeted for the administration of large volume, highly viscous biologics (outside of the diabetes class) is emerging. We are not aware of any company that commercially markets these systems in a volume size of 5mL or larger. Companies which are active in the more general market for patch pump infusion systems targeted for use with insulin include large established companies such as BD and Medtronic, as well as smaller companies such as Insulet.

#### **Research and Development**

During the fiscal years ended June 30, 2011 and 2010, we invested approximately \$9.6 million and \$10.9 million, respectively, on research and development of our technologies. Research and development costs include activities related to the research, development, design, testing, and manufacturing of prototypes of our products. They also include clinical activities and regulatory costs as well as expenses associated with certain consultants engaged in research and development activities along with a portion of the overhead costs we incur to operate our manufacturing facility.

#### **Employees**

As of September 1, 2011, we had 129 employees and associates, of whom 100 are engaged in operations activities including research and development, quality assurance and manufacturing activities, 7 are engaged in sales, marketing and clinical activities and 22 are engaged in finance, legal and other administrative functions. Most of our employees and all of our executive officers are located at our York, Pennsylvania facility. A small number of our employees, mainly focused on research and development, are located in Radnor, Pennsylvania and Australia. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relations with our employees to be good.

## Corporate History

Unilife Corporation was incorporated in Delaware on July 2, 2009 as a wholly-owned subsidiary of UMSL. As we describe in more detail under “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Redomiciliation,” on January 27, 2010, Unilife Corporation became the parent company of UMSL upon completion of the redomiciliation and UMSL’s shareholders and option holders exchanged their interests in UMSL for equivalent interests in Unilife Corporation. Our principal executive offices are located at 250 Cross Farm Lane, York, Pennsylvania 17406. Our telephone number is +1 717 384 3400.

UMSL was incorporated on June 28, 1985, in South Australia, Australia. The registered office of UMSL is located at Suite 3, Level 11, 1 Chifley Square, Sydney NSW 2000. Originally known as Musgrave Block Holdings Limited, UMSL acquired all of the issued shares of Unitract Pty Limited in November 2002, and changed its name to Unitract Limited (now Unilife Medical Solutions Limited), listed on the Australian Securities Exchange, or ASX under the ticker “UNI” and continued the business operations of Unitract Pty Limited and the development of Unitract Pty Limited’s retractable syringe project. In January 2007, in order to obtain a manufacturing presence in the United States, UMSL acquired all the stock of Integrated BioSciences, Inc., a Pennsylvania-based company, which in February 2009 changed its corporate name to Unilife Medical Solutions, Inc. At the time of its acquisition by UMSL, Integrated BioSciences, Inc. was in the business of contract manufacturing of syringes for third parties and developing automated assembly equipment.

## Financial Information about Geographical Areas

See note 3 to our consolidated financial statements for information regarding our sales by geographic area.

## Available Information

We maintain an internet website at [www.unilife.com](http://www.unilife.com). Our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports are available free of charge through the “Investor Relations” portion of our website, as soon as reasonably practicable after they are filed with the Securities and Exchange Commission. The information posted on our website is not incorporated into this Annual Report on Form 10-K.

## Directors and Executive Officers

The following table sets forth the name, age and position of each of our directors and executive officers.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Slavko James Joseph Bosnjak	62	Chairman and Director
Alan Shortall	57	Director and Chief Executive Officer
John Lund	45	Director
William Galle	71	Director
Jeff Carter	53	Director
Mary Katherine Wold	58	Director
Marc S. Firestone	51	Director
Ramin Mojdehbakhsh	49	Chief Operating Officer and Executive Vice President
R. Richard Wieland II	66	Chief Financial Officer and Executive Vice President
Mark V. Iampietro	58	Vice President of Quality and Regulatory Affairs
Stephen Allan	37	Vice President of Marketing and Communications
J. Christopher Naftzger	44	Vice President, General Counsel, Corporate Secretary and Chief Compliance Officer

## Biographical Summaries

*Slavko James Joseph Bosnjak.* Mr. Bosnjak has served as a director of UMSL since February 2003 and of Unilife Corporation since November 2009 and as Chairman of the board of UMSL since April 2006 and of Unilife

## Table of Contents

Corporation since November 2009, Mr. Bosnjak has been a co-owner and director of the Le Meridien Lav Hotel in Split, Croatia since 2002 and is chairman and co-founder of Ultimate Outdoor Ltd., an Australian outdoor advertising company, Mr. Bosnjak is chairman, and has an indirect interest through the family company Bosnjak Investment Group Pty Ltd, of Chiron Commercial Vehicles Pty Ltd and its subsidiaries, situated in Malaysia, a company which manufactures bus bodies for export to Australia. Mr Bosnjak was a director of Bosnjak Holdings Pty Ltd and its subsidiaries including Westbus Pty Ltd. from 1975 to 2001 and the chairman of Westbus Pty Ltd, between 1990 and 2001. He has also held positions on Commonwealth and New South Wales government advisory bodies, including the Greater Western Sydney Economic Development Board, and the GROW Employment Council. Mr. Bosnjak also served as the Chairman of the Tourism Council of Australia and Bus 2000 Ltd, which coordinated bus services for the Sydney 2000 Olympic Games. Mr. Bosnjak was awarded an Order of Australia Medal in 1994 for his services to transport and the community, and also holds an honorary doctorate from the University of Western Sydney for his services related to employment growth and economic development.

*Alan Shortall.* Mr. Shortall has served as Chief Executive Officer and director of UMSL since September 2002 and of Unilife Corporation since July 2009. Mr. Shortall founded Unilife in July 2002 and has guided the growth of Unilife since then. In 2008, the trade magazine *Medical Device and Diagnostic Industry* named him as one of 100 Notable People in the medical device industry worldwide. Mr. Shortall is the brother of Eugene Shortall, our Senior Vice President of Business Development.

*John Lund.* Mr. Lund has served as a director of UMSL and Unilife Corporation since November 2009. Mr. Lund has also served as managing partner of M&A Holdings, LLC, a private consulting company since July 2003, and as Vice President Finance and Controller of E-rewards, Inc., an internet market research company since February 2009. Mr. Lund also served as Vice President and Controller of Nexstar Broadcasting Group, Inc., a NASDAQ listed television broadcasting company, from March 2008 to November 2008, Vice President of Finance and Corporate Controller of LQ Management, LLC (LaQuinta) from November 2006 to March 2008, and Corporate Controller of ExcellerateHRO from January 2005 to October 2006. Prior to that, Mr. Lund held Controller and Chief Financial Officer positions for various companies, and was a Manager at KPMG.

*William Galle.* Mr. Galle has served as a director of UMSL since June 2008 and of Unilife Corporation since November 2009. Mr. Galle was also an independent director of American Marketing Complex in New York City from October 2007 to December 2009. Since 2009, Mr. Galle has been affiliated with Bradley Woods, a 40 year-old New York City-based independent research and investment banking firm specializing in federal regulatory and legislative developments impacting substantial investor portfolios. Mr. Galle is President of Diversified Portfolio Strategies LLC in Washington D.C. since 1993, which provides alternative investment advisory services for institutions and substantial investors. Mr. Galle is a graduate of Columbia University, Rutgers University, and the New York Institute of Finance.

*Jeff Carter.* Mr. Carter has served as a director of UMSL since April 2006 and of Unilife Corporation since November 2009. From February 2005 until January 2009, Mr. Carter served as Chief Financial Officer of UMSL. He has also served as Company Secretary of UMSL from March 2007 to July 2010. Mr. Carter is a chartered accountant and holds a master's degree in applied finance from Macquarie University of Sydney. Mr. Carter was a Chief Financial Officer of various publicly listed healthcare companies prior to joining UMSL. Also, Mr. Carter was Strategic Planning Manager for Coca-Cola Amatil and Manager Corporate Development International for Santos. He has international experience with these companies and was formerly a Senior Manager of Touche Ross before moving into investment banking with Canadian Imperial Bank of Commerce.

*Mary Katherine Wold.* Ms. Wold has served as a director of Unilife Corporation since May 2010. Ms. Wold is President and Chief Executive Officer of the Church Pension Group, which provides retirement, health, and life insurance benefits to its clergy and lay employees of the U.S. Episcopal Church. Ms. Wold served as Senior Vice President of Finance from 2007 to 2009, Senior Vice President of Tax and Treasury from 2005 to 2007 and Vice President of Tax from 2002 to 2005, of Wyeth, a NYSE-listed pharmaceutical company, which was acquired by Pfizer in October 2009. Prior thereto, Ms. Wold spent 17 years with the international law firm of Shearman & Sterling based in New York, specializing in international tax planning for multinational corporations and in the tax aspects of mergers and acquisitions, capital markets and private equity transactions. Ms. Wold received her law

degree from the University of Michigan and her Bachelor of Arts degree from Hamline University in St. Paul, Minnesota.

*Marc S. Firestone.* Mr. Firestone has served as a director of Unilife Corporation since July 2010. Mr. Firestone serves as Executive Vice President and General Counsel for Kraft Foods Inc., a Fortune 100 company. Prior to his position at Kraft Foods, Mr. Firestone held senior executive positions for Philip Morris Companies and its subsidiaries, including as Senior Vice President and General Counsel, Philip Morris International, and Senior Vice President of Regulatory Affairs, Phillip Morris Companies. Before joining Philip Morris, he was an attorney with Arnold & Porter in Washington, D.C. He holds a juris doctorate from Tulane University School of Law in New Orleans, and a bachelor's degree from Washington & Lee University in Virginia.

*Ramin Mojdehbakhsh.* Mr. Mojdehbakhsh has served as Chief Operating Officer and Executive Vice President since February 2011. Mr. Mojdehbakhsh served as Vice President and General Manager of BD Pharmaceutical Systems, North America between 2008 and 2010 and Worldwide Vice President of Research and Development, BD Medical between 2002 and 2008. Dr. Mojdehbakhsh received a Ph.D. in Computer Science from the University of Minnesota, Minneapolis, MN and his MBA from Kellogg Graduate School of Management, Northwestern University, Evanston, Illinois.

*R. Richard Wieland II.* Mr. Wieland has served as Chief Financial Officer and Executive Vice President since June 2010. Mr. Wieland served as Chief Financial Officer of Cytochroma Inc., a privately-held specialty pharmaceutical company, from May 2008 to May 2009 and served as Executive Vice President and Chief Financial Officer of Advanced Life Sciences Holdings, Inc., a Nasdaq-listed clinical-stage biopharmaceutical company, from June 2004 to April 2008. Mr. Wieland obtained his B.A. in Accounting and Economics from Monmouth College and his M.B.A. from Washington University.

*Mark V. Iampietro.* Mr. Iampietro has served as Vice President of Quality and Regulatory Affairs of UMSL since October 2008 and of Unilife Corporation since November 2009. From May 2002 to July 2008, Mr. Iampietro was Vice President of Quality, Regulatory and Clinical Operations at Spherics, Inc., a pharmaceutical manufacturer, where he managed various phases of quality, regulatory, and clinical programs. Mr. Iampietro holds American Society for Quality certifications as both a quality and reliability engineer and holds a Bachelor of Science degree in life sciences with a minor in engineering from Worcester Polytechnic Institute.

*Stephen Allan.* Mr. Allan has served as Vice President of Marketing and Communications of UMSL since October 2008 and of Unilife Corporation since November 2009. He served as our Director of Communications from November 2007 to October 2008 and our Manager of Communications from July 2002 to November 2007. Prior to joining Unilife, Mr. Allan owned and operated his own Australian public relations firm, which assisted in the management of media relations and government liaison for industry groups in the transport, tourism and economic development sectors. He managed media liaison activities relating to bus transportation during the Sydney 2000 Olympic Games. He also spent five years as a journalist for various Sydney-based newspaper groups. Mr. Allan holds a Bachelor of Communications from Charles Sturt University.

*J. Christopher Naftzger.* Mr. Naftzger has served as Vice President, General Counsel, Corporate Secretary and Chief Compliance Officer of Unilife Corporation since July 2010. Mr. Naftzger served as Assistant General Counsel and Assistant Secretary of Chesapeake Corporation, a NYSE-traded packaging company for the pharmaceutical and healthcare industries, from July 2007 to May 2009 and served as Senior Counsel of Koch Industries, Inc., the second largest privately held company in the U.S., from June 2006 to June 2007. Prior to joining Koch, Mr. Naftzger was a partner at Blank Rome LLP, an international Am Law 100 firm. Mr. Naftzger obtained his B.A. in History and Political Science from Hanipden-Sydney College and his J.D. from the Willamette University College of Law.

#### **Item 1A. Risk Factors**

*Our business faces many risks. We believe the risks described below are the material risks facing the Company. However, the risks described below may not be the only risks we face. Additional unknown risks or risks that we currently consider immaterial may also impair our business operations. If any of the events or circumstances described below actually occurs, our business, financial condition or results of operations could suffer, and the*



*trading price of our shares of common stock could decline significantly. Investors should consider the specific risk factors discussed below, and the other information contained or incorporated by reference herein and the other documents that we file from time to time with the Securities and Exchange Commission.*

### **Risks Relating to Our Business**

*We need additional funding to meet our capital needs. Such funding may not be available on favorable terms, if at all, and may be dilutive to our existing stockholders.*

We need to obtain additional funding for our product development programs and commercialization efforts. We cannot provide assurance that we will be able to raise additional funding, if needed, on terms favorable to us, or at all. If we raise additional funds from debt financing, we may be obligated to abide by restrictive covenants contained in the debt financing agreements, which may make it more difficult for us to operate our business. If we raise additional funds through the issuance of equity securities, our shares of common stock may suffer dilution. If we are unable to secure additional funding, our ability to continue our product development and commercialization programs would be delayed, reduced or eliminated.

*We have received an audit report that includes an explanatory paragraph stating that our recurring losses from operations raise substantial doubt about our ability to continue as a going concern on our 2011 consolidated financial statements.*

The continuation of our company as a going concern is dependent upon our attaining and maintaining profitable operations and/or raising additional capital. Our independent registered public accounting firm included, in their audit report on our consolidated financial statements for the year ended June 30, 2011, an explanatory paragraph regarding the substantial doubt about our ability to continue as a going concern. Our consolidated financial statements contain additional note disclosures describing our liquidity. As a result of this uncertainty, we may have a more difficult time obtaining necessary financing.

*Our success depends in large part on our ability to achieve substantial commercial sales of the Unifill syringe to customers. If we experience problems or delays in securing favorable agreements to supply the Unifill syringe to customers, our business, including our ability to generate significant revenues, will be materially and adversely affected.*

The Unifill syringe is our primary product and, to date, we have derived substantially all of our revenues from our exclusive licensing and industrialization agreements with Sanofi related to its development. However, we have completed the industrialization program and our ability to generate significant revenues will now depend on our ability to negotiate successfully one or more supply agreements for the Unifill syringe with Sanofi and/or other pharmaceutical companies and to begin supplying substantial quantities of the product under such agreements. We cannot predict with certainty if and when we will be able to enter into any supply agreements for the Unifill syringe or what the terms of any such agreements will be. If we are unable to secure favorable supply agreements for the Unifill syringe in a timely manner, our ability to generate significant revenues will be materially and adversely affected.

*We have recently devoted significant attention and resources towards the development of other advanced drug delivery systems. We cannot assure you that we will be able to complete the development of and successfully commercialize these systems.*

A significant element of our recent strategy focuses on developing advanced drug delivery systems that deliver greater benefits to pharmaceutical companies, healthcare workers and patients. These new advanced drug delivery systems are a response to changes in technologies, industry standards and the needs of pharmaceutical companies. Other device companies, and pharmaceutical companies, are attempting to develop alternative therapies or drug administration systems such as needle-free or intradermal injection technology for the treatment or prevention of various diseases. Our success will depend on developing and commercializing new advanced drug delivery systems in order to meet the changing conditions of the marketplace. The development of these advanced drug delivery

systems requires significant research and development, clinical evaluations, regulatory approvals and expenditures of capital. The results of our product development efforts may be affected by a number of factors, including our ability to innovate, develop and manufacture new products, complete clinical trials, obtain regulatory approvals and secure customer orders for these products. In addition, patents obtained by others can preclude or delay our commercialization of a product. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. The development of new or improved products, processes or technologies by other companies may render our products or proposed products obsolete or less competitive.

***We do not expect to be profitable unless and until we negotiate commercial supply agreements for the Unifill syringe and/or we enter into commercial development agreements and commercial supply agreements with our pharmaceutical partners for other advanced drug delivery systems.***

In addition to the expenses related to the completion of the industrialization program for the Unifill syringe, we have incurred and will continue to incur significant expenses related to the development of other advanced drug delivery systems. We will also incur general and administrative expenses related to increasing our manufacturing operations, expanding our sales and marketing capabilities, seeking regulatory approvals, and complying with the requirements related to being a public company in both the United States and Australia. We will not be profitable unless we are successful in selling the Unifill syringe and/or developing and commercializing our other advanced drug delivery systems.

***The Unifill syringe has been designed to be compatible with the drug manufacturing systems currently utilized by Sanofi, which may hinder our ability to sell the product to other pharmaceutical customers whose manufacturing processes may not be compatible with our current product designs.***

The Unifill syringe has been designed to be compatible with the drug filling and packaging systems of Sanofi. To our knowledge, the majority of fill-finish lines are designed and operated in a similar way. However, while the standard glass barrels to be used for the Unifill syringe are also currently utilized by most pharmaceutical companies, the specific processes used by other pharmaceutical companies to fill, manufacture or package prefilled syringes with an injectable drug product may vary from those of Sanofi. Furthermore, pharmaceutical companies may in some cases require the use of materials which are biocompatible with a particular drug compound and to which we do not have access. Such events may require design, material or process changes to our product, or restrict our ability to enter into supply relationships with other pharmaceutical companies and accordingly, may have a material adverse effect on our results of operations and financial condition.

***We may encounter difficulties managing our growth, which could materially harm our business.***

We have rapidly expanded our operations, including our research and development, product development, regulatory, manufacturing, sales, marketing and administrative functions. This expansion has placed, and is expected to continue to place, a significant strain on our management, operational and financial resources. To manage our growth and to develop and commercialize our products, we will be required to improve existing, and implement new, operational and financial systems, procedures and controls and expand, train and manage our growing employee base. In addition, we will need to manage relationships with various manufacturers, suppliers, customers and other organizations. Our failure to accomplish any of these tasks could materially harm our business.

***We depend on our executive officers and key personnel and the loss of them could adversely affect our business.***

Our success depends upon the efforts and abilities of our executive officers and other key personnel, particularly Mr. Alan Shortall, our Chief Executive Officer, and Dr. Ramin Mojdeh, our Chief Operating Officer, to provide strategic direction, manage our operations and maintain a cohesive and stable environment. Although we have employment agreements with Mr. Shortall, Dr. Mojdeh and other key personnel, as well as incentive compensation plans that provide various economic incentives for them to remain with us, these agreements and incentives may not be sufficient to retain them. Our ability to operate successfully and manage our potential future growth also depends significantly upon our ability to attract, retain and motivate highly skilled and qualified

research, technical, clinical, regulatory, sales, marketing, managerial and financial personnel. We face intense competition for such personnel, and we may not be able to attract, retain and motivate these individuals. The loss of our executive officers or other key personnel for any reason or our inability to hire, retain and motivate additional qualified personnel in the future could prevent us from sustaining or growing our business. In addition, we have a limited history of operations under our current officers and directors. Our officers have not worked together for an extensive length of time. If for any reason our management members cannot work efficiently as a team, our business will be adversely affected.

***We will continue to incur significant costs as a result of being a public company in both the United States and Australia.***

We are subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Being a public reporting company in the United States entails significant expense, including costs required for us to comply with the Sarbanes-Oxley Act of 2002. In addition, because our shares of common stock are also listed on the Australian Securities Exchange ("ASX") in the form of CDIs, we are also required to file financial information and make certain other filings with the ASX. Our status as a reporting company in both the United States and Australia makes some activities more time-consuming and costly and causes us to incur legal, accounting and other expenses that are higher than those that are typically incurred by companies that are subject to only one reporting authority.

***Our manufacturing facilities and the manufacturing facilities of our suppliers must comply with applicable regulatory requirements. If we or they fail to achieve or maintain regulatory approval for these manufacturing facilities, our business and our results of operations would be harmed.***

Commercialization of our products requires access to, or the development of, manufacturing facilities that meet applicable regulatory standards to manufacture a sufficient supply of our products. In addition, the FDA must approve facilities that manufacture our products for US commercial purposes, as well as the manufacturing processes and specifications for the product. Suppliers of components of, and products used to manufacture, our products must also comply with FDA and foreign regulatory requirements, which often require significant time, money and record-keeping and quality assurance efforts and subject us and our suppliers to potential regulatory inspections and stoppages. We and our suppliers may not satisfy these requirements. If we or our suppliers do not achieve or maintain required regulatory approval for our manufacturing operations, our commercialization efforts could be delayed, which would harm our business and our results of operations.

***If we experience interruptions in our manufacturing operations, our business will suffer.***

We currently manufacture our products at our York, Pennsylvania facility, with no alternate facilities available. If we were to experience a manufacturing disruption as a result of damage or destruction of the building, equipment failure, acts of God or other force majeure events, our ability to satisfy our obligations to our customers would be adversely affected, which would harm our business and our results of operations.

***The costs of raw materials have a significant impact on the level of expenses that we incur. If the prices of raw materials and related factors such as energy prices increase, and we cannot pass those price increases on to our customers, our results of operations and financial condition would suffer.***

We use a number of raw materials including polymer plastics. The prices of many of these raw materials, such as those sourced from petroleum-based raw materials, are cyclical and volatile. While we would generally attempt to pass along increased costs to our customers in the form of sales price increases, we might not be able to do so, for competitive or contract-related reasons or otherwise. If we could not set our prices to reflect the costs of our raw materials, our results of operations and our financial condition would suffer.



*Disruptions in the supply of key raw materials and difficulties in the supplier qualification process could adversely impact our operations.*

We employ a supply chain management strategy which seeks to source components and materials from a number of established third party companies. Where possible, we seek to establish dual contracts for the supply of particular components or services. However, there is a risk that our supply lines may be interrupted in the event of a supplier production problem, material recall or financial difficulties. If one of our suppliers is unable to supply materials required for production of our products or our strategies for managing these risks are unsuccessful, we may be unable to complete the production of sufficient quantities of product to fulfill customer orders, or complete the qualification of new replacement materials for some programs in time to meet future production requirements. Prolonged disruptions in the supply of any of our key raw materials, difficulty in completing qualification of new sources of supply, or in implementing the use of replacement materials or new sources of supply, could have a material adverse effect on our results of operations, our financial condition or cash flows.

*Some companies we may utilize for the supply of components are also competitors, and they could elect to cease supply relationships with us in the future for competitive reasons.*

Some companies we may utilize for the supply of components for the Unifill syringe also develop and market their own safety products which can be attached onto standard prefilled syringes. These companies may elect to cease supply relationships with us in the future for competitive reasons. This may disrupt our supply chain, cause difficulties in the qualification of new sources of supply and impair our ability to supply customer orders. Such events may have a material adverse effect on our results of operations, our financial condition or cash flows.

*The medical device industry is very competitive.*

Competition in the medical device industry is intense. We face this competition from a wide range of companies. These include large medical device companies, most of which have greater financial and human resources, distribution channels and sales and marketing capabilities than we do. Our ability to compete effectively depends upon our ability to distinguish our company and our products from our competitors and their products. Factors affecting our competitive position include, for example, product design and performance, product safety, sales, marketing and distribution capabilities, success and timing of new product development and introductions and intellectual property protection.

*We are subject to extensive regulation.*

We are subject to extensive regulation by the FDA pursuant to the FDC Act, by comparable agencies in other countries, and by other regulatory agencies and governing bodies. Our products must receive clearance or approval from the FDA or counterpart non-U.S. regulatory agencies before they can be marketed or sold.

The process for obtaining marketing approval or clearance may take a significant period of time and require the expenditure of substantial resources. The process may also require changes to our products or result in limitations on the indicated uses of the products. As a result, our expectations with respect to marketing approval or clearance may prove to be inaccurate and we may not be able to obtain marketing approval or clearance in a timely manner or at all. In addition, regulatory requirements outside the U.S. change frequently, requiring prompt action to maintain compliance, particularly when product modifications are required. Following the introduction of a product, these agencies also periodically review our manufacturing processes and product performance. Our failure to comply with the applicable good manufacturing practices, adverse event reporting, clinical trial and other requirements of these agencies could delay or prevent the production, marketing or sale of our products and result in fines, delays or suspensions of regulatory clearances, closure of manufacturing sites, seizures or recalls of products and damage to our reputation.

*The FDA 510(k) clearance or premarket approval processes may impact our ability to market and sell our products.*

Before a new medical device, or a significant change involving a new use of or claim for an existing medical device, can be distributed commercially in the United States, it must receive either 510(k) clearance or premarket

approval from the FDA, unless an exemption exists. Either process can be expensive and lengthy. We have received 510(k) clearance that covered the production of our Unitract 1mL syringe by a contractor outside the United States as well as at our Pennsylvania manufacturing facility. Our Unifill syringe does not require 510(k) clearance because it will be sold to drug manufacturers for use as drug packaging. The FDA may, however, revise existing regulations or adopt additional regulations, each of which could prevent or delay 510(k) clearance or premarket approval of our new or modified devices, or could impact our ability to market our currently cleared devices. The FDA, for example, has recently announced its intention to review the 510(k) process and consider enhancements that could impact future 510(k) submissions. It has also encouraged manufacturers to consult with the FDA as to the appropriate 510(k) clearance process for any new product. Such changes could result in additional scrutiny by the FDA of 510(k) applications that we will submit for our new or modified devices and could result in delays and increased costs in obtaining FDA clearances, which could materially impact our business, financial condition and results of operations.

We also may be required to obtain either 510(k) clearance or premarket approval from the FDA for some of our new advanced drug delivery systems. Obtaining such FDA clearances could result in delays in bringing these new advanced drug delivery systems to market and could materially impact our business, financial condition and results of operations.

***We may face significant uncertainty in the industry due to government healthcare reform.***

The healthcare industry in the United States is subject to fundamental changes due to the ongoing healthcare reform and the political, economic and regulatory influences. In March 2010, comprehensive healthcare reform legislation was signed into law in the United States through the passage of the Patient Protection and Affordable Health Care Act and the Health Care and Education Reconciliation Act. Among other initiatives, the legislation provides for a 2.3% annual excise tax on the sales of certain medical devices in the United States, commencing in January 2013. This enacted excise tax may adversely affect our operating expenses and results of operations. In addition, various healthcare reform proposals have also emerged at the state level. We cannot predict with certainty what healthcare initiatives, if any, will be implemented at the state level, or what ultimate effect of federal healthcare reform or any future legislation or regulation may have on us or on our customers' purchasing decisions regarding our products and services.

***We are subject to regulation by governments around the world, and if these regulations are not complied with, existing and future operations may be curtailed, and we could be subject to liability.***

The design, development, manufacturing, marketing and labeling of our products are subject to regulation by governmental authorities in the United States, Europe and other countries, including the FDA. The regulatory process can result in required modification or withdrawal of existing products and a substantial delay in the introduction of new products. Also, it is possible that regulatory approval may not be obtained for a new product. Our business may be adversely affected by changes in the regulation of drug products and medical devices.

Our target pharmaceutical customers are also subject to government regulations for the manufacturing, approval, marketing and labeling of therapeutic drug products. An effect of the governmental regulation of our customers' drug products and manufacturing processes is that compliance with regulations makes it costly and time consuming to transition to the use of our devices for existing products, or to secure approval for pipeline products targeted for use with our devices. If regulation of our customers' products incorporating our devices increases over time, it is likely that this would adversely affect our sales and profitability.

***Product defects could adversely affect the results of our operations.***

The design, manufacture and marketing of medical devices involve certain inherent risks. Manufacturing or design defects, unanticipated use of our products, or inadequate disclosure of risks relating to the use of the product can lead to injury or other adverse events. These events could lead to recalls or safety alerts relating to our products (either voluntary or required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of a product from the market. Any recall could result in significant costs, as well as negative publicity and damage to our reputation that could reduce demand for our products. Personal injuries

relating to the use of our products can also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals.

*We may be sued for product liability, which could adversely affect our business.*

The design, manufacture and marketing of medical devices carries a significant risk of product liability claims. We may be held liable if any product we develop and commercialize causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or consumer use. In addition, the safety studies we must perform and the regulatory approvals required to commercialize our medical safety products will not protect us from any such liability. We carry product liability insurance. However, if there were to be product liability claims against us, our insurance may be insufficient to cover the expense of defending against such claims, or may be insufficient to pay or settle such claims. Furthermore, we may be unable to obtain adequate product liability insurance coverage for commercial sales of any of our approved products. If such insurance is insufficient to protect us, our results of operations will suffer. If any product liability claim is made against us, our reputation and future sales will be damaged, even if we have adequate insurance coverage. We also intend to seek product liability insurance for any approved products that we may develop or acquire in the future. There is no guarantee that such coverage will be available when we seek it or at a reasonable cost to us.

*We may be unable to protect our intellectual property rights or may infringe on the intellectual property rights of others.*

Our success depends in part on our ability to obtain and maintain protection in the United States and other countries of the intellectual property relating to or incorporated into our technology and products. Our issued patents expire at various dates between 2018 and 2030. Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us with any competitive advantage or adequate protection. In particular, the advanced drug delivery systems which we are developing and for which we have filed patent applications are relatively new inventions, and we cannot be sure that we will be able to obtain patents on these inventions. Our issued and future patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of terms of patent protection we may have for our products. Changes in patent laws or their interpretation in the United States and other countries could also diminish the value of our intellectual property or narrow the scope of our patent protection. In addition, the legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims or file lawsuits against third parties. This can entail significant costs to us and divert our management's attention from developing and commercializing our products.

There also can be no assurance that third parties will not assert that our products infringe their patent or other intellectual property rights. Any claims, with or without merit, could be time-consuming, result in costly litigation, divert the efforts of our technical and management personnel or require us to pay substantial damages. If we are unsuccessful in defending ourselves against these types of claims, we may be required to do one or more of the following:

- stop, delay or abandon our ongoing or planned commercialization of the product that is the subject of the suit;
- attempt to obtain a license to sell or use the relevant technology or substitute technology, which license may not be available on reasonable terms or at all;
- redesign those products that use the relevant technology; or
- pay substantial damages which could adversely impact our financial condition and ability to execute our business plan and operations.

*If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.*

In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how. We generally seek to protect this information by confidentiality agreements with our employees, consultants, scientific advisors and third parties. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

*Impairment of our goodwill, which represents a significant portion of our total assets, would adversely affect our operating results and we may never realize the full value of our goodwill.*

As of June 30, 2011, we had \$13.3 million of goodwill on our balance sheet, which represented 15% of our total assets. We recorded this goodwill primarily from our historical acquisition activities. Goodwill is subject to, at a minimum, an annual impairment assessment of its carrying value. Any material impairment of our goodwill would likely have a material adverse impact on our results of operations.

*Fluctuations in foreign currency exchange rates could adversely affect our financial condition and results of operations.*

Currently, the majority of our revenues have been derived from payments under our industrialization agreement with Sanofi which provides that Sanofi will pay us in euros, while we incur most of our operating expenses in U.S. dollars or Australian dollars. Changes in foreign currency exchange rates can affect the value of our assets and liabilities, and the amount of our revenues and expenses. We do not currently try to mitigate our exposure to currency exchange rate risks by using hedging transactions. We cannot predict future changes in foreign currency exchange rates, and as a result, we may suffer losses as a result of future fluctuations.

#### **Risk Factors Related to Our Shares of Common Stock**

*The trading price of our shares of common stock may fluctuate significantly.*

The price of our shares of common stock may be volatile, which means that it could decline substantially within a short period of time. The trading price of the shares may fluctuate, and investors may experience a decrease in the value of the shares that they hold, sometimes regardless of our operating performance or prospects. The trading price of our common stock could fluctuate significantly for many reasons, including the following:

- future announcements concerning our business and that of our competitors including in particular, the progress of our commercial sales for the Unifill syringe and the development programs for the other advanced drug delivery devices;
- regulatory developments, enforcement actions bearing on advertising, marketing or sales of our current or pipeline products;
- quarterly variations in operating results;
- introduction of new products or changes in product pricing policies by us or our competitors;
- acquisition or loss of significant customers, distributors or suppliers;
- business acquisitions or divestitures;
- changes in third party reimbursement practices;
- fluctuations of investor interest in the medical device sector; and
- fluctuations in the economy, world political events or general market conditions.

*If there are substantial sales of our shares of common stock, our share price could decline.*

As of September 1, 2011, we had 64,058,508 shares of common stock outstanding. All of those shares of common stock other than 5,204,945 shares held by our affiliates are freely tradable under the Securities Act. Shares held by our affiliates are eligible for resale pursuant to Rule 144. If our stockholders sell a large number of shares of common stock the public market perceives that our stockholders might sell a large number of shares, the prices at which our common stock trades could decline significantly.

In addition, as of September 1, 2011, 13,069,398 shares of our common stock are subject to outstanding stock options and warrants. We have registered the shares issuable upon the exercise of options granted under our 2009 Stock Incentive Plan. In addition, we have effective registration statements covering the resale of shares of our common stock that are issuable upon the exercise of our remaining options and warrants. If these options and warrants are exercised and the holders choose to sell their shares, it could have an adverse effect on the market price for our common stock.

*We do not intend to pay cash dividends in the foreseeable future.*

For the foreseeable future, we do not intend to declare or pay any dividends on our common stock. We intend to retain our earnings, if any, to finance the development and expansion of our business and product lines. Any future decision to declare or pay dividends will be made by our board of directors and will depend upon a number of factors including our financial condition and results of operations. In addition, under our current bank financing agreements, we are not permitted to pay cash dividends without the prior written consent of the lender.

*We may be subject to arbitrage risks.*

Investors may seek to profit by exploiting the difference, if any, in the price of our shares of common stock on the Nasdaq and our CDIs on the ASX. Such arbitrage activities could cause our stock price in the market with the higher value to decrease to the price set by the market with the lower value.

*Our certificate of incorporation, bylaws, the Delaware General Corporation Law and the terms of our industrialization agreement with Sanofi may delay or deter a change of control transaction.*

Certain provisions of our certificate of incorporation and bylaws may have the effect of deterring takeovers, such as those provisions authorizing our board of directors to issue, from time to time, any series of preferred stock and fix the designation, powers, preferences and rights of the shares of such series of preferred stock; prohibiting stockholders from acting by written consent in lieu of a meeting; requiring advance notice of stockholder intention to put forth director nominees or bring up other business at a stockholders' meeting; prohibiting stockholders from calling a special meeting of stockholders; requiring a <sup>662</sup> / 3 % majority stockholder approval in order for stockholders to amend our bylaws or adopt new bylaws; and providing that, subject to the rights of preferred shares, the number of directors is to be fixed exclusively by our board of directors. Section 203 of the Delaware General Corporation Law, from which we did not elect to opt out, provides that if a holder acquires 15% or more of our stock without prior approval of our board of directors, that holder will be subject to certain restrictions on its ability to acquire us within three years. In addition, our industrialization agreement with Sanofi provides to Sanofi the right to match a change of control proposal and to terminate the industrialization agreement under certain circumstances of a change of control event. See "Business — Commercial Relationships — Sanofi." These provisions may delay or deter a change of control of us, and could limit the price that investors might be willing to pay in the future for shares of our common stock.

**Item 1B. Unresolved Staff Comments**

None.



## Item 2. Properties

Our 165,000 square foot global headquarters and manufacturing facility is located on 38 acres of land in York, Pennsylvania. The facility includes 110,000 square feet of production space and 54,000 square feet of office space. The property is subject to a mortgage held by a local bank.

We also have a short term lease for office space in Radnor, Pennsylvania to support our research and development activities.

We also lease 1,100 square feet of office space in Sydney, Australia which is used for certain finance and administrative operations.

## Item 3. Legal Proceedings

In the ordinary course of our business, we may be subject to various claims, pending and potential legal actions for damages, investigations relating to governmental laws and regulations and other matters arising out of the normal conduct of our business. We are not aware of any material pending legal proceedings to which we or any of our subsidiaries is a party or of which any of our properties is the subject.

## Item 4. Removed and Reserved

## PART II

## Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

### Market Information

Commencing February 16, 2010, our shares of common stock began trading on the Nasdaq Global Market under the symbol "UNIS". Our shares of common stock have also traded in the form of CHESS Depositary Interests ("CDIs"), each CDI representing one-sixth of a share of our common stock, on the Australian Securities Exchange ("ASX") under the symbol "UNS" since January 18, 2010. Prior to that date, the ordinary shares of our predecessor Unilife Medical Solutions Limited ("UMSL") were traded on the ASX under the symbol "UNT".

The following table sets forth, for the periods indicated, the high and low closing prices for our common stock on the Nasdaq Global Market (commencing February 16, 2010), the high and low closing prices for our CDIs on the ASX (from January 18, 2010 through February 15, 2010) and the high and low closing prices for the ordinary shares of UMSL (prior to January 18, 2010). The prices of our CDIs (and previously ordinary shares of UMSL) have been adjusted to give effect to the six for one exchange ratio and have been converted to U.S. dollars using the exchange rate on the last day of each respective quarter.

Period	High (US\$)	Low (US\$)
<b>Fiscal Year 2011:</b>		
First Quarter	6.30	4.61
Second Quarter	6.25	5.24
Third Quarter	5.89	4.15
Fourth Quarter	5.86	4.24
<b>Fiscal Year 2010:</b>		
First Quarter	7.20	1.62
Second Quarter	6.30	4.68
Third Quarter	17.90	5.04
Fourth Quarter	8.04	5.28

### Holders

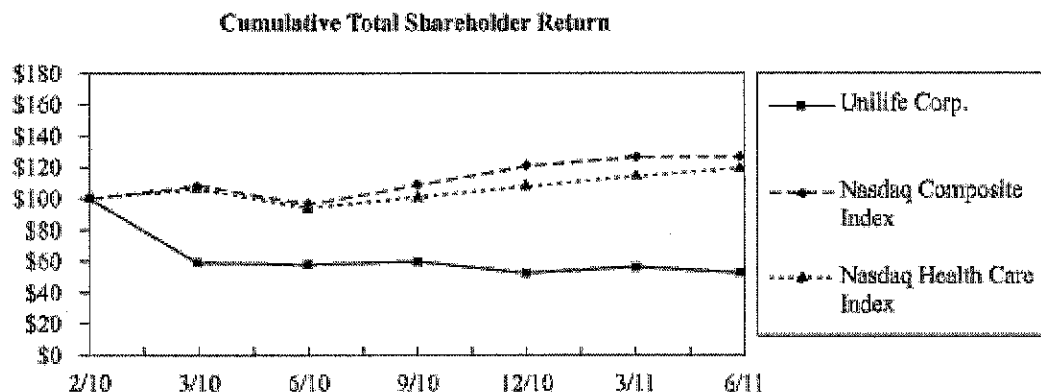
As of September 1, 2011, we had 64,058,508 shares of common stock outstanding, and there were 278 holders of record of our common stock, including Chess Depositary Nominees which held shares of our common stock on behalf of 8,429 CDI holders. The closing sales price for our common stock on September 1, 2011 was \$4.34 as reported by the Nasdaq Global Market.

## Dividends

We currently intend to retain any earnings to finance research and development and the operation and expansion of our business and do not anticipate paying any cash dividends for the foreseeable future. The declaration and payment of any dividends in the future by us will be subject to the sole discretion of our board of directors and will depend upon many factors, including our financial condition, earnings, capital requirements of our operating subsidiaries, covenants associated with certain of our debt obligations, legal requirements, regulatory constraints and other factors deemed relevant by our board of directors. Moreover, if we determine to pay any dividend in the future, there can be no assurance that we will continue to pay such dividends. In addition, under our bank financing agreements, we are not permitted to pay cash dividends without the prior written consent of the lender.

## Performance Graph

The performance graph shown below compares the change in cumulative total shareholder return on shares of common stock with the Nasdaq Stock Market Index (US) and the NASDAQ Health Care Index (US) from February 16, 2010, our first day of trading on the Nasdaq Global Market, through our fiscal 2011 year ended June 30, 2011. The graph sets the beginning value of shares of common stock and the indices at \$100, and assumes that all quarterly dividends were reinvested at the time of payment. This graph does not forecast future performance of shares of common stock.



## Item 6. Selected Financial Data

The following table presents our selected consolidated financial data as of and for each of the years in the five year period ended June 30, 2011. The statements of operations data for the years ended June 30, 2011, 2010 and 2009 and the balance sheet data as of June 30, 2011 and 2010 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. All such data should be read in conjunction with the information under "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our consolidated financial statements and the related notes thereto included elsewhere in this report. The statements of operations data for the year ended June 30, 2008 and 2007 and the balance sheet data as of June 30, 2009, 2008 and 2007 have been derived from our audited consolidated financial statements not included in this Annual Report on Form 10-K. Historical results are not necessarily indicative of the results to be expected in the future.

	Year Ended June 30,				
	2011	2010	2009	2008	2007
(In thousands, except share data)					
<b>Statements of Operations Data:</b>					
Revenues(a)	\$ 6,650	\$ 11,422	\$19,976	\$ 3,500	\$ 2,070
Net loss	(40,682)	(29,748)	(517)	(8,537)	(8,969)
Basic and diluted loss per share	(0.70)	(0.64)	(0.02)	(0.26)	(0.38)
<b>Balance Sheet Data:</b>					



	As of June 30,				
	2011	2010	2009	2008	2007
Total assets	\$89,478	\$64,817	\$32,212	\$18,499	\$16,926
Long-term debt, including current portion	22,687	2,741	3,133	7,209	4,261

(a) Includes \$3.9 million, \$8.9 million and \$16.1 million in connection with our exclusive licensing agreement and our industrialization agreement with Sanofi in the years ended June 30, 2011, 2010 and 2009, respectively.

#### Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion and analysis includes certain forward-looking statements that involve risks, uncertainties and assumptions. You should review the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by such forward-looking statements. See "Cautionary Note Regarding Forward-Looking Information" at the beginning of this report. References to our fiscal year refer to the fiscal year ending June 30.*

#### Redomiciliation

On January 27, 2010, Unilife Medical Solutions Limited, an Australian corporation ("UMSL"), completed a redomiciliation from Australia to the State of Delaware pursuant to which stockholders and option holders of UMSL exchanged their interests in UMSL for equivalent interests in Unilife Corporation, a Delaware corporation ("Unilife") and Unilife became the parent company of UMSL and its subsidiaries. The redomiciliation was conducted by way of schemes of arrangement under Australian law. The issuance of Unilife common stock and stock options under the schemes of arrangement was exempt from registration under Section 3(a)(10) of the Securities Act of 1933, as amended. The redomiciliation was approved by the Australian Federal Court, and approved by UMSL shareholders and option holders.

In connection with the redomiciliation, holders of UMSL ordinary shares or share options received one share of Unilife common stock or an option to purchase one share of Unilife common stock, for every six UMSL ordinary shares or share options, respectively, held by such holders, unless the holder elected to receive in lieu of Unilife common stock, Chess Depositary Interests of Unilife, or CDIs (each representing one-sixth of one share of Unilife common stock), in which case such holder received one CDI for every UMSL ordinary share. All share and per share amounts in this Annual Report on Form 10-K have been restated to reflect the one for six share recapitalization effected in connection with the redomiciliation.

On February 16, 2010, Unilife's common stock began trading on the Nasdaq Global Market under the symbol "UNIS."

#### Overview

We are a U.S. based developer and manufacturer of a diversified portfolio of advanced drug delivery systems. We collaborate with pharmaceutical and biotechnology companies seeking to optimize drug lifecycles and generate differentiation for their brand in competitive therapeutic markets through the use of innovative devices that can improve patient care, protect healthcare workers and prevent disease. We have developed a broad portfolio of drug delivery systems in direct response to unmet market needs for injectable drugs including macromolecule biologics.

Our main product is the Unifill ready-to-fill syringe, which is designed to be supplied to pharmaceutical manufacturers in a form that is ready for filling with their injectable drugs and vaccines. We have a strategic partnership with Sanofi, a large global pharmaceutical company, pursuant to which Sanofi has paid us a 10.0 million euros exclusivity fee and has paid us 17.0 million euros to fund our industrialization program for the Unifill syringe. We are also in discussions with other pharmaceutical companies that are seeking to obtain access to the Unifill syringe.

In addition, we manufacture our Unitract 1mL insulin syringes at our FDA-registered manufacturing facility in Pennsylvania, which are designed for primarily for use in healthcare facilities and by patients who self-administer prescription medication such as insulin.

## **Recent Developments**

### ***Equipment Lease Agreement***

On August 15, 2011, we entered into a Master Lease Agreement with Varilease Finance, Inc. ("Varilease"). Under the Master Lease Agreement, Varilease will provide up to \$10.0 million of lease financing for production equipment for the Unifill ready-to-fill syringe. We have the option of selling and leasing back existing equipment or using the facility to lease additional equipment.

Under the terms of the Master Lease Agreement, we will lease the equipment from Varilease for a two-year base term, and we will pay rent in equal monthly installments of up to \$0.4 million over the base term.

The Master Lease Agreement contains covenants and provisions for events of default customarily found in lease agreements. We may prepay the monthly rent payments without penalty. At the end of the lease term, we have the option to extend the lease, return the equipment or purchase the equipment, as defined in the agreement.

## **Critical Accounting Policies and Estimates**

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States of America. This requires management to make certain estimates, judgments and assumptions that could affect the amounts reported in the consolidated financial statements and accompanying notes. The following accounting policies require significant estimates, judgments and assumptions.

### ***Goodwill***

Goodwill is the excess of purchase price over the fair value of net assets acquired in business acquisitions. Goodwill is subject to, at a minimum, an annual impairment assessment of its carrying value. Additional impairment assessments would be performed if events and circumstances warranted such additional assessments during the year. Goodwill impairment is deemed to exist if the net book value of our reporting unit exceeds its estimated fair value. Estimated fair value of our reporting unit is determined utilizing the value implied by our year end quoted stock price. We did not record any goodwill impairments during fiscal 2011, 2010 or 2009.

The Company has one reporting unit. The reporting unit is comprised of our Unitract and Unifill syringe business, the base technology which we obtained as part of our November 2002 acquisition of Unitract Syringe Pty Limited and the manufacturing capability which we obtained in our January 2007 acquisition of Integrated BioSciences, Inc.

In estimating the reporting unit's fair value for purposes of the Company's fiscal 2011 impairment assessment, management compared the carrying value of our reporting unit to our market capitalization as of June 30, 2011, which is our annual impairment testing date. Our market capitalization of \$331.0 million, based on the quoted stock price on the Nasdaq was in excess of our stockholders' equity of \$53.6 million. Management also considered that market capitalization through early September 2011 continued to be in excess of the carrying value.

### ***Share-Based Compensation***

We grant stock options, restricted stock and common stock as compensation to our employees, directors and consultants. Certain employee and director awards vest over stated vesting periods and others also require achievement of specific performance or market conditions. We expense the grant-date fair value of awards to employees and directors over their respective vesting periods. To the extent that employee and director awards vest only upon the achievement of a specific performance condition, expense is recognized over the period from the date management determines that the performance condition is probable of achievement through the date they are expected to be met. Awards granted to consultants are sometimes granted for past services, in which case their fair value is expensed on their grant date, while other awards require future service, or the achievement of performance or market conditions. Timing of expense recognition for consultant awards is similar to that of employee and director awards; however,

aggregate expense is re-measured each quarter end based on the then fair value of the award through the vesting date of the award. We estimate the fair value of stock options using the Black-Scholes option-pricing model, with the exception of market-based grants, which are valued based on Barrier and Monte Carlo option-pricing models. Option pricing methods require the input of highly subjective assumptions, including the expected stock price volatility.

### Revenue Recognition

We recognize revenue from licensing fees, industrialization efforts and products sales.

In June 2008, we entered into an exclusive licensing arrangement to allow Sanofi to use certain of our intellectual property in order and solely to develop in collaboration with us, our Unifill syringe for use in and sale to the pre-filled syringe market. The \$10.0 million up-front, non-refundable fee paid for this license is being amortized over the five year expected life of the related agreement. In late fiscal 2009, we entered into an industrialization agreement with Sanofi, under which specific payment amounts and completion dates were established for achievement of certain pre-defined milestones in our development of the Unifill syringe. Revenue is recognized upon achievement of the "at risk" milestone events, which represents the culmination of the earnings process related to such events. Milestones include specific phases of the project such as product design, prototype availability, user tests, manufacturing proof of principle and the various steps to complete the industrialization of the product. Revenue recognized is commensurate with the milestones achieved and we have no future performance obligations related to previous milestone payments as each milestone payment is non-refundable when received.

We recognize revenue from sales of products at the time of shipment and when title passes to the customer.

### Results of Operations

The following table summarizes our results of operations for the fiscal years ended June 30, 2011, 2010 and 2009:

	Year Ended June 30,		
	2011	2010	2009
	(in thousands, except per share data)		
<b>Revenues:</b>			
Industrialization fees	\$ 1,350	\$ 6,318	\$13,601
Licensing fees	2,527	2,566	2,456
Product sales and other	2,773	2,538	3,919
Total revenues	6,650	11,422	19,976
Cost of product sales	2,597	2,471	3,426
Gross profit	4,053	8,951	16,550
<b>Operating expenses:</b>			
Research and development	9,631	10,934	2,209
Selling, general and administrative	31,571	26,257	13,780
Depreciation and amortization	4,009	2,314	915
Total operating expenses	45,211	39,505	16,904
Operating loss	(41,158)	(30,554)	(354)
Interest expense	511	125	249
Interest income	(399)	(1,066)	(361)
Other (income) expense, net	(588)	135	275
Net loss	<u>\$(40,682)</u>	<u>\$(29,748)</u>	<u>\$ (517)</u>
<b>Loss per share:</b>			
Basic and diluted loss per share	<u>\$ (0.70)</u>	<u>\$ (0.64)</u>	<u>\$ (0.02)</u>

*Fiscal Year 2011 Compared to Fiscal Year 2010*

*Revenues.* Revenues decreased by \$4.8 million or 42%. Revenues from our industrialization agreement with Sanofi decreased from \$6.3 million to \$1.4 million due to the achievement of a majority of the related milestones during fiscal 2010. As of June 30, 2011, there was one remaining milestone payment to be recognized which was dependent upon the production of commercially viable units of our Unifill syringe. This remaining milestone was achieved during July 2011 and we received the related 1.0 million euros during September 2011. Revenues from our exclusive licensing agreement with Sanofi decreased from \$2.6 million to \$2.5 million. We have recognized and will continue to recognize revenue from the exclusive licensing agreement on a straight-line basis over the remaining term of the agreement. Since these revenues are based in euros, the \$0.1 million decrease resulted from fluctuations in foreign currency translation rates. Revenues from product sales of our contract manufacturing business increased from \$2.5 million to \$2.8 million, primarily as a result of increased sales to one of our most significant contract manufacturing customers during the first and second quarters of fiscal 2011. We discontinued contract manufacturing activities in December 2010 in order to focus our efforts on the Unifill syringe and our additional drug delivery devices.

*Cost of product sales.* Cost of product sales increased by \$0.1 million or 5%, which was attributable to a higher level of product sales under our contract manufacturing sales activity. Our cost of product sales during fiscal 2011 includes amounts related to the write-off of obsolete inventory.

*Research and development expenses.* Research and development expenses decreased by \$1.3 million. During fiscal 2010, we incurred a charge of \$4.3 million in connection with the issuance of 833,333 fully-vested shares of common stock to certain employees in consideration of their transfer to us of certain intellectual property rights. This decrease was partially offset by an increase in expenditures incurred to finalize the product specifications of our Unifill syringe and develop our additional drug delivery devices.

*Selling, general and administrative expenses.* Selling, general and administrative expenses increased by \$5.3 million or 20%. During fiscal 2011, we recorded \$9.0 million of share-based compensation expense, an increase of \$3.3 million compared to fiscal 2010. Our share-based compensation expense during fiscal 2011 relates primarily to restricted stock and stock options issued to new employees, directors and consultants under our 2009 Stock Incentive Plan. Additionally, during fiscal 2010 and the first half of fiscal 2011, we increased the workforce at our York, Pennsylvania facility, and as a result, we incurred payroll expenses and recruiting fees during the fiscal 2011 of \$11.0 million, an increase of \$3.2 million compared to fiscal 2010. These amounts were partially offset by a decrease of \$2.7 million in legal and consulting fees due to significant costs incurred during fiscal 2010 in connection with our redomiciliation to the United States.

*Depreciation and amortization expense.* Depreciation and amortization expense increased by \$1.7 million or 73% which was attributable to \$4.0 million of machinery placed into service during October 2009 relating to our 1mL syringe and the completion of construction of our new headquarters and manufacturing facility. Included in this amount is a \$0.5 million loss on the disposal of certain pieces of equipment during fiscal 2011. We expect our depreciation and amortization expense to increase in the future as a result of our purchases of machinery for the Unifill syringe.

*Interest expense.* Interest expense increased by \$0.4 million, primarily as a result of interest related to our \$18.0 million in debt financing obtained in October 2010 for the construction of our new headquarters and manufacturing facility.

*Interest income.* Interest income decreased by \$0.7 million, primarily as a result of lower cash balances and lower interest rates during fiscal 2011.

*Other (income) expense.* Other income during fiscal 2011 includes the receipt of a \$0.5 million opportunity grant from the Commonwealth of Pennsylvania.

*Net loss and loss per share.* Net loss for fiscal 2011 and 2010 was \$40.7 million and \$29.7 million, respectively. Basic and diluted loss per share was \$0.70 and \$0.64, respectively, on weighted average shares outstanding of 57,891,024 and 46,837,066, respectively. The increase in the weighted average shares outstanding



was primarily due to the issuance of common stock in connection with our October 2009 and December 2010 equity financings.

#### **Fiscal Year 2010 Compared to Fiscal Year 2009**

*Revenues.* Revenues decreased by \$8.6 million or 43%. Revenues from our industrialization agreement with Sanofi decreased from \$13.6 million to \$6.3 million due to the nature and timing of milestones achieved during fiscal 2010. Revenues from our exclusive licensing agreement with Sanofi increased from \$2.5 million to \$2.6 million. We have recognized and will continue to recognize the revenue from the exclusive licensing agreement on a straight-line basis over the remaining term of the agreement. Since these revenues are based in euros, the \$0.1 million variation in revenues results from fluctuations in foreign currency translation rates. Revenues from product sales of our contract manufacturing business decreased from \$3.9 million to \$2.5 million principally because most of our efforts were devoted to the development of the Unifill syringe in fiscal 2010.

*Cost of product sales.* Cost of sales decreased by \$1.0 million or 28%. The decrease was attributable to a reduction in product sales under our contract manufacturing sales activity.

*Research and development expenses.* Research and development expenses increased by \$8.7 million, primarily as a result of \$4.3 million incurred in connection with the issuance of 833,333 fully-vested shares of common stock to certain employees in consideration of their transfer to us of certain intellectual property rights. The increase was also a result of additional expenditures to finalize the product specifications of our Unifill syringe.

*Selling, general and administrative expenses.* Selling, general and administrative expenses increased by \$12.5 million or 91%. During fiscal 2010, we increased the workforce at our Pennsylvania facility, and as a result, we incurred payroll expenses and recruiting fees during fiscal 2010 of \$7.8 million, an increase of \$4.1 million compared to fiscal 2009. Additionally, during fiscal 2010, we incurred legal and consulting fees of \$6.4 million, an increase of \$3.4 million compared to fiscal 2009. The increase was due primarily to expenses we incurred related to our redomiciliation and Nasdaq listing. Additionally, during fiscal 2010, we recorded \$5.7 million in share-based compensation expense, an increase of \$2.7 million compared to fiscal 2009. Our share-based compensation expense during fiscal 2010 relates primarily to restricted stock and stock options issued to employees and consultants during the year. Our share-based compensation expense during fiscal 2009 included \$1.5 million recorded in December 2008 for the issuance of 1.7 million shares of common stock to our Chief Executive Officer.

*Depreciation and amortization expense.* Depreciation and amortization expense increased by \$1.4 million or 153% which was primarily attributable to \$1.0 million of property plant and equipment additions placed in service during fiscal 2010. Additionally, during October 2009, we placed \$4.0 million of machinery to manufacture our 1mL syringe in service.

*Interest expense.* Interest expense decreased by \$0.1 million, primarily as a result of our lower levels of outstanding debt.

*Interest income.* Interest income increased by \$0.7 million, primarily as a result of higher cash balances during fiscal 2010.

*Other (income) expense.* Other (income) expense decreased by \$0.1 million primarily due to lower foreign exchange losses as a result of the appreciation of the U.S. dollar against the Australian dollar.

*Net loss and loss per share.* Net loss for fiscal 2010 and 2009 was \$29.7 million and \$0.5 million, respectively. Basic and diluted loss per share was \$0.64 and \$0.02, respectively, on weighted average shares outstanding of 46,837,066 and 34,426,353, respectively. The increase in the weighted average shares outstanding was primarily due to the issuance of common stock in connection with our October 2009 equity financing.

#### **Liquidity and Capital Resources**

To date, we have funded our operations primarily from a combination of equity issuances, borrowings under our bank loans and payments from Sanofi under our exclusive licensing and industrialization agreements. As of June 30, 2011, cash and cash equivalents were \$17.9 million, restricted cash was \$2.4 million and our long-term debt was \$22.7 million. As of June 30, 2010, cash and cash equivalents were \$20.8 million and our long-term debt

was \$2.7 million. During September 2011, we received 1.0 million euros from Sanofi related to the achievement of the final milestone under the industrialization agreement.

During October 2010, we secured \$18.0 million of external financing from Metro Bank ("Metro") for the construction of our new manufacturing facility. We used \$6.9 million of the proceeds to repay amounts borrowed in August 2010 under our credit agreement with Univest.

During December 2010, we received \$2.25 million from the Commonwealth of Pennsylvania in low-interest financing for land and the construction of our new corporate headquarters and manufacturing facility.

During December 2010 we raised \$33.4 million, net of issuance costs, through a private placement and share purchase plan for our Australian and New Zealand stockholders.

During August 2011 we entered into an equipment lease which will provide for up to \$10.0 million of additional external financing.

We believe that our cash and cash equivalents on hand are sufficient to sustain planned operations through the third quarter of fiscal 2012.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. We anticipate incurring additional losses until such time that we can generate significant revenue from product sales.

The following table summarizes our cash flows during the fiscal years ended June 30, 2011, 2010 and 2009:

	Year Ended June 30,		
	2011	2010	2009
	(In thousands)		
Net cash provided by (used in):			
Operating activities	\$(28,521)	\$(12,390)	\$ 6,795
Investing activities	(30,037)	(18,132)	(2,912)
Financing activities	53,838	49,488	(3,265)

#### *Fiscal Year 2011 Compared to Fiscal Year 2010*

##### *Net Cash Used in Operating Activities*

Net cash used in operating activities during fiscal 2011 was \$28.5 million compared to \$12.4 million during fiscal 2010. The decrease in cash flow was primarily due to \$10.3 million of higher net loss after adding back depreciation and amortization, loss on disposal of property, plant and equipment and share-based compensation expense.

##### *Net Cash Used in Investing Activities*

Net cash used in investing activities during fiscal 2011 was \$30.0 million, primarily as a result of construction costs incurred in connection with our new headquarters and manufacturing facility, as well as costs incurred in connection with the purchase of machinery and related equipment.

##### *Net Cash Provided by Financing Activities*

Net cash provided by financing activities during fiscal 2011 was \$53.8 million compared to \$49.5 million during fiscal 2010. During fiscal 2011, we received \$33.4 million from the issuance of common stock in connection with our December 2010 private placement and share purchase plan, as well as \$3.2 million upon the exercise of stock options. Additionally, during fiscal 2011, we received \$20.2 million in aggregate proceeds from our external financing from Metro and the Commonwealth of Pennsylvania. During fiscal 2010, we received \$47.1 million in connection with our October 2009 private placement and share purchase plan, as well as \$2.3 million upon the exercise of stock options.

**Fiscal Year 2010 Compared to Fiscal Year 2009****Net Cash (Used in) Provided by Operating Activities**

Net cash used in operating activities during fiscal 2010 was \$12.4 million compared to net cash provided by operating activities of \$6.8 million during fiscal 2009. The decrease in cash flow was primarily due to \$20.8 million of higher net loss after adding back depreciation and amortization and share-based compensation expense.

**Net Cash Used in Investing Activities**

Net cash used in investing activities was \$18.1 million during fiscal 2010, primarily as a result of \$17.6 million of costs incurred in connection with the purchase of machinery related to the lines for our Unifill syringe as well as the purchase of the land and construction costs in connection with our new headquarters and manufacturing facility.

**Net Cash Provided by (Used in) Financing Activities**

Net cash provided by financing activities during fiscal 2010 was \$49.5 million compared to net cash used in financing activities of \$3.3 million during fiscal 2009. During fiscal 2010, we received \$47.1 million from the issuance of common stock related to our private placement and share purchase plan, and \$2.3 million upon the exercise of stock options. During fiscal 2009, we elected to terminate a licensing agreement that we determined was no longer consistent with our business strategies, and, as a final settlement, we repaid \$2.3 million of the \$3.0 million that we had originally received in 2008 under the licensing agreement, while retaining \$0.7 million to cover related legal fees.

**Contractual Obligations**

The following table provides information regarding our contractual obligations as of June 30, 2011:

	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years (In thousands)	3-5 Years	More Than 5 Years
Long-term debt and related interest	\$32,835	\$ 2,091	\$ 4,166	\$ 3,983	\$ 22,595
Capital leases	209	91	93	25	—
Operating leases	112	60	47	5	—
Total contractual obligations	<u>\$33,156</u>	<u>\$ 2,242</u>	<u>\$ 4,306</u>	<u>\$ 4,013</u>	<u>\$ 22,595</u>

Our term loans bear interest at rates ranging from prime (3.25% as of June 30, 2011) plus 1.50% to 6.0%. The future contractual obligations for interest is based upon rates in this range.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements as such term is defined in the SEC rules.

**Recently Issued Accounting Pronouncements**

In March 2010, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2010-17, "Milestone Method of Revenue Recognition, a consensus of the FASB Emerging Issues Task Force (Issue No. 08-9)." ("ASU 2010-17"). ASU 2010-17 provides guidance about the criteria that must be met to use the milestone method of revenue recognition. This ASU is effective for milestones achieved in fiscal years and interim periods within those years, beginning after June 15, 2010. We adopted ASU 2010-17 on July 1, 2010 and its adoption did not have a material impact on our consolidated financial statements.

In June 2011, the FASB issued ASU 2011-05, "Comprehensive Income" ("ASU 2011-05"). ASU 2011-05 removes certain presentation options and requires entities to report components of net income and comprehensive income in either one continuous statement of comprehensive income or two separate but consecutive statements. There is no change to the items that are reported in other comprehensive income. ASU 2011-05 is effective for



annual and interim periods beginning after December 15, 2011. Other than additional presentation of other comprehensive loss outside of the statements of stockholders' equity and comprehensive loss, the adoption of ASU 2011-05 will not have an impact on our consolidated financial statements.

**Item 7A. *Quantitative and Qualitative Disclosures About Market Risk***

We are exposed to market risk from changes in interest rates and foreign currency exchange rates. Changes in these factors could cause fluctuations in our results of operations and cash flows.

**Interest Rate Risk**

Our exposure to interest rate risk is limited to our cash and cash equivalents that are invested in money market funds with highly liquid short term investments and our variable interest rate term loans. We currently do not utilize derivative instruments to mitigate changes in interest rates.

**Foreign Currency Exchange Rate Fluctuations**

Certain of our revenues are derived from payments under our industrialization agreement received in euros while we incur most of our expenses in U.S. dollars and Australian dollars. In addition, a portion of our cash and cash equivalents and investments are held at Australian banking institutions and are denominated in Australian dollars. We are exposed to foreign currency exchange rate risks on these amounts. We currently do not utilize options or forward contracts to mitigate changes in foreign currency exchange rates. For U.S. reporting purposes, we translate all assets and liabilities of our non-U.S. entities into U.S. dollars using the exchange rate as of the end of the related period and we translate all revenues and expenses of our non-U.S. entities using the average exchange rate during the applicable period.

Item 8. *Financial Statements and Supplementary Data*

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
<b>Audited Consolidated Financial Statements</b>	
Management's Report on Internal Control Over Financial Reporting	46
Reports of Independent Registered Public Accounting Firms	47
Consolidated Balance Sheets as of June 30, 2011 and 2010	50
Consolidated Statements of Operations for the years ended June 30, 2011, 2010 and 2009	51
Consolidated Statements of Stockholders' Equity and Comprehensive Loss for the years ended June 30, 2011, 2010 and 2009	52
Consolidated Statements of Cash Flows for the years ended June 30, 2011, 2010 and 2009	53
Notes to Consolidated Financial Statements	54

### Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting was designed to provide reasonable assurance to management and our Board of Directors regarding the reliability of financial reporting and the fair presentation of our consolidated financial statements.

With the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our evaluation, our management concluded that our internal control over financial reporting was effective as of June 30, 2011 to provide reasonable assurance regarding the reliability of financial reporting and the fair presentation of our consolidated financial statements.

KPMG LLP, an independent registered public accounting firm, audited our internal control over financial reporting as of June 30, 2011. Their audit report can be found on page 47.

/s/ Alan Shortall

Alan Shortall  
Chief Executive Officer

/s/ R. Richard Wieland II

R. Richard Wieland II  
Executive Vice President and Chief Financial Officer

/s/ Dennis P. Pyers

Dennis P. Pyers  
Vice President, Controller and Chief Accounting Officer

September 13, 2011

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders  
Unilife Corporation:

We have audited Unilife Corporation and subsidiaries (the Company) internal control over financial reporting as of June 30, 2011, based on criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of June 30, 2011, based on criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Unilife Corporation as of June 30, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for the years then ended, and our report dated September 13, 2011 expressed an unqualified opinion on those consolidated financial statements. Our report dated September 13, 2011 contains an explanatory paragraph that states there is substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

/s/ KPMG LLP

Harrisburg, Pennsylvania  
September 13, 2011

# Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders  
Unilife Corporation:

We have audited the accompanying consolidated balance sheets of Unilife Corporation and subsidiaries (the Company) as of June 30, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Unilife Corporation and subsidiaries as of June 30, 2011 and 2010, and the results of their operations and their cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in note 2 to the consolidated financial statements, the Company has incurred recurring losses from operations and estimates that its existing cash and cash equivalents will last only through the third quarter of fiscal 2012, which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of June 30, 2011, based on criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated September 13, 2011 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

Harrisburg, Pennsylvania  
September 13, 2011

**Report of Independent Registered Public Accounting Firm**

Board of Directors and Stockholders  
Unilife Corporation  
Lewisberry, Pennsylvania

We have audited the accompanying consolidated statements of operations, stockholders' equity and comprehensive loss and cash flows of Unilife Corporation and subsidiaries for the year ended June 30, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of operations and cash flows of Unilife Corporation and subsidiaries for the year ended June 30, 2009 in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO Audit (WA) Pty Ltd

Perth, Western Australia  
September 13, 2011

UNILIFE CORPORATION AND SUBSIDIARIES

Consolidated Balance Sheets

	June 30,	
	2011	2010
	(In thousands, except share data)	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 17,910	\$ 20,750
Restricted cash	2,400	—
Accounts receivable	13	1,556
Inventories	626	797
Prepaid expenses and other current assets	381	637
Total current assets	21,330	23,740
Property, plant and equipment, net	54,020	29,972
Goodwill	13,265	10,792
Intangible assets, net	42	40
Other assets	821	273
Total assets	\$ 89,478	\$ 64,817
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 2,405	\$ 6,044
Accrued expenses	2,696	2,911
Current portion of long-term debt	2,274	1,648
Deferred revenue	2,706	2,188
Total current liabilities	10,081	12,791
Long-term debt, less current portion	20,413	1,093
Deferred revenue	5,412	6,563
Total liabilities	35,906	20,447
Commitments and Contingencies (Note 8)		
Stockholders' Equity:		
Preferred stock, \$0.01 par value, 50,000,000 shares authorized as of June 30, 2011; none issued or outstanding as of June 30, 2011 and 2010	—	—
Common stock, \$0.01 par value, 250,000,000 shares authorized as of June 30, 2011, 19,350,000 and 54,751,000 shares issued and outstanding as of June 30, 2011 and 2010, respectively	193	546
Additional paid-in capital	169,391	172,397
Accumulated other comprehensive income	3,775	1,075
Treasury stock, at cost, 19,350 shares as of June 30, 2011	(100)	—
Total stockholders' equity	53,572	44,370
Total liabilities and stockholders' equity	\$ 89,478	\$ 64,817

See accompanying notes to the consolidated financial statements.



UNILIFE CORPORATION AND SUBSIDIARIES

Consolidated Statements of Operations

	Year Ended June 30,		
	2011	2010	2009
	(In thousands, except share data)		
<b>Revenues:</b>			
Industrialization fees	\$ 1,350	\$ 6,318	\$13,601
Licensing fees	2,527	2,566	2,456
Product sales and other	2,773	2,538	3,919
Total revenues	6,650	11,422	19,976
Cost of product sales	2,597	2,471	3,426
Gross profit	4,053	8,951	16,550
<b>Operating expenses:</b>			
Research and development	9,631	10,934	2,209
Selling, general and administrative	31,571	26,257	13,780
Depreciation and amortization	4,009	2,314	915
Total operating expenses	45,211	39,505	16,904
Operating loss	(41,158)	(30,554)	(354)
Interest expense	511	125	249
Interest income	(399)	(1,066)	(361)
Other (income) expense, net	(588)	135	275
Net loss	<u>\$(40,682)</u>	<u>\$(29,748)</u>	<u>\$ (517)</u>
<b>Loss per share:</b>			
Basic and diluted loss per share	<u>\$ (0.70)</u>	<u>\$ (0.64)</u>	<u>\$ (0.02)</u>

See accompanying notes to the consolidated financial statements.

## UNILIFE CORPORATION AND SUBSIDIARIES

## Consolidated Statements of Stockholders' Equity and Comprehensive Loss

	Common Stock		Additional-	Accumulated	Accumulated	Treasury	Total
	Shares	Amount	Paid-In Capital	Deficit	Other Comprehensive Income	Stock	
(In thousands, except share data)							
Balance as of July 1, 2008	34,295,718	\$ 343	\$ 53,835	\$ (49,385)	\$ 4,714	\$ —	\$ 9,507
Comprehensive loss:							
Net loss	—	—	—	(517)	—	—	(517)
Foreign currency translation	—	—	—	—	(1,854)	—	(1,854)
Comprehensive loss	—	—	—	—	—	—	(2,371)
Issuance of options and warrants to purchase common stock	—	—	3,059	—	—	—	3,059
Issuance of common stock upon exercise of stock options	97,532	1	37	—	—	—	38
Issuance of common stock upon conversion of convertible notes	520,000	5	616	—	—	—	621
Issuance of common stock in connection with Employee Share Plan	45,885	—	—	—	—	—	—
Issuance of stock options in connection with the acquisition of Integrated BioSciences, Inc.	—	—	457	—	—	—	457
Grant of common stock to employee	1,666,667	17	(17)	—	—	—	—
Balance as of June 30, 2009	36,625,802	366	57,987	(49,902)	2,860	—	11,311
Comprehensive loss:							
Net loss	—	—	—	(29,748)	—	—	(29,748)
Foreign currency translation	—	—	—	—	(1,785)	—	(1,785)
Comprehensive loss	—	—	—	—	—	—	(31,533)
Issuance of options and warrants to purchase common stock	—	—	3,463	—	—	—	3,463
Issuance of restricted stock	1,818,000	18	2,236	—	—	—	2,254
Issuance of common stock in connection with private placement and share purchase plan, net of issuance costs	10,544,961	106	47,011	—	—	—	47,117
Issuance of common stock upon exercise of stock options	1,606,419	17	2,332	—	—	—	2,349
Issuance of common stock to employees	833,333	8	4,331	—	—	—	4,339
Issuance of common stock to former shareholders of Unitract Syringe Pty Limited	3,333,333	33	5,037	—	—	—	5,070
Balance as of June 30, 2010	54,761,848	548	122,397	(79,650)	1,075	—	44,370
Comprehensive loss:							
Net loss	—	—	—	(40,682)	—	—	(40,682)
Foreign currency translation	—	—	—	—	2,700	—	2,700
Comprehensive loss	—	—	—	—	—	—	(37,982)
Issuance of options and warrants to purchase common stock	—	—	4,071	—	—	—	4,071
Issuance of restricted stock, net of forfeitures	420,000	4	6,442	—	—	—	6,446
Issuance of common stock in connection with private placement and share purchase plan, net of issuance costs	7,048,373	70	33,361	—	—	—	33,431
Issuance of common stock upon exercise of stock options	1,670,998	17	3,193	—	—	—	3,210
Issuance of common stock to employees	23,184	—	126	—	—	—	126
Purchase of treasury stock	—	—	—	—	—	(100)	(100)
Balance as of June 30, 2011	63,924,403	\$ 639	\$ 169,590	\$ (120,332)	\$ 3,775	\$ (100)	\$ 53,572

See accompanying notes to the consolidated financial statements.

## UNILIFE CORPORATION AND SUBSIDIARIES

## Consolidated Statements of Cash Flows

	Year Ended June 30,		
	2011	2010	2009
	(In thousands, except share data)		
<b>Cash flows from operating activities:</b>			
Net loss	\$(40,682)	\$(29,748)	\$ (517)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization	3,482	2,314	915
Loss on disposal of property, plant and equipment	527	—	5
Share-based compensation expense	9,022	10,056	3,059
Changes in assets and liabilities:			
Accounts receivable	1,739	5,852	(6,172)
Inventories	176	302	(40)
Prepaid expenses and other current assets	266	(385)	(126)
Other assets	(552)	270	(232)
Accounts payable	(515)	863	586
Accrued expenses	543	656	(506)
Deferred revenue	(2,527)	(2,570)	9,823
<b>Net cash (used in) provided by operating activities</b>	<b>(28,521)</b>	<b>(12,390)</b>	<b>6,795</b>
<b>Cash flows from investing activities:</b>			
Purchases of property, plant and equipment	(30,037)	(17,562)	(2,926)
Proceeds from the sale of property, plant and equipment	—	—	14
Purchases of certificates of deposit	—	(9,106)	—
Proceeds from the redemption of certificates of deposit	—	8,536	—
<b>Net cash used in investing activities</b>	<b>(30,037)</b>	<b>(18,132)</b>	<b>(2,912)</b>
<b>Cash flows from financing activities:</b>			
Proceeds from the issuance of common stock, net of issuance costs	33,431	47,117	—
Proceeds from the exercise of options to purchase common stock	3,210	2,349	38
Proceeds from the issuance of long-term debt	20,190	—	88
Principal payments on long-term debt and capital lease agreements	(493)	(411)	(3,391)
Proceeds from the issuance of note payable	6,900	—	—
Principal payments on note payable	(6,900)	—	—
Purchase of treasury stock	(100)	—	—
(Increase) decrease in restricted cash	(2,400)	433	—
<b>Net cash provided by (used in) financing activities</b>	<b>53,838</b>	<b>49,488</b>	<b>(3,265)</b>
Effect of exchange rate changes on cash	1,880	(1,843)	122
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(2,840)</b>	<b>17,123</b>	<b>740</b>
Cash and cash equivalents at beginning of year	20,750	3,627	2,887
Cash and cash equivalents at end of year	<u>\$ 17,910</u>	<u>\$ 20,750</u>	<u>\$ 3,627</u>
<b>Supplemental disclosure of cash flow information</b>			
Cash paid for interest	<u>\$ 514</u>	<u>\$ 135</u>	<u>\$ 183</u>
<b>Supplemental disclosure of non-cash activities</b>			
Purchases of property, plant and equipment in accounts payable and accrued expenses	<u>\$ 1,143</u>	<u>\$ 5,051</u>	<u>\$ —</u>
Purchases of property, plant and equipment pursuant to capital lease agreements	<u>\$ 249</u>	<u>\$ —</u>	<u>\$ —</u>
Issuance of common stock to former shareholders of Unifrac Syringe Pty Limited	<u>\$ —</u>	<u>\$ 5,070</u>	<u>\$ —</u>
Purchases of property, plant and equipment through the issuance of warrants	<u>\$ 1,621</u>	<u>\$ —</u>	<u>\$ —</u>

See accompanying notes to the consolidated financial statements.

**UNILIFE CORPORATION AND SUBSIDIARIES****Notes to Consolidated Financial Statements****1. Description of Business**

Unilife Corporation (collectively with its consolidated subsidiaries, the “Company”) and subsidiaries is a U.S. based developer and manufacturer of advanced drug delivery systems. The primary target customers for the Company’s products include pharmaceutical and biotechnology companies seeking to optimize drug lifecycles and generate differentiation for their brand in competitive therapeutic markets through the use of innovative devices that can improve patient care, protect healthcare workers and prevent disease. Customers also include suppliers of medical equipment to healthcare facilities and distributors to patients who self-administer prescription medication.

**2. Liquidity**

The Company has incurred recurring losses from operations and anticipates incurring additional losses until such time that it can generate sufficient sales of its proprietary range of advanced drug delivery systems. Management estimates that cash and cash equivalents of \$17.9 million as of June 30, 2011 are sufficient to sustain planned operations only through the third quarter of fiscal 2012.

Therefore, additional funding will be needed in fiscal 2012 by the Company to support its operations and capital expenditure requirements. Management has identified several possible funding strategies which may be available. In addition to sales of its Unitract and Unifill syringe products to existing partners, the Company is also in discussions with additional pharmaceutical companies pertaining to the Unifill syringe and other pipeline products. Should the Company enter into commercial relationships relating to the industrialization, commercial supply or preferred use of a device within a particular therapeutic market, the Company may pursue additional funding or revenue streams. The Company may seek to raise additional funds through the sale of additional equity or debt securities. There can be no assurance that any such funding will be available when needed or on acceptable terms. These various factors raise substantial doubt about the Company’s ability to continue as a going concern.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

During August 2011, the Company entered into an equipment lease which will provide for up to \$10.0 million of additional external financing.

**3. Summary of Significant Accounting Policies*****Principles of Consolidation***

The consolidated financial statements include the accounts of Unilife Corporation and its wholly-owned subsidiaries. The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP.”) All intercompany accounts and transactions have been eliminated in consolidation.

On September 1, 2009, Unilife Medical Solutions Limited, an Australian Corporation (“UMSL”), entered into a Merger Implementation Agreement with Unilife Corporation, a newly-formed Delaware subsidiary of UMSL, pursuant to which stockholders and option holders of UMSL would exchange their existing interests in UMSL for equivalent interests in Unilife Corporation and Unilife Corporation would become the parent or ultimate parent of UMSL and its subsidiaries. The redomiciliation transaction was approved by the Australian Federal Court and the stockholders and option holders of UMSL and was completed on January 27, 2010. In the redomiciliation each holder of UMSL ordinary shares or share options received one share of common stock or one stock option of Unilife Corporation for every six UMSL ordinary shares or share options, respectively, held by such holder, unless a holder of UMSL ordinary shares elected to receive, in lieu of common stock, Chess Depository Interests, or CDIs of Unilife



# UNILIFE CORPORATION AND SUBSIDIARIES

## Notes to Consolidated Financial Statements — (Continued)

(each representing one-sixth of a share of Unilife common stock) in which case such holder received one CDI of Unilife for each ordinary share of UMSL. All share and per share data have been retroactively restated to reflect the one for six share recapitalization.

References to the “Company” include Unilife Corporation and its consolidated subsidiaries, including UMSL, unless the context otherwise requires. References to “Unilife” are references solely to Unilife Corporation.

References to A\$ mean the lawful currency of the Commonwealth of Australia. References to € or euros are to the lawful currency of the European Union.

### *Use of Estimates*

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The estimates are principally in the areas of revenue recognition and share-based compensation expense. Management bases its estimates on historical experience and various assumptions that are believed to be reasonable under the circumstances. Actual results could differ from those estimates.

### *Cash and Cash Equivalents*

Cash and cash equivalents consist primarily of cash on hand, deposits at banks and other short-term highly liquid investments with original maturities of three months or less. Cash equivalents are stated at cost which approximates fair value.

### *Accounts Receivable*

Accounts receivable are stated at amounts due from customers, which also represents the net realizable amount. The Company evaluates the collectability of its accounts receivable on a periodic basis and has historically not recorded an allowance for doubtful accounts. In instances in which management becomes aware of circumstances that may impair a particular customer’s ability to meet its obligation, the related receivable would be written off. Accounts receivable as of June 30, 2010 consists principally of amounts due from a single pharmaceutical company related to the achievement of certain milestones under the related industrialization agreement described in Note 13.

### *Inventories*

Inventories consist primarily of plastic syringe components and include direct materials, direct labor and manufacturing overhead. Inventories are stated at the lower of cost or market, with cost determined using the first in, first out method. The Company routinely reviews its inventory for obsolete, slow moving or otherwise impaired inventory and records estimated impairments in the periods in which they occur. Inventories consist of the following:

	June 30,	
	2011	2010
	(In thousands)	
Raw materials	\$387	\$649
Work in process	210	148
Finished goods	29	
Total inventories	<u>\$626</u>	<u>\$797</u>

**UNILIFE CORPORATION AND SUBSIDIARIES**  
**Notes to Consolidated Financial Statements — (Continued)**

***Property, Plant and Equipment***

Property, plant and equipment, including significant improvements, are recorded at cost, net of accumulated depreciation and amortization. Repairs and maintenance are expensed as incurred.

Depreciation and amortization expense is recorded on a straight-line basis over the estimated useful life of the asset as listed below:

<u>Asset Category</u>	<u>Useful Lives</u>
Building	40 years
Machinery and equipment	2 to 15 years
Computer software	3 to 7 years
Furniture and fixtures	7 years
Leasehold improvements	Shorter of leasehold improvement life or remaining term of lease

Interest expense incurred during the construction of the new headquarters and manufacturing facility have been capitalized as one of the elements of cost and are amortized over the useful life of the building. Interest capitalized during the year ended June 30, 2011 was \$0.3 million with no such capitalized interest during the years ended June 30, 2010 or 2009.

The Company reviews the carrying value of the long-lived assets periodically to determine if facts and circumstances exist that would suggest that assets might be impaired or that the useful lives should be modified. Among the factors the Company considers in making the evaluation are changes in market position and profitability. If facts and circumstances exist which may indicate impairment, the Company will prepare a projection of the undiscounted cash flows of the asset group and determine if the long-lived assets are recoverable based on these undiscounted cash flows. If impairment is indicated, an adjustment will be made to reduce the carrying amount of these assets to their fair value.

***Goodwill and Intangible Assets***

Goodwill is the excess of purchase price over the fair value of net assets acquired in business acquisitions. Goodwill is subject to, at a minimum, an annual impairment assessment of its carrying value. Additional impairment assessments would be performed if events and circumstances warranted such additional assessments during the year. Goodwill impairment is deemed to exist if the net book value of the Company's reporting unit exceeds its estimated fair value. Estimated fair value of the Company's reporting unit is determined utilizing the value implied by the Company's year-end quoted stock price. The Company performs its annual impairment test at the end of its fiscal year. There were no impairments recorded on goodwill during the years ended June 30, 2011, 2010 or 2009.

Definite-lived intangible assets include patents which are amortized on a straight-line basis over their estimated useful lives of 15 years. The Company reviews intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. When factors indicate a possible impairment, if the sum of the estimated undiscounted future cash flows expected to result from the use and eventual disposition of an asset is less than the carrying amount of the asset, an impairment may be recognized. Measurement of an impairment loss is based on the excess of the carrying value of the asset over its fair value. There were no impairments recorded on intangible assets during the years ended June 30, 2011, 2010 or 2009.

***Deferred Financing Costs***

Deferred financing costs are included in other assets on the consolidated balance sheets and consist of costs incurred in connection with debt financings. These costs are amortized over the term of the related debt using the effective interest rate method.



**UNILIFE CORPORATION AND SUBSIDIARIES****Notes to Consolidated Financial Statements — (Continued)*****Income Taxes***

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Deferred tax assets are recorded to the extent the Company believes they will more likely than not be realized. In making such determinations, the Company considers all available positive and negative evidence, including future reversals of existing temporary differences, projected future taxable income, tax planning strategies and recent financial operations. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected more likely than not to be realized.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. The Company's policy is to include interest and penalties related to uncertain tax positions within the provision (benefit) for income taxes within the Company's consolidated statements of operations.

***Fair Value of Financial Instruments***

The carrying value of financial instruments such as accounts receivable, accounts payable and accrued expenses are reasonable estimates of their fair value because of the short maturity of these items. The Company believes that the current carrying amount of its long-term debt approximates fair value because the interest rates on these instruments are similar to those rates that the Company would currently be able to receive for similar instruments of comparable maturity.

***Share-Based Compensation***

The Company grants stock options, restricted stock and common stock as compensation to its employees, directors and consultants. Certain employee and director awards vest over stated vesting periods and others also require achievement of specific performance or market conditions. The Company expenses the grant-date fair value of awards to employees and directors over their respective vesting periods. To the extent that employee and director awards vest only upon the achievement of a specific performance condition, expense is recognized over the period from the date management determines that the performance condition is probable of achievement through the date they are expected to be met. Awards granted to consultants are sometimes granted for past services, in which case their fair value is expensed on their grant date, while other awards require future service, or the achievement of performance or market conditions. Timing of expense recognition for consultant awards is similar to that of employee and director awards; however, aggregate expense is re-measured each quarter-end based on the then fair value of the award through the vesting date of the award. The Company estimates the fair value of stock options using the Black-Scholes option-pricing model, with the exception of market-based grants, which are valued based on Barrier and Monte Carlo option pricing models. Option pricing methods require the input of highly subjective assumptions, including the expected stock price volatility. See Note 4 for additional information regarding share-based compensation.

***Foreign Currency Translation***

The Australian dollar ("A\$") is the functional currency for the Company's Australian operations. Assets and liabilities denominated in foreign currencies are translated into U.S. dollars at the rate of exchange existing at the end of the period. Revenues and expenses are translated at the average exchange rates during the applicable period. Adjustments resulting from these translations are recorded in accumulated other comprehensive income within the

**UNILIFE CORPORATION AND SUBSIDIARIES****Notes to Consolidated Financial Statements — (Continued)**

Company's consolidated balance sheets and will be included in income upon sale or liquidation of the foreign investment. Gains and losses from foreign currency transactions, denominated in a currency other than the functional currency, are recorded in other expense (income) within the Company's consolidated statements of operations and aggregated \$0.1 million, \$0.1 million and \$0.3 million during the years ended June 30, 2011, 2010 and 2009, respectively.

***Comprehensive Income (Loss)***

Comprehensive income (loss) includes net income (loss) and other comprehensive income (loss). The Company's other comprehensive income (loss) consists only of foreign currency translation adjustments.

***Revenue Recognition***

The Company recognizes revenue from licensing fees, industrialization efforts and product sales.

In June 2008, the Company entered into an exclusive licensing arrangement to allow its pharmaceutical partner to use certain of the Company's intellectual property in order and solely to develop in collaboration with the Company, the Company's Unifill syringe for use in and sale to the pre-filled syringe market. The 10.0 million euro up-front, non-refundable fee paid for this license is being amortized over the 5 year expected life of the related agreement. In late fiscal 2009, the Company entered into an industrialization agreement with its pharmaceutical partner, under which specific payment amounts and completion dates were established for achievement of certain pre-defined milestones in its development of the Unifill syringe. Revenue is recognized upon achievement of the "at risk" milestone events, which represents the culmination of the earnings process related to such events. Milestones include specific phases of the project such as product design, prototype availability, user tests, manufacturing proof of principle and the various steps to complete the industrialization of the product. Revenue recognized is commensurate with the milestones achieved and the Company has no future performance obligations related to previous milestone payments as each milestone payment is non-refundable when received.

The Company recognizes revenue from sales of products at the time of shipment and when title passes to the customer. Product sales from B. Braun, a customer who accounted for 10% or more of the Company's revenue, were \$2.5 million, \$2.5 million and \$2.6 million during the years ended June 30, 2011, 2010 and 2009, respectively.

***Advertising Costs***

Advertising costs are expensed in the period incurred. The Company incurred total advertising costs of \$0.6 million, \$0.5 million and \$0.1 million during the years ended June 30, 2011, 2010 and 2009, respectively.

***Research and Development Costs***

Research and development costs, which primarily consist of salaries, benefits and contracted services are expensed as incurred.

***Earnings (Loss) Per Share***

Basic earnings (loss) per share is computed as net income (loss) divided by the weighted average number of shares outstanding during the period. Diluted earnings per share reflect the potential dilution that could occur from common shares issued through common stock equivalents. The dilutive effect of potential common shares, consisting of non-participating restricted stock and outstanding options to purchase common stock, is calculated using the treasury stock method.

Unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents, whether paid or unpaid, are considered participating securities and are included in the computation of earnings (loss) per share according to the two class method if the impact is dilutive. Shares of the Company's unvested

## UNILIFE CORPORATION AND SUBSIDIARIES

## Notes to Consolidated Financial Statements — (Continued)

restricted stock are considered participating securities. However, in the event of a net loss, participating securities are excluded from the calculation of both basic and diluted earnings (loss) per share.

**Government Grants**

Government grants are recognized when there is reasonable assurance that the grant will be received and all attached conditions will be complied with.

**Business Segments**

The Company operates in one reportable segment, which includes the design, development and manufacture of advanced drug delivery systems. Sales by geographic location are as follows:

	Years Ended June 30,		
	2011	2010	2009
	(In thousands)		
Domestic	\$2,773	\$ 2,538	\$ 3,919
International	3,877	8,884	16,057
	<u>\$6,650</u>	<u>\$11,422</u>	<u>\$19,976</u>

**Reclassifications**

Certain amounts in the consolidated statements of operations were reclassified from selling, general and administrative expenses to research and development expenses during the years ended June 30, 2010 and 2009. Management has determined that activities performed by certain employees were more closely associated with research and development activities and has reclassified those items on the accompanying consolidated statements of operations.

This reclassification did not affect the consolidated balance sheets or consolidated statements of cash flows. Additionally, the reclassification did not affect operating loss or net loss on the consolidated statements of operations. The following table summarizes the as reported and as adjusted amounts related to the reclassification discussed above:

	Year Ended June 30,	
	2010	2009
	(In thousands)	
Research and development — as reported	\$ 8,495	\$ 1,048
Research and development — as adjusted	\$10,934	\$ 2,209
Selling, general and administrative — as reported	\$28,696	\$14,941
Selling, general and administrative — as adjusted	\$26,257	\$13,780

**Recently Issued Accounting Pronouncements**

In March 2010, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2010-17, "Milestone Method of Revenue Recognition, a consensus of the FASB Emerging Issues Task Force (Issue No. 08-9)" ("ASU 2010-17"). ASU 2010-17 provides guidance about the criteria that must be met to use the milestone method of revenue recognition. This ASU is effective for milestones achieved in fiscal years and interim periods within those years, beginning after June 15, 2010. The Company adopted ASU 2010-17 on July 1, 2010 and its adoption did not have a material impact on its consolidated financial statements.

In June 2011, the FASB issued ASU 2011-05, "Comprehensive Income" ("ASU 2011-05"). ASU 2011-05 removes certain presentation options and requires entities to report components of net income and comprehensive income in either one continuous statement of comprehensive income or two separate but consecutive statements.

## UNILIFE CORPORATION AND SUBSIDIARIES

### Notes to Consolidated Financial Statements — (Continued)

There is no change to the items that are reported in other comprehensive income. ASU 2011-05 is effective for annual and interim periods beginning after December 15, 2011. Other than additional presentation of other comprehensive loss outside of the statements of stockholders' equity and comprehensive loss, the adoption of ASU 2011-05 will not have an impact on the Company's consolidated financial statements.

#### 4. Equity Transactions and Share-Based Compensation

In October and November 2009, the Company issued 10,544,961 shares of common stock and 3,145,767 options to purchase common stock for aggregate proceeds of A\$50.9 million (\$47.1 million), net of issuance costs, through a combination of a U.S. and Australian private placement and a share purchase plan for the Company's Australian and New Zealand stockholders. Of these options, 50% are exercisable at A\$7.50 per share, and 50% are exercisable at A\$12.00 per share. The Company also issued 497,662 options to purchase common stock to certain brokers as consideration for their services in connection with the private placement, which are exercisable at A\$5.10 per share. All of the options described above are immediately exercisable and will expire in November 2012.

In November 2009, the Company issued 3,333,333 shares of common stock to the former stockholders of Unitract Syringe Pty Limited. These shares were issued in full satisfaction of the Company's obligation for the purchase of that business which had been accrued for on the date of purchase.

In January 2010, the Company issued 833,333 fully vested shares of common stock to certain employees in consideration of their transfer to the Company of certain intellectual property rights and recognized \$4.3 million of share-based compensation expense classified in research and development expense.

In December 2010, the Company issued 7,048,373 shares of common stock and 2,268,934 options to purchase common stock for aggregate proceeds of A\$34.1 million (\$33.4 million), net of issuance costs, through an Australian private placement and a share purchase plan for the Company's Australian and New Zealand stockholders. Of these options, 50% are exercisable at A\$7.50 per share, and 50% are exercisable at A\$12.00 per share. The options became exercisable in June 2011 and will expire in December 2013.

The Company recognized share-based compensation expense related to stock options, grants of restricted stock and common stock to employees, directors and consultants of \$9.0 million, \$10.1 million and \$3.1 million during the years ended June 30, 2011, 2010 and 2009, respectively.

As of June 30, 2011, the total compensation cost related to all non-vested awards not yet recognized is \$10.3 million. This amount is expected to be recognized over a remaining weighted average period of 1.62 years.

#### *Stock Options and Warrants*

The Company has granted stock options to certain employees and directors under the Employee Share Option Plan (the "Plan"). The Plan is designed to assist in the motivation and retention of employees and to recognize the importance of employees to the long-term performance and success of the Company. The Company has also granted stock options to certain consultants outside of the Plan. The majority of the options to purchase common stock vest on the anniversary of the date of grant, which ranges from one to three years. Additionally, certain stock options vest upon the closing price of the Company's common stock reaching certain minimum levels, as defined in the agreements. Share-based compensation expense related to options granted to employees is recognized on a straight-line basis over the related vesting term. Share-based compensation expense related to options granted to consultants is recognized ratably over each vesting tranche of the options.

During the year ended June 30, 2010, the Company granted 383,333 options to purchase common stock to certain employees and directors under the Plan. The options are exercisable at prices ranging from A\$2.10 to A\$7.20 per share and vest over a period of three years. The weighted average grant date fair value of the options is \$2.08 per share.

**UNILIFE CORPORATION AND SUBSIDIARIES****Notes to Consolidated Financial Statements — (Continued)**

During the year ended June 30, 2010, the Company granted 3,643,429 options to purchase common stock outside of both the Plan and the Stock Incentive Plan in connection with the Company's November 2009 private placement as discussed above.

In November 2009, the Company adopted the 2009 Stock Incentive Plan (the "Stock Incentive Plan"). The Stock Incentive Plan provides for a maximum of 6,000,000 shares of common stock to be reserved for the issuance of stock options and other stock-based awards. Commencing on January 1, 2011, and on each January 1st thereafter, through January 1, 2019, the share reserve will automatically adjust so that it will equal 12.5% of the weighted average number of shares of common stock outstanding reduced by the sum of any shares of common stock issued under the Stock Incentive Plan and any shares of common stock subject to outstanding awards under the Stock Incentive Plan.

In November 2009, the Company's compensation committee approved a new incentive package for its Chief Executive Officer, which included the issuance of 834,000 options to purchase common stock under the Stock Incentive Plan. The options were issued on February 3, 2010 following stockholder approval of the incentive package. The options are exercisable at \$6.64 per share and vest upon the trading price of the Company's common stock reaching certain minimum levels on Nasdaq, which range from \$9.45 to \$17.82 per share. The grant date fair value of the options was \$3.18 per share and the fair value of the options is being expensed on a straight-line basis over a derived service period of 1.92 years.

In January 2010, the Company issued 1,000,000 options to purchase common stock to a consultant under the Stock Incentive Plan in consideration for various services to be performed for the Company. The options to purchase common stock are exercisable at A\$6.33 per share and vest upon the trading price of the Company's CDIs reaching certain minimum levels on the Australian Securities Exchange, which range from A\$1.75 to A\$3.22 per share. The options are re-measured each reporting date and as of June 30, 2011 were valued at \$2.29 per option, which is being expensed ratably over the vesting period of each tranche, which ranges from 1.30 years to 2.0 years. The options will be re-valued on a quarterly basis and marked to market until exercised.

In June 2010, the Company issued 240,000 options to purchase common stock to its Chief Financial Officer under the Stock Incentive Plan. The options are exercisable at \$5.28 per share and vest upon the market capitalization of the Company reaching certain minimum levels, ranging from \$500.0 million to \$1,500.0 million. The grant date fair value of the options was \$2.38 per share and the fair value of the options is being expensed on a straight-line basis over a derived service period of 2.70 years.

During the year ended June 30, 2010, the Company granted 70,000 additional options to purchase common stock to certain employees under the Stock Incentive Plan. The options are exercisable at \$5.80 per share and vest over a period of three years. The weighted average grant date fair value of the options was \$2.71 per share.

In December 2010, the Company issued 375,000 warrants to Keystone Redevelopment Group, LLC ("Keystoue") and 225,000 warrants to L2 Architecture ("L2") outside of both the Plan and the Stock Incentive Plan. The warrants issued to Keystone were in partial consideration for managing the development of the Company's new headquarters and manufacturing facility and the warrants issued to L2 were in partial consideration for the custom design of the facility. The warrants issued to both Keystone and L2 are exercisable at \$5.30 per warrant vested immediately upon issuance and were valued at \$2.70 per warrant. The aggregate fair value of the warrants of \$1.6 million has been capitalized and included as a component of the cost of the building.

In December 2010, the Company issued 2,268,934 options to purchase common stock outside of both the Plan and the Stock Incentive Plan in connection with the Company's December 2010 private placement as discussed above.

In February 2011, the Company issued 300,000 options to purchase common stock to its Chief Operating Officer under the Stock Incentive Plan. The options are exercisable at \$4.85 per share and vest in eight equal installments based upon the achievement of operational and product milestones as determined by the compensation



# UNILIFE CORPORATION AND SUBSIDIARIES

## Notes to Consolidated Financial Statements — (Continued)

committee of the board of directors. The weighted average grant date fair value of the options was \$2.73 per share and the fair value of the options is being expensed on a straight-line basis over a weighted average estimated service period of 1.31 years.

During year ended June 30, 2011, the Company granted 1,193,517 additional options to purchase common stock to certain employees and directors under the Stock Incentive Plan. The weighted average exercise price of the options was \$5.75 per share. The majority of the options vest over a period of three years, with the exception of 360,000 options, which vest upon meeting certain performance targets, as defined in the agreements. The weighted average grant date fair value of the options was \$2.80 per share.

In April and May 2011, the Company granted 300,000 options to purchase common stock to certain employees under the Stock Incentive Plan, with a weighted average exercise price of \$5.02 per share for which the performance-based vesting terms have not been mutually agreed upon between the parties. Due to the fact that material terms have not been mutually agreed upon between the grantees and the Company, the criteria for establishing a grant under Accounting Standards Codification ("ASC") Topic 718, "Compensation — Stock Compensation" has not been met. As a result, share-based compensation expense recorded during the year ended June 30, 2011 does not include any amounts related to these awards.

The following is a summary of activity related to stock options held by employees and board members during the year ended June 30, 2011:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (In Years)	Aggregate Intrinsic Value (In thousands)
Outstanding as of July 1, 2010	4,058,701	\$ 3.70		
Granted	1,493,517	5.57		
Exercised	(573,031)	2.14		
Cancelled	(279,976)	3.86		
Outstanding as of June 30, 2011	4,699,211	\$ 4.48	4.1	\$ 5,455
Exercisable as of June 30, 2011	2,044,169	\$ 2.64	2.2	\$ 5,072

The following is a summary of activity related to stock options and warrants held by non-employees during the year ended June 30, 2011:

	Number of Options and Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (In Years)	Aggregate Intrinsic Value (In thousands)
Outstanding as of July 1, 2010	6,355,642	\$ 7.15		
Granted	2,868,934	9.28		
Exercised	(1,097,967)	2.07		
Outstanding as of June 30, 2011	8,126,609	\$ 8.59	2.2	\$ 1,759
Exercisable as of June 30, 2011	7,126,609	\$ 8.85	2.0	\$ 1,759

The aggregate intrinsic value is defined as the difference between the market value of the Company's common stock as of the end of the period and the exercise price of the in-the-money stock options. The total intrinsic value of



UNILIFE CORPORATION AND SUBSIDIARIES

Notes to Consolidated Financial Statements — (Continued)

stock options exercised during the years ended June 30, 2011, 2010 and 2009 was \$6.0 million, \$5.8 million and \$93,000, respectively. Of the 3,655,042 non vested options, 1,000,000 are held by a consultant.

The Company currently uses authorized and unissued shares to satisfy stock option exercises.

The weighted average fair value of stock options granted during the years ended June 30, 2011, 2010 and 2009 was \$2.65, \$3.13 and \$0.62 per share, respectively. The weighted average fair value of \$2.65 per share during the year ended June 30, 2011 does not include the weighted average fair value of the stock options granted in connection with the Company's 2010 private placement of \$1.26 per share. The weighted average fair value of \$3.13 per share during the year ended June 30, 2010 does not include the weighted average fair value of the stock options granted in connection with the Company's 2009 private placement of \$2.49 per share.

The following is a summary of outstanding and exercisable stock options held by employees and board members as of June 30, 2011:

Range of Exercise Prices	Outstanding Options			Exercisable Options		
	Outstanding as of June 30, 2011	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (In Years)	Exercisable as of June 30, 2011	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (In Years)
\$0.00 — \$2.10	1,733,337	\$ 2.08	2.0	1,666,667	\$ 2.09	1.9
\$2.11 — \$4.85	475,000	3.88	6.4	179,167	2.76	3.1
\$4.86 — \$7.63	2,490,874	6.26	5.2	198,335	7.20	3.7
	<u>4,699,211</u>	<u>\$ 4.48</u>	<u>4.1</u>	<u>2,044,169</u>	<u>\$ 2.64</u>	<u>2.2</u>

The following is a summary of outstanding and exercisable stock options held by non-employees as of June 30, 2011:

Range of Exercise Prices	Outstanding Options			Exercisable Options		
	Outstanding as of June 30, 2011	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (In Years)	Exercisable as of June 30, 2011	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (In Years)
\$0.00 — \$2.10	535,245	\$ 1.88	1.2	535,245	\$ 1.88	1.2
\$2.11 — \$6.71	2,176,662	5.90	3.3	1,176,662	5.19	3.0
\$6.72 — \$12.72	5,414,702	10.33	1.8	5,414,702	10.33	1.8
	<u>8,126,609</u>	<u>\$ 8.59</u>	<u>2.2</u>	<u>7,126,609</u>	<u>\$ 8.85</u>	<u>2.0</u>

The Company used the following weighted average assumptions in calculating the fair value of options and warrants granted during the year ended June 30, 2011, the period from January 27, 2010 to June 30, 2010 (the period

## UNILIFE CORPORATION AND SUBSIDIARIES

## Notes to Consolidated Financial Statements — (Continued)

subsequent to the Company's redomiciliation), the period from July 1, 2009 to January 26, 2010 (the period prior to the Company's redomiciliation) and the year ended June 30, 2009 (prior to the Company's redomiciliation):

	Year Ended June 30, 2011	Period From January 27, 2010 to June 30, 2010	Period From July 1, 2009 to January 26, 2010	Year Ended June 30, 2009
Number of stock options granted	2,093,517	1,144,000	1,383,333	3,850,000
Expected dividend yield	0%	0%	0%	0%
Risk-free interest rate	1.96%	2.35%	4.10%	4.76%
Expected volatility	59%	60%	79%	80%
Expected life (in years)	5.15	3.99	4.23	4.4

The assumptions noted above for the year ended June 30, 2011 do not include amounts related to the 2,268,934 options issued in the Company's December 2010 private placement as discussed above. The assumptions noted above for the period from July 1, 2009 to January 26, 2010 do not include amounts related to the 3,643,429 options issued in the Company's October 2009 private placement, as discussed above.

Subsequent to the Company's redomiciliation, the fair value of each stock option was estimated at the grant date using the Black-Scholes option pricing model, with the exception of grants subject to market conditions, which were valued using a Monte Carlo option pricing model. The Company has not historically paid dividends to its stockholders and, as a result, assumed a dividend yield of 0%. The risk free interest rate is based upon the rates of U.S. Treasury bonds with a term equal to the expected term of the option. Due to the Company's limited Nasdaq trading history, the expected volatility used to value options granted after January 27, 2010 is based upon a blended rate of the historical share price of the Company's stock on the Australian Securities Exchange and the volatility of peer companies traded on U.S. exchanges operating in the same industry as the Company. The expected term of the options to purchase common stock issued to employees and directors is based upon the simplified method, which is the mid-point between the vesting date of the option and its contractual term unless a reasonable alternate term is estimated by management. The expected term of the options to purchase common stock issued to consultants is based on the contractual term of the awards.

Prior to the Company's redomiciliation, the fair value of each stock option was estimated at the grant date using the Black-Scholes option pricing model, with the exception of grants subject to market conditions which were valued based on a Barrier option pricing model. The Company has not historically paid dividends to its stockholders and, as a result, assumed a dividend yield of 0%. The risk free interest rate is based upon the rates of Australian bonds with a term equal to the expected term of the option. The expected volatility is based upon the historical share price of the Company's common stock on the Australian Securities Exchange. The expected term of the stock options to purchase common stock is based upon the outstanding contractual term of the stock option on the date of grant.

### Restricted Stock

The Company has granted shares of restricted stock to certain employees and consultants under the Stock Incentive Plan. During the period prior to vesting, the holder of the non-vested restricted stock will have the right to vote and the right to receive all dividends and other distributions declared. All non-vested shares of restricted stock are reflected as outstanding; however, they have been excluded from the calculation of basic earnings per share.

For employees, the fair value of restricted stock is measured on the date of grant using the closing price of the Company's common stock on that date. Share-based compensation expense for restricted stock issued to employees is recognized on a straight-line basis over the requisite service period, which is generally the longest vesting period. For restricted stock granted to consultants, the fair value of the awards will be re-valued on a quarterly basis and

## UNILIFE CORPORATION AND SUBSIDIARIES

## Notes to Consolidated Financial Statements — (Continued)

marked to market until vested. Share-based compensation expense for restricted stock issued to consultants is recognized ratably over each vesting tranche.

In November 2009, the Company's compensation committee approved the issuance of 1,166,000 shares of restricted stock to the Company's Chief Executive Officer under the Stock Incentive Plan. The shares were issued in February 2010 following stockholder approval. The shares of restricted stock vest upon the satisfaction of certain performance targets, as defined in the agreement. The grant date fair value of the restricted shares was \$6.64 per share.

In June 2010, the Company issued 80,000 shares of restricted stock to the Company's Chief Financial Officer under the Stock Incentive Plan. The shares of restricted stock vest on certain anniversaries from the date of grant, ranging from one to three years. The grant date fair value of the restricted shares was \$5.28 per share.

In March 2010, the Company issued 572,000 shares of restricted stock to certain employees and a consultant. The majority of the shares of restricted stock vest on certain anniversaries from the date of grant, ranging from one to three years. The remaining shares vest upon the satisfaction of certain performance targets, as defined in the agreements. The weighted average grant date fair value of the restricted shares was \$6.07 per share.

In February 2011, the Company issued 120,000 shares of restricted stock to its Chief Operating Officer under the Stock Incentive Plan. A total of 80,000 shares of the restricted stock vest on certain anniversaries from the date of grant, ranging from one to three years and a total of 40,000 shares of restricted stock vest upon the achievement of certain performance conditions, as defined in the agreement. The grant date fair value of the restricted shares was \$4.85 per share.

The following is a summary of activity related to restricted stock awards during the year ended June 30, 2011.

	Number of Restricted Stock Awards	Weighted Average Grant Date Fair Value
Unvested as of July 1, 2010	1,818,000	\$ 6.40
Granted	470,000	5.24
Vested	(281,000)	6.07
Forfeited	(50,000)	5.46
Unvested as of June 30, 2011	1,957,000	\$ 6.19

*Grants of Common Stock to Employees*

During the year ended June 30, 2009 the Company granted 45,885 shares of common stock to certain employees. The Company recorded a charge to operations of \$44,000 related to the issuance of these awards.

During the year ended June 30, 2009, the Company granted 1,666,667 shares of common stock to its Chief Executive Officer. The shares are subject to certain transfer restrictions in which 833,333 cannot be sold until the first anniversary of the date of grant and 833,334 cannot be sold until the second anniversary of the date of grant. During the year ended June 30, 2009, the Company recorded a charge to operations of \$1.5 million related to the issuance of these awards.

During the year ended June 30, 2011, the Company granted 23,184 shares of common stock to certain employees. The Company recorded a charge to operations of \$0.1 million related to the issuance of these awards.

**UNILIFE CORPORATION AND SUBSIDIARIES**  
**Notes to Consolidated Financial Statements — (Continued)**

**5. Property, Plant and Equipment and Construction-in-Progress**

Property, plant and equipment consist of the following:

	June 30,	
	2011	2010
	(In thousands)	
Building	\$31,866	\$ —
Machinery and equipment	16,130	10,848
Computer software	2,457	528
Furniture and fixtures	323	737
Construction in progress	5,734	18,560
Land	2,036	2,036
Leasehold improvements	58,546	33,735
Less: accumulated depreciation and amortization	(4,526)	(3,763)
Property, plant and equipment, net	<u>\$54,020</u>	<u>\$29,972</u>

Construction in progress as of June 30, 2011 consisted primarily of amounts incurred in connection with machinery and equipment. Construction in progress as of June 30, 2010 consisted primarily of amounts incurred in connection with the construction of the Company's new manufacturing facility and machinery and equipment.

**6. Goodwill and Intangible Assets**

The changes in the carrying amount of goodwill during the years ended June 30, 2010 and 2011 are as follows:

	(In thousands)
Balance as of July 1, 2009	\$ 10,235
Foreign currency translation	557
Balance as of June 30, 2010	10,792
Foreign currency translation	2,473
Balance as of June 30, 2011	<u>\$ 13,265</u>

Intangible assets consist of patents acquired in a business acquisition of \$0.1 million. Related accumulated amortization as of June 30, 2011 and 2010 was \$63,000 and \$40,000 respectively, and future amortization expense is scheduled to be \$7,000 annually.

**7. Accrued Expenses**

Accrued expenses consist of the following:

	June 30,	
	2011	2010
	(In thousands)	
Accrued payroll and other employee related expenses	\$1,737	\$1,405
Accrued machinery and equipment costs	231	—
Accrued construction costs related to the new manufacturing facility	—	1,003
Accrued other	728	503
Total accrued expenses	<u>\$2,696</u>	<u>\$2,911</u>

## UNILIFE CORPORATION AND SUBSIDIARIES

## Notes to Consolidated Financial Statements — (Continued)

**8. Commitments and Contingencies**

The Company leases certain facilities, office equipment and automobiles under non-cancellable operating leases. The future minimum lease payments related to the Company's non-cancellable operating lease commitments as of June 30, 2011 were as follows:

For the Year Ending June 30,

	(In thousands)
2012	\$ 60
2013	33
2014	14
2015	3
2016	2
	<u>\$ 112</u>

Rental expenses under operating leases during the years ended June 30, 2011, 2010 and 2009 was \$0.7 million, \$0.6 million and \$0.7 million, respectively.

From time to time, the Company is involved in various legal proceedings, claims, suits and complaints arising out of the normal course of business. Based on the facts currently available to the Company, management believes that these claims, suits and complaints are adequately provided for, covered by insurance, without merit or not probable that an unfavorable outcome will result.

**9. Long-Term Debt**

Long-term debt consists of the following:

	June 30,	
	2011	2010
	(In thousands)	
Mortgage loans	\$17,940	\$ —
Bank term loans	2,095	2,393
Commonwealth of Pennsylvania financing authority loan	2,227	—
Commonwealth of Pennsylvania assisted machinery loans	237	332
Other	188	16
	<u>22,687</u>	<u>2,741</u>
Less: current portion of long-term debt	<u>2,274</u>	<u>1,648</u>
Total long-term debt	<u>\$20,413</u>	<u>\$1,093</u>

**Mortgage Loans**

In October 2010, the Company entered into a loan agreement with Metro Bank ("Metro"), pursuant to which Metro agreed to provide the Company with two notes in the amounts of \$14.25 million and \$3.75 million. The proceeds received have been used to finance the purchase of the land and construction of the Company's new corporate headquarters and manufacturing facility in York, Pennsylvania, including the repayment of a \$6.9 million bridge construction loan with Univest.

The \$14.25 million term note matures 20 years from completion of construction of the Company's new corporate headquarters and manufacturing facility and the \$3.75 million term note matures on October 20, 2020. During construction, the Company paid only interest on both term notes at the Prime Rate plus 1.50% per annum,



## UNILIFE CORPORATION AND SUBSIDIARIES

## Notes to Consolidated Financial Statements — (Continued)

with a floor of 4.50% per annum. For a period of five years subsequent to construction, the Company will pay principal and interest on both term notes, with interest at a fixed rate based on the 5 year Treasury-bill plus 300 basis points per annum, with a floor of 6.0% per annum. Commencing five years subsequent to construction through the maturity dates for each term note, the Company will pay principal and interest on both term notes, with interest at a rate to be negotiated by the parties, or if no rate is negotiated, based upon the Prime Rate plus 1.0% per annum, with a floor not to exceed 250 basis points over the Prime Rate. The Company will also pay one final payment of principal and interest upon the maturity of each term note.

The loan agreement contains certain customary covenants, including the maintenance of a Debt Service Reserve Account in the amount of \$2.4 million, classified as restricted cash on the consolidated balance sheet, which will remain in place until the Company and Metro agree on the financial covenants. The Company was in compliance with its debt covenants as of June 30, 2011. However, the Company is not certain that it will be able to maintain the Debt Service Reserve Account balance for a period of 12 months from June 30, 2011. The Company may prepay the loan, but will incur a prepayment penalty of 2.0% during the first three years. The U.S. Department of Agriculture has guaranteed \$10.0 million of the loan.

As of June 30, 2011, \$14.19 million was outstanding under the \$14.25 million note and the full amount was outstanding under the \$3.75 million note.

**Bank Term Loans**

Bank term loans consist of two term loans payable. The loans bear interest at a rate of prime (3.25% as of June 30, 2011) plus 1.50% (4.75% as of June 30, 2011) per annum and mature on dates ranging from December 2020 through August 2021. The borrowings under the bank term loans are collateralized by the Company's accounts receivable, inventories and certain machinery and equipment. In February 2011, the bank term loan agreements were amended so that the covenants are consistent with those under the Company's mortgage loans as discussed above, thus removing the covenants that were in violation as of June 30, 2010. Due to the previous violation of the bank term loan covenants as of June 30, 2010 and the uncertainty of being able to maintain the Debt Service Reserve Account balance for a period of 12 months from June 30, 2011, the \$1.2 million long-term portion outstanding as of June 30, 2011 under these bank term loans is classified in the current portion of long-term debt.

**Commonwealth of Pennsylvania Financing Authority Loan**

In October 2009, the Company accepted a \$5.45 million offer of assistance from the Commonwealth of Pennsylvania which included up to \$2.25 million in financing for land and the construction of its new manufacturing facility. In December 2010, Unilife Cross Farm LLC, a subsidiary of the Company ("Cross Farm"), received the \$2.25 million loan which bears interest at a rate of 5.0% per annum, matures in January 2021 and is secured by a third mortgage on its new facility. In connection with the loan agreement, Cross Farm entered into an intercreditor agreement by which the Commonwealth of Pennsylvania agreed that it would not exercise its rights in the event of a default by Cross Farm without the consent of Metro, who holds the first and second mortgages on its new facility.

**Commonwealth of Pennsylvania Assisted Machinery Loans**

The Company has qualified for two Commonwealth of Pennsylvania assisted loans for the purchase of specific machinery and equipment. These loans bear interest at rates ranging from 2.75% to 3.25% per annum and mature on dates ranging from July 2011 through July 2013. The borrowings under these loans are collateralized by the related equipment.



**UNILIFE CORPORATION AND SUBSIDIARIES**  
**Notes to Consolidated Financial Statements — (Continued)**

As of June 30, 2011, aggregate maturities of long-term obligations are as follows:

**For the Year Ending June 30,**

	(In thousands)
2012	\$ 1,121
2013	1,147
2014	1,154
2015	1,114
2016	1,152
Thereafter	16,999
	<u>\$ 22,687</u>

**10. Loss Per Share**

The Company's net loss per share is as follows:

	Year Ended June 30,		
	2011	2010	2009
	(In thousands, except share and per share data)		
<b>Numerator</b>			
Net loss	\$ (40,682)	\$ (29,748)	\$ (517)
<b>Denominator</b>			
Weighted average number of shares used to compute basic loss per share	57,891,024	46,837,066	34,426,353
Effect of dilutive options to purchase common stock	—	—	—
Weighted average number of shares used to compute diluted loss per share	57,891,024	46,837,066	34,426,353
<b>Basic and diluted loss per share</b>	<u>\$ (0.70)</u>	<u>\$ (0.64)</u>	<u>\$ (0.02)</u>

Due to the Company's net losses, unvested shares of restricted stock (participating securities) totaling 1,959,828 and 489,178 were excluded from the calculation of basic and diluted loss per share during the years ended June 30, 2011 and 2010, respectively. There were no shares of restricted stock outstanding during the year ended June 30, 2009.

In addition, stock options (non-participating securities) totaling 8,998,164, 8,234,060, and 5,362,310 during the years ended June 30, 2011, 2010 and 2009, respectively, were excluded from the calculation of diluted loss per share as their effect would have been anti-dilutive. Certain of these stock options were excluded solely due to the Company's net loss position. Had the Company reported net income during the years ended June 30, 2011, 2010 and 2009, these shares would have had an effect of 1,861,935, 2,316,360, and 237,610 diluted shares, respectively, for purposes of calculating diluted loss per share.

**UNILIFE CORPORATION AND SUBSIDIARIES**  
**Notes to Consolidated Financial Statements — (Continued)**

**11. Income Taxes**

For the years ended June 30, 2011, 2010 and 2009, income (loss) before income taxes consists of the following:

	Years Ended June 30,		
	2011	2010	2009
	(In thousands)		
Domestic	\$ (41,529)	\$ (26,773)	\$ (1,448)
International	847	(2,975)	931
	<u>\$ (40,682)</u>	<u>\$ (29,748)</u>	<u>\$ (517)</u>

**Tax Rate Reconciliation**

Income tax expense (benefit) is as follows:

	Year Ended June 30,								
	2011			2010			2009		
	Current	Deferred	Total	Current	Deferred	Total	Current	Deferred	Total
	(In thousands)								
U.S. Federal	\$ —	\$ (13,907)	\$ (13,907)	\$ —	\$ (8,692)	\$ (8,692)	\$ —	\$ (1,070)	\$ (1,070)
State	—	(4,086)	(4,086)	—	(2,554)	(2,554)	—	(339)	(339)
International	—	279	279	—	553	553	—	(663)	(663)
Changes in valuation allowance	—	17,714	17,714	—	10,693	10,693	—	2,072	2,072
Income tax provision	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

Income tax expense (benefit) was \$0 for the years ended June 30, 2011, 2010 and 2009 and differed from the amounts computed by applying the U.S. federal income tax rate to pretax income as a result of the following:

	Year Ended June 30,		
	2011	2010	2009
Tax at U.S. statutory rate	(35)%	(35)%	(35)%
State taxes, net of federal benefit	(10)%	(9)%	(11)%
Non-deductible and non-taxable items	1%	7%	2%
Change in valuation allowance	44%	37%	44%
	<u>0%</u>	<u>0%</u>	<u>0%</u>

## UNILIFE CORPORATION AND SUBSIDIARIES

## Notes to Consolidated Financial Statements — (Continued)

*Significant Components of Deferred Taxes*

The tax effects of temporary differences and net operating losses that give rise to significant portions of deferred tax assets (liabilities) at June 30, 2011 and 2010 are presented below:

	June 30,	
	2011	2010
	(In thousands)	
Net operating loss carryforwards	\$ 31,572	\$ 15,640
Share-based compensation expense	5,984	2,038
Deferred revenue	2,435	2,625
Depreciation differences	(677)	(190)
Valuation allowance	(39,314)	(20,113)
Net deferred taxes	\$ —	\$ —

The valuation allowance for deferred tax assets as of June 30, 2011 and 2010 was \$39.3 million and \$20.1 million, respectively. The net change in the total valuation allowance was an increase of \$19.2 million. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible or prior to the expiration of the net operating loss carryforwards. Management considers the scheduled reversal of deferred tax liabilities (including the impact of available carryback and carryforward periods), projected future taxable income, and tax-planning strategies in making the assessment as to the realizability of deferred tax assets. Based upon the level of historical taxable income and uncertainty regarding projections for future taxable income over the periods in which the deferred tax assets are deductible or can be utilized, management does not believe it is more likely than not that the Company will realize the benefits of these net operating losses and deductible temporary differences, as of June 30, 2011 and 2010. Therefore a full valuation allowance has been provided. The amount of the net deferred tax assets considered realizable, however, could change if estimates of future taxable income during the carryforward period are increased.

As of June 30, 2011, the Company had net operating loss carryforwards for U.S. federal, state and Australian income tax purposes of approximately \$55.7 million, \$55.7 million and \$23.5 million, respectively, which are available to offset future taxable income. The U.S. federal and state net operating loss carryforwards begin to expire in 2023. The Australian net operating losses do not expire.

The Australian net operating loss carryforwards of approximately \$23.5 million as of June 30, 2011 are subject to either the continuity of ownership or same business test (as defined under Australian tax law) that could limit or substantially eliminate the Company's ability to use these carryforwards. If there have been or will be changes in the Company's ownership or Australian business operations before these net operating loss carryforwards are utilized, they may be unavailable to reduce taxable income in the future. Further, under provision of the Internal Revenue Code, the utilization of a U.S. corporation's federal and state net operating loss carryforwards may be significantly limited following a change in ownership of greater than 50% within a three-year period. The Company's federal and state net operating loss carryforwards may, therefore, be subject to an annual limitation. In addition, state net operating loss carryforwards may be further limited in Pennsylvania, which has a limitation equal to the greater of 20% of taxable income after modifications and apportionment, or \$3.0 million on state net operating losses utilized in any one year.

The Company has adopted the provisions of Interpretation 48, included in ASC Subtopic 740-10. Management has evaluated the tax positions taken and has concluded that no liability for unrecognized tax benefits was required to be recorded for the years ended June 30, 2011, 2010 and 2009.

**UNILIFE CORPORATION AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements — (Continued)**

The Company files Australian, U.S. federal and state income tax returns. The Company is not subject to examination in any jurisdiction at this time. As a result of the net operating losses in prior years, the statute of limitations will remain open for a period following any utilization of net operating loss carryforwards and as such these periods remain subject to examination.

**12. Employee Benefit Plan**

The Company has a retirement savings 401(k) plan covering all U.S. employees. Participating employees may contribute up to 100% of their pre-tax earnings, subject to the statutory limits. During the years ended June 30, 2011, 2010 and 2009, the Company did not match any employee contributions.

**13. Business Alliances**

*Sanofi*

The Company signed an exclusive licensing agreement and an industrialization agreement with Sanofi, a multinational pharmaceutical company, between June 2008 and July 2009. Under the terms of these agreements, Sanofi has agreed to pay the Company an aggregate of approximately \$36.4 million in exclusivity fees and industrialization milestone payments for the exclusive right to negotiate the purchase of the Unifill ready-to-fill (prefilled) syringe (Unifill syringe or product).

Pursuant to the exclusive licensing agreement, Sanofi has paid the Company a 10.0 million euro (\$13.0 million) up front non-refundable one-time fee. During the year ended June 30, 2009, the Company recognized \$2.5 million of this up-front payment as revenue and deferred \$10.6 million, which is being recognized on a straight-line basis over the remaining term of the agreement.

Pursuant to the industrialization agreement, Sanofi has agreed to pay the Company up to 17.0 million euros (\$23.4 million) in milestone-based payments to fund the completion of the Company's industrialization program for the Unifill syringe. As of June 30, 2011 there is one remaining milestone payment of 1.0 million euro to be recognized under the industrialization agreement.

This exclusive right for Sanofi to negotiate for the purchase of the Unifill syringe is limited to the therapeutic drug classes of anti-thrombotic agents, vaccines and four confidential sub-classes until June 30, 2014 (exclusivity list). The Company is able to negotiate with other pharmaceutical companies seeking to utilize the Unifill syringe with drugs targeted for use in therapeutic drug classes outside of those retained by Sanofi under its exclusivity list. Upon mutual agreement by both parties, Sanofi may add additional therapeutic sub-classes to the exclusivity list for the Unifill syringe provided the Company has not previously signed exclusive terms for the product to a third party. The Company is not obligated to sell more than 30% of its annual production capacity for the Unifill syringe to Sanofi without written notification up to two years in advance.

*Stason Pharmaceuticals*

In March 2010, the Company signed an exclusive five year agreement with Stason Pharmaceuticals, a U.S. based pharmaceutical company, to market its Unitract 1mL syringe in Japan, China and Taiwan. Under the agreement, Stason Pharmaceuticals is required to purchase a minimum of 1.0 million units of the Unitract 1mL syringe per year during the term of the contract, subject to regulatory approval of the Unitract 1mL in those markets, which is currently pending.

UNILIFE CORPORATION AND SUBSIDIARIES

Notes to Consolidated Financial Statements — (Continued)

14. Financial Instruments

The Company does not hold or issue financial instruments for trading purposes. The estimated fair values of the Company's financial instruments are as follows:

	June 30, 2011		June 30, 2010	
	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
	(In thousands)			
<b>Assets :</b>				
Cash equivalents — certificates of deposit	\$1,000	\$1,000	\$18,629	\$18,629

The carrying amount of the Company's cash equivalents, which includes certificates of deposit, accounts receivable, accounts payable and accrued expenses approximate their fair value due to the short term maturities of these items. The estimated fair value of the Company's debt approximates its carrying value based upon the rates that the Company would currently be able to receive for similar instruments of comparable maturity.

The Company categorizes its assets and liabilities measured at fair value into a fair value hierarchy that prioritizes the inputs used in pricing the asset or liability. The three levels of the fair value hierarchy are as follows:

*Level 1* — Quoted prices in active markets for identical assets or liabilities.

*Level 2* — Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

*Level 3* — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

The levels in the fair value hierarchy within which a fair value measurement in its entirety falls is based on the lowest level input that is significant to the fair value measurement in its entirety.

The following table presents the Company's assets that are measured at fair value on a recurring basis for the periods presented:

	Fair Value Based On		
	Quoted Market Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	(In thousands)		
Cash equivalents — certificates of deposit (June 30, 2011)	\$—	\$ 1,000	\$—
Cash equivalents — certificates of deposit (June 30, 2010)	\$—	\$18,629	\$—

UNILIFE CORPORATION AND SUBSIDIARIES

Notes to Consolidated Financial Statements — (Continued)

15. Quarterly Results (unaudited)

	Quarter Ended September 30, 2010	Quarter Ended December 31, 2010	Quarter Ended March 31, 2011	Quarter Ended June 30, 2011
(In thousands, except per share data)				
<b>Year Ended June 30, 2011</b>				
Revenues	\$ 3,543	\$ 1,762	\$ 650	\$ 695
Gross profit	2,368	938	200	547
Net loss	(7,246)	(10,358)	(12,533)	(10,545)
Basic and diluted loss per share	\$ (0.14)	\$ (0.19)	\$ (0.20)	\$ (0.17)

	Quarter Ended September 30, 2009	Quarter Ended December 31, 2009	Quarter Ended March 31, 2010	Quarter Ended June 30, 2010
(In thousands, except per share data)				
<b>Year Ended June 30, 2010</b>				
Revenues	\$ 3,108	\$ 3,245	\$ 2,417	\$ 2,652
Gross profit	2,279	2,771	1,885	2,016
Net loss	(2,064)	(5,915)	(12,064)	(9,705)
Basic and diluted loss per share	\$ (0.06)	\$ (0.13)	\$ (0.23)	\$ (0.18)

Per share amounts for the quarters may not add to the annual amount due to differences in the weighted average common shares outstanding during the periods.

16. Subsequent Events

On August 15, 2011, the Company entered into a Master Lease Agreement with Varilease Finance, Inc. ("Varilease"). Under the Master Lease Agreement, Varilease will provide up to \$10.0 million of lease financing for production equipment for the Unifill ready-to-fill syringe. The Company has the option of selling and leasing back existing equipment or using the facility to lease additional equipment.

Under the terms of the Master Lease Agreement, the Company will lease the equipment from Varilease for a two-year base term, and the Company will pay rent in equal monthly installments of up to \$0.4 million over the base term.

The Master Lease Agreement contains covenants and provisions for events of default customarily found in lease agreements. The Company may prepay the monthly rent payments without penalty. At the end of the lease term, the Company has the option to extend the lease, return the equipment or purchase the equipment, as defined in the agreement.



**Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

None.

**Item 9A. *Controls and Procedures***

**Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, performed an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 ("Exchange Act")) as of the end of the period covered by this Annual Report on Form 10-K. Our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective insofar as they are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms, and they include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting and the Report of Independent Registered Public Accounting Firm is included in Item 8 of this Annual Report on Form 10-K.

**Changes in Internal Control**

There has not been any change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter ended June 30, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. *Other Information***

None.

**PART III**

**Item 10. *Directors, Executive Officers and Corporate Governance***

The information required by this Item 10 regarding directors and corporate governance is incorporated by reference to our definitive proxy statement for our 2011 Annual Meeting of Stockholders (the "2011 Proxy Statement") under the headings "Election of Directors" and "Information on our Board of Directors and Corporate Governance". Information regarding executive officers is set forth in Item 1 of Part I of this Report under the caption "Executive Officers."

**Item 11. *Executive Compensation***

The information required by this Item 11 is incorporated by reference to the 2011 Proxy Statement under the headings of "Executive Compensation" and "Director Compensation".

**Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

Except as set forth below, the information required by Item 12 is incorporated by reference to the 2011 Proxy Statement under the heading "Security Ownership of Certain Beneficial Owners and Management," "Equity Compensation Plan Information," and "Equity Compensation Plan Information."

## ASX-Required Disclosure

### *Corporations Act 2001 (Cth) and Repurchases of Securities*

We are not subject to Chapters 6, 6A, 6B and 6C of the Corporations Act dealing with the acquisition of our shares (in particular, relating to substantial shareholdings and takeovers).

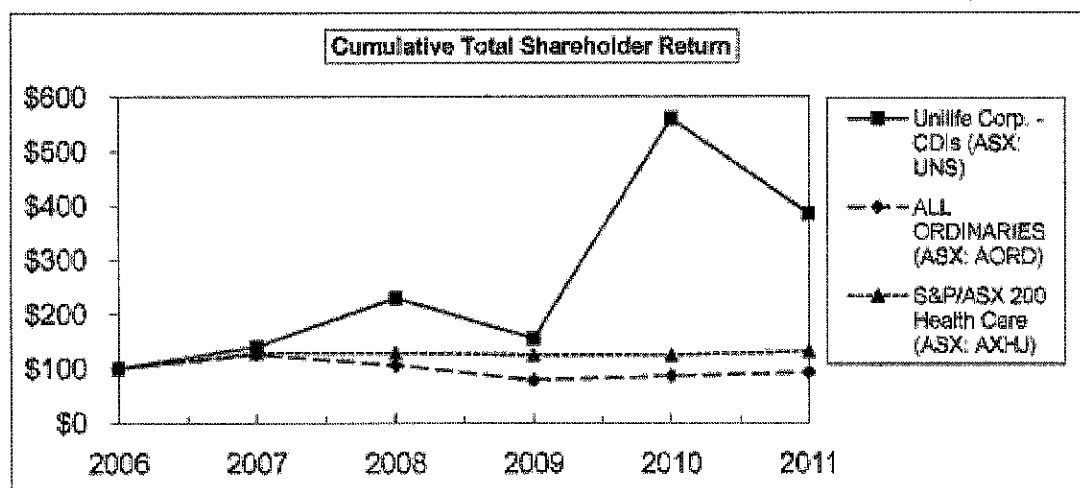
Under the Delaware General Corporation Law, we are generally permitted to purchase or redeem our outstanding shares out of funds legally available for that purpose without obtaining stockholder approval, provided that (i) our capital is not impaired; (ii) such purchase or redemption would not cause our capital to become impaired; (iii) the purchase price does not exceed the price at which the shares are redeemable at our option and (iv) immediately following any such redemption, we shall have outstanding one or more shares of one or more classes or series of stock, which shares shall have full voting powers. Our certificate of incorporation does not create any further limitation on our purchase or redemption of our shares.

### *Australian Disclosure Requirements*

As part of our ASX listing, we are required to comply with various disclosure requirements as set out under the ASX Listing Rules. The following information is intended to comply with the ASX Listing Rules and is not intended to fulfill information required by this Annual Report on Form 10-K.

### *Comparative Performance Graph*

The performance graph shown below compares the change in cumulative total stockholder return of Unilife Corporation's Chess Depository Interest (CDI), the ASX All Ordinaries Index and the S&P/ASX 200 Health Care Index for the five year period ended June 30, 2011. The graph sets the beginning value of shares of CDIs and the indices at \$100, and assumes that all quarterly dividends were reinvested at the time of payment. This graph does not forecast future performance of shares of the Company's common stock or CDIs.



*Distribution of Common Stock and CDI Holders as of September 1, 2011*

	Common Stock		CDIs	
	Number of Holders	Number of Shares of Common Stock	Number of Holders	Number of CDIs
1 — 1,000	163	50,850	1,396	747,030
1,001 — 5,000	62	140,415	2,580	7,561,548
5,001 — 10,000	14	91,027	1,263	10,022,720
10,001 — 100,000	31	1,137,433	2,712	86,511,951
100,001 — and over	8	62,658,133	478	160,943,796
	<u>278</u>	<u>64,077,858</u>	<u>8,429</u>	<u>265,787,045</u>

The number of stockholders holding less than a marketable parcel of shares was 863 as of September 1, 2011.

There is no current on-market buy-back of the Company's securities.

**Twenty Largest CDI Holders as of September 9, 2011**

Rank	Name	Number of CDIs Held	% of CDIs Outstanding
1.	Merkaba Limited	7,263,588	2.74
2.	National Nominees Limited	5,289,512	2.00
3.	J P Morgan Nominees Australia Limited	4,560,594	1.72
4.	Admark Investments Pty Ltd <JS Pinto Super Fund A/C>	3,937,047	1.49
5.	Joseph Kaal	3,833,990	1.45
6.	Penila Investments Pty Ltd <Hornung S/F A/C>	3,657,799	1.38
7.	Mr Bradley Gavin Downes	3,014,169	1.14
8.	Mr Dennis Banks + Mrs Janine Banks <Banks Super Fund A/C>	2,580,591	0.97
9.	Citicorp Nominees Pty Limited	2,457,850	0.93
10.	Thorley Management Pty Ltd <Thorley Investment A/C>	2,322,498	0.88
11.	Omaha Nominees Pty Ltd <The PJH A/C>	2,017,645	0.76
12.	Mr Dennis John Banks <The Banks Family A/C>	1,919,671	0.72
13.	ABN Amro Clearing Sydney Nominees Pty Ltd <Custodian A/C>	1,841,026	0.69
14.	JP Morgan Nominees Australia Limited <Cash Income A/C>	1,673,814	0.63
15.	J & N Kaal Pty Ltd <Kaal Superfund A/C>	1,585,365	0.60
16.	Hertogs Investments Pty Limited	1,400,000	0.53
17.	Mr Peter Marcus Barr + Mrs Kay Ellen Barr <Regnal Super Fund A/C>	1,322,427	0.50
18.	Mirraboopa Investments Limited	1,200,000	0.45
19.	KAS Investments & Development Pty Ltd <KAS Investments S/F A/C>	1,054,890	0.40
20.	Mrs. Cherie Ann Lauder + Mr. John William Lauder <J&C Lauder Family S/F A/C>	1,013,234	0.38
<b>Total</b>		<b><u>53,945,910</u></b>	<b><u>20.36</u></b>

**General Information**

The name of the Company Secretary is Mr. J. Christopher Naftzger.

The complete mailing address, including zip code, of our principal executive offices is 250 Cross Farm Lane, York, Pennsylvania 17406.

**Table of Contents**

The address of the principal registered office in Australia is Suite 3, Level 1, 1 Chifley Square, Sydney NSW 2000 and our telephone number there is +61 2 8346 6500. The ASX Liaison Officer is Mr. Jeff Carter.

Registers of securities are held at Computershare Investor Services Pty Limited, Level 2, 45 St Georges Terrace Perth WA 6000 Australia, Investor Enquiries +61 8 9323 2000 (within Australia) +61 3 9415 4677 (outside Australia).

***Voting Rights***

Unilife's by-laws provide that each stockholder has one vote for every share of common stock entitled to vote held of record by such stockholder and a proportionate vote for each fractional share of stock entitled to vote so held, unless otherwise provided by Delaware General Corporation Law or in the certificate of incorporation.

If holders of CDIs wish to attend Unilife's general meetings, they will be able to do so. Under the ASX Listing Rules, Unilife, as an issuer of CDIs, must allow CDI holders to attend any meeting of the holders of the underlying securities unless relevant U.S. law at the time of the meeting prevents CDI holders from attending those meetings.

In order to vote at such meetings, CDI holders have the following options:

- (a) instructing CDN, as the legal owner, to vote the Unilife Shares underlying their CDIs in a particular manner. The instruction form must be completed and returned to Unilife's share registry prior to the meeting;
- (b) informing Unilife that they wish to nominate themselves or another person to be appointed as CDN's proxy for the purposes of attending and voting at the general meeting;
- (c) converting their CDIs into a holding of Unilife and voting these at the meeting (however, if thereafter the former CDI holder wishes to sell their investment on ASX, it would be necessary to convert Unilife Shares back to CDIs).

As holders of CDIs will not appear on Unilife's share register as the legal holders of Unilife Shares, they will not be entitled to vote at a Unilife stockholder meetings unless one of the above steps is undertaken.

Proxy forms and details of these alternatives will be included in each notice of meeting sent to CDI holders by Unilife.

Holders of options are not entitled to vote.

***Australian Corporate Governance Statement***

The Board of Directors and employees of Unilife Corporation ("Unilife" or the "Company") are committed to developing, promoting and maintaining a strong culture of good corporate governance and ethical conduct.

The Board of Directors confirms that the Company's corporate governance framework is generally consistent with the Australian Securities Exchange's ("ASX") Corporate Governance Council's "Corporate Governance Principles and Recommendations (2nd Edition)" ("ASX Governance Recommendations"), other than as set out below. To this end, the Company provides below a review of its governance framework using the same numbering as adopted for the Principles as set out in the ASX Governance Recommendations.

Copies of the Company's charters, codes and policies may be downloaded from the corporate governance section of the Unilife website ([www.unilife.com](http://www.unilife.com)).

The Company redomiciled to the United States in January 2010 and listed on Nasdaq in February 2010. As a result and to meet Nasdaq listing requirements, the policies and practices adopted by the Company are predominantly "U.S.-focused".

## **Principle 1 — Lay solid foundations for management and oversight**

*Recommendation 1.1 — Establish the functions reserved to the board and those delegated to senior executives and disclose those functions*

The primary responsibility of:

(a) the Board of Directors is to exercise their business judgment to act in what they reasonably believe to be in the best interests of the Company and its stockholders; and

(b) the Chief Executive Officer is to oversee the day-to-day performance of Unilife (pursuant to Board delegated powers).

The Board's responsibilities are recognized and documented on an aggregated basis via the Charter of the Board of Directors, which is available on the corporate governance section of the Company's website.

While day-to-day management has been delegated to the Chief Executive Officer, it is noted that the following matters are specifically reserved for the attention of the Board:

(a) providing input into and final approval of management's development of corporate strategy and performance objectives;

(b) reviewing, ratifying and monitoring systems of risk management and internal control, codes of conduct, and legal compliance;

(c) ensuring appropriate resources are available to senior executives;

(d) approving and monitoring the progress of major capital expenditure, capital management and acquisitions and divestments; and

(e) approving and monitoring financial and other reporting.

*Recommendation 1.2 — Disclose the process for evaluating the performance of senior executives*

Information regarding executive compensation required by Item 11 of Form 10-K, including a discussion in relation to the mechanics concerning the evaluation of performance of the Company's senior executives, including relevant benchmarking activities, will be contained in the 2011 Proxy Statement under the caption "Executive Compensation," and is incorporated by reference.

*Recommendation 1.3 — Disclosure of information under Principle 1 of the ASX Governance Recommendations*

### *Reporting Requirement*

The Company fully complied with Recommendation 1.1 to 1.3 during the fiscal year ended June 30, 2011.

## **Principle 2 — Structure the Board to add value**

*Recommendation 2.1 — A majority of the board should be independent directors*

*Recommendation 2.2 — The chair should be an independent director*

*Recommendation 2.3 — The roles of Chairman and Chief Executive Officer should not be exercised by the same individual*

The Board of Directors is currently comprised of seven directors. The seven directors include six non-executive directors (including the Chairman of the Board) and one executive director (being the Chief Executive Officer) with the role of Chairman and Chief Executive Officer being exercised by different individuals. Five of the six non-executive directors are "independent" as defined in the Nasdaq listing rules.

At the Company's expense, the Board collectively or directors (acting as individuals) are entitled to seek advice from independent external advisers in relation to any matter which is considered necessary to fulfill their

relevant duties and responsibilities. Individual directors seeking such advice must obtain the approval of the Chairman. Any advice so obtained will be made available to the Board.

*Recommendation 2.4 — The board should establish a nomination committee*

The Company has established a Nominating and Corporate Governance Committee which consists of all independent directors (including the Chairman of the Nominating and Corporate Governance Committee). The members of the Nominating and Corporate Governance Committee are Mr. Bosnjak, Mr. Lund, Mr. Galle and Mr. Firestone (Chair). A copy of the Nominating and Corporate Governance Committee Charter is available on the corporate governance section of the Company's website.

*Reporting Requirement*

The Company fully complied with Recommendation 2.1 to 2.4 during the fiscal year ended June 30, 2011.

*Recommendation 2.5 — Disclose the process for evaluating the performance of the Board, its committees and individual directors*

*Reporting Requirement*

In connection with its upcoming 2011 Proxy Statement, the Corporate Governance & Nominating Committee has undertaken a formal review of the performance of the Board, its committees and individual directors, which will be completed prior to the nomination of the slate of the board of directors for the upcoming proxy.

*Recommendation 2.6 — Disclosure of information under Principle 2 of the ASX Governance Recommendations*

*Reporting Requirement*

Information regarding our directors, including biographical information and share ownership information required by Items 10 and 12 of Form 10-K will be included in the 2011 Proxy Statement under the captions "Election of Directors" and "Security Ownership of Certain Beneficial Owners and Management."

**Principle 3 — Promote ethical and responsible decision-making**

*Recommendation 3.1 — Establish a Code of Conduct and disclose it.*

The Company has adopted a Code of Business Conduct and Ethics which is available on the corporate governance section of the Company's website.

*Recommendation 3.2 — Establish a policy concerning trading in Company securities by directors, senior executives and employees and disclose it*

The Company has adopted an Insider Trading Policy which is available on the corporate governance section of the Company's website.

*Recommendation 3.3 — Disclosure of information under Principle 3 of the ASX Governance Recommendations*

*Reporting Requirement*

The Company fully complied with Recommendation 3.1 to 3.3 during the fiscal year ended June 30, 2011.



**Principle 4 — Safeguard integrity in financial reporting**

*Recommendation 4.1 — The Board should establish an Audit Committee*

*Recommendation 4.2 — The Audit Committee should: (a) consist of non-executive directors only; (b) consist of a majority of independent directors; (c) be chaired by an independent chair who is not chair of the Board; and (d) have at least three members*

*Recommendation 4.3 — The Audit Committee should have a formal charter*

The Company has established an Audit Committee which consists only of non-executive directors all of whom are independent (including the Chairman of the Audit Committee). The members of the Audit Committee are Mr. Bosnjak, Mr. Lund (Chair) and Ms. Wold.

The Audit Committee Charter is available on the corporate governance section of the Company's website.

*Reporting Requirement*

The Company fully complied with Recommendation 4.1 to 4.3 during the fiscal year ended June 30, 2011.

*Recommendation 4.4 — Disclosure of information under Principle 4 of the ASX Governance Recommendations*

*Reporting Requirement*

Information regarding the skills, experience and expertise of directors, including audit committee members in accordance with U.S disclosure requirements, will be included in the 2011 Proxy Statement.

In Item 9A of this Annual Report on Form 10-K, we have disclosed information regarding the Company's Controls and Procedures, including management's evaluation of the effectiveness of our disclosure controls and procedures and management's evaluation of the effectiveness of our internal control over financial reporting.

**Principle 5 — Make timely and balanced disclosure**

*Recommendation 5.1 — Establish written policies designed to ensure compliance with ASX Listing Rule disclosure requirements and to ensure accountability at a senior executive level for that compliance and disclose those policies*

*Recommendation 5.2 — Disclosure of information under Principle 5 of the ASX Governance Recommendations*

Unilife is committed to providing timely and balanced disclosure to the market and, in consequence, to meeting its continuous disclosure requirements. The Company established a Disclosure Committee for the purpose of ensuring significant matters requiring public disclosure are communicated to management and disclosed in a timely manner.

In accordance with its commitment to fully comply with its continuous disclosure requirements, the Company has adopted a Continuous Disclosure Policy, together with other internal mechanisms and reporting requirements.

*Reporting Requirement*

The Company fully complied with Recommendation 5.1 and 5.2 during the fiscal year ended June 30, 2011.

**Principle 6 — Respect the rights of shareholders**

*Recommendation 6.1 — Design a communications policy for promoting effective communication with shareholders and encourage their participation at stockholder's meetings and disclose those policies*

*Recommendation 6.2 — Disclosure of information under Principle 6 of the ASX Governance Recommendations*

While the Company has not adopted a formal communications policy as recommended under Recommendation 6.1, the Company communicates information to shareholders through a range of media including annual reports, public (ASX and SEC) announcements and via the Company's website. Key financial information and stock performance are also available on the Company's website. Shareholders can raise questions with the Company by contacting the Company via telephone, facsimile, post or email, with relevant contact details being available on the Company's website.

All shareholders are invited to attend the Company's Annual Meeting of Stockholders, either in person or by proxy. The Board regards the Annual Meeting as an excellent forum in which to discuss issues relevant to the Company and thereby encourages full participation by shareholders. Shareholders have an opportunity to submit questions to the Board and the Company's auditors. The meeting is also webcast to provide access to those shareholders who are unable to attend the Annual Meeting.

*Reporting requirement*

Save as set out above, the Company fully complied with Recommendation 6.1 and 6.2 for the fiscal year ended June 30, 2011.

**Principle 7 — Recognize and manage risk**

*Recommendation 7.1 — Establish policies for the oversight and management of material business risks and disclose it*

The risks that the Company faces are continually changing in line with the development of the Company. The primary risks faced by the Company during the fiscal year ended June 30, 2011 included liquidity or funding risk and operational risks associated with the finalization of the Company's industrialization of its Unifill syringe.

The Company operates in an environment where it is required to actively manage fundamental risks such as the integrity of the Company's intellectual property portfolio, disaster management, exchange rate risk and the risk of losing key management personnel.

In simple terms, risk is inherent in all business activities undertaken by Unilife. Unfortunately, many of these risks are beyond the control of the Company and, as such, it is important that risk be mitigated on a continuous basis, particularly if the Company is to preserve shareholder value.

The Board of Directors has approved a Risk Management Policy, which is designed to ensure that risks including, amongst others, technology risks, economic risks, financial risks and other operational risks are identified, evaluated and mitigated to enable the achievement of the Company's goals.

*Reporting requirement*

The Company fully complied with Recommendation 7.1 for the fiscal year ended June 30, 2011.

*Recommendation 7.2 — Require management to design and implement the risk management and internal control system to manage the Company's material business risks and report to it whether those risks are being managed effectively (and makes disclosures therein); Disclose that management has reported to the Board as to the effectiveness of the Company's management of its material business risks*

Management provides the Board with frequent (i.e. generally monthly) updates on the state of the Company's business, including the risks that the Company faces from time-to-time. This update includes up-to-date financial information, operational activity, clinical status and competitor updates. These updates are founded on internal

communications that are fostered internally through weekly management meetings and other internal communications. These processes operate in addition to the Company's Quality System, complaint handling processes, employee policies and standard operating procedures.

The Risk Management Policy also requires that, the Chief Executive Officer and the Chief Financial Officer will, at least on an annual basis, provide written assurances to the Board in writing that:

- all assurances given by management in respect of the integrity of financial statements are founded on sound systems of risk management and internal compliance and control which implements the policies adopted by the Board; and
- the Company's risk management and internal compliance and control system is operating efficiently and effectively in all material respects.

In addition, the Board of Directors holds regular meetings for the purposes of discussing and reviewing operational developments.

The Company fully complied with Recommendation 7.2 for the fiscal year ended June 30, 2011.

*Recommendation 7.3 — Disclose whether the Board has received assurance from the Chief Executive Officer and the Chief Financial Officer that the declaration under Section 295A of the Corporations Act is founded on a sound system of risk management and internal control and is operating effectively in all material respects in relation to financial reporting risks*

*Reporting requirement*

As the Company prepares and files its financial statements under U.S. accounting practices and laws, management is required to provide representations to the Board on a wide range of issues, including in relation to the effectiveness of the Company's disclosure controls and procedures as well as the design or operation of internal control over financial reporting. However, as the Company is incorporated in the US and is not bound by certain financial reporting provisions under the Australian Corporations Act 2001 (Cth) no declaration is required under Section 295A of the Corporations Act. To this end, shareholders' attention is drawn to Item 9A. of this Annual Report on Form 10-K and the certifications provided by the Chief Executive Officer and the Chief Financial Officer at the end of the Form 10-K. As stated above, Item 9A of this Annual Report on Form 10-K discloses information regarding the Company's controls and procedures, including management's evaluation of the effectiveness of our disclosure controls and procedures and management's evaluation of the effectiveness of our internal control over financial reporting.

For the reasons stated above, the Company has complied with Recommendation 7.3 for the fiscal year ended June 30, 2011.

*Recommendation 7.4 — Disclosure of information under Principle 7 of the ASX Governance Recommendations*

*Reporting requirement*

Except as disclosed above, the Company believes that the aforementioned reporting meets, or exceeds, the requirements of Recommendation 7.2 to 7.4 for the fiscal year ended June 30, 2011.

**Principle 8 — Remunerate fairly and responsibly**

*Recommendation 8.1 — Establish a Remuneration Committee*

The Company has established a Compensation Committee which consists of solely independent directors (including the Chairman of the Compensation Committee). The members of the Compensation Committee are Mr. Bosnjak (Chair), Mr. Galle and Mr. Lund. A copy of the Compensation Committee Charter is available on the corporate governance section of the Company's website.

*Recommendation 8.2 — Clearly distinguish the structure of non-executive directors' remuneration from that of executive directors and senior executives*

As noted above in the discussion regarding Recommendation 1.2, Item 11 of this Annual Report on Form 10-K includes disclosure relating to the structure of non-executive director's, executive director's and senior executives remuneration practices and policies, including its annual performance review process, its external benchmarking review and its meritorious approach to employee performance.

*Reporting requirement*

As previously disclosed no review or other form of assessment has been undertaken in relation to the directors.

*Recommendation 8.3 — Disclosure of information under Principle 8 of the ASX Governance Recommendations*

With the exception noted above, the Company complied with the Recommendation 8.1 to 8.3 during the year ended June 30, 2011.

This report is made in accordance with a resolution of the Board of Directors.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information required by this Item 13 is incorporated by reference to the 2011 Proxy Statement under the headings "Information on our Board of Directors and Corporate Governance" and "Certain Relationships and Related Transactions."

**Item 14. Principal Accountant Fees and Services**

The information required by this Item 14 is incorporated into this report by reference to the 2011 Proxy Statement under the heading "Ratification of Appointment of the Independent Registered Public Accounting Firm."

**PART IV****Item 15. Exhibits and Financial Statement Schedules**

(a) Documents files as part of this report:

(1) Financial Statements

The financial statements required by this Item 15 are set forth in Part II, Item 8 of this report.

(b) Exhibits. The following Exhibits are filed as a part of this report

Exhibit No.	Description of Exhibit	Included Herewith	Incorporated by Reference Herein		
			Form	Exhibit	Filing Date
2.1	Amended and Restated Merger Implementation Agreement dated as of September 1, 2009 between Unilife Medical Solutions Limited and Unilife Corporation		10	2.1	February 11, 2010
2.2	Share Purchase Agreement among Unilife Medical Solutions Limited, Edward Paukovits, Jr., Keith Bocchicchio, and Daniel Adlon dated as of October 25, 2006 and amended as of September 26, 2007		10	2.2	January 6, 2010
3.1	Certificate of Incorporation of Unilife Corporation		10	3.1	November 12, 2009
3.2	Amended and Restated Bylaws of Unilife Corporation		8-K	3.1	August 17, 2010

## Table of Contents

Exhibit No.	Description of Exhibit	Included Herewith	Incorporated by Reference Herein		
			Form	Exhibit	Filing Date
4.1	Form of Common Stock Certificate		10	4.1	November 12, 2009
10.1	Exclusive Agreement dated as of June 30, 2008 between Unilife Medical Solutions Limited and Sanofi Winthrop Industrie		10	10.1	November 12, 2009
10.2*	First Amendment dated as of June 29, 2009 to Exclusive Agreement dated as of June 30, 2008 between Unilife Medical Solutions Limited and Sanofi Winthrop Industrie		10	10.2	November 12, 2009
10.3*	Industrialization Agreement dated as of June 30, 2009 between Unilife Medical Solutions Limited and Sanofi Winthrop Industrie		10	10.3	February 6, 2010
10.4	Business Lease, dated as of August 17, 2005, between Integrated BioSciences, Inc. and AMC Delancey Heartland Partners, L.P.		10	10.4	November 12, 2009
10.5	Agreement dated as of September 15, 2003 between Integrated BioSciences, Inc. and B. Braun Medical, Inc. and amendments thereto		10	10.5	February 1, 2010
10.6	Promissory Note, dated as of December 30, 2005 between Integrated BioSciences, Inc. and Commerce Bank		10	10.6	November 12, 2009
10.7	Promissory Note, dated as of August 25, 2006 between Integrated BioSciences, Inc. and Commerce Bank		10	10.7	November 12, 2009
10.8	Employment Agreement, dated as of October 26, 2008 between Unilife Medical Solutions Limited and Alan Shortall		10	10.8	November 12, 2009
10.9	Employment Agreement, dated as of February 15, 2005 between Unilife Medical Solutions Limited and Jeff Carter		10	10.9	November 12, 2009
10.10	Employment Agreement, dated as of November 10, 2009 between Unilife Medical Solutions, Inc. and Daniel Calvert		10	10.10	November 12, 2009
10.11	Employment Agreement, dated as of November 10, 2009 between Unilife Medical Solutions, Inc. and Bernhard Opitz		10	10.11	November 12, 2009
10.12	Employment Agreement, dated as of November 10, 2009 between Unilife Medical Solutions, Inc. and Mark Iampietro		10	10.12	November 12, 2009
10.13	Employment Agreement, dated as of November 10, 2009 between Unilife Medical Solutions, Inc. and Stephen Allan		10	10.13	November 12, 2009
10.14	Employment Agreement, dated as of November 10, 2009 between Unilife Medical Solutions, Inc. and Eugene Shortall		10	10.14	November 12, 2009
10.15	Consulting Agreement, dated as of January 22, 2009 between Unilife Medical Solutions Limited and Joblak Pty Ltd		10	10.15	November 12, 2009
10.16	Deed of Mutual Release, dated January 12, 2009 between Unilife Medical Solutions Limited and Jeff Carter		10	10.16	November 12, 2009

## Table of Contents

Exhibit No.	Description of Exhibit	Included Herewith	Incorporated by Reference Herein		
			Form	Exhibit	Filing Date
10.17	Unilife Corporation Employee Stock Option Plan		10	10.17	November 12, 2009
10.18	Unilife Corporation 2009 Stock Incentive Plan		10	10.18	November 12, 2009
10.19	Unilife Medical Solutions Limited Exempt Employee Share Plan		10	10.19	November 12, 2009
10.20	Agreement dated November 12, 2009 between Unilife Medical Solutions, Inc. and Mikron Assembly Technology		10	10.20	February 10, 2010
10.21	Purchase and Mutual Indemnification Agreement dated November 16, 2009 between Unilife Cross Farm LLC and Greenspring Partners, LP		10	10.21	January 6, 2010
10.22	Offer of assistance dated October 16, 2009 from the Commonwealth of Pennsylvania to Unilife Medical Solutions and acceptance of the offer		10	10.22	January 6, 2010
10.23	Agreement Between Unilife Cross Farm LLC and L2 Architecture dated as of December 29, 2009, as amended		10	10.23	January 6, 2010
10.24	Agreement between Unilife Cross Farm LLC and HSC Builders & Construction Managers dated as of December 14, 2009, as amended		10	10.24	January 6, 2010
10.25	Development Agreement, dated December 14, 2009 between Unilife Cross Farm LLC and Keystone Redevelopment Group LLC		10	10.25	February 1, 2010
10.26	Amended and Restated Operating Agreement dated December 14, 2009 of Unilife Cross Farm LLC		10	10.26	January 6, 2010
10.27	Form of Share Purchase Agreement between Unilife Medical Solutions Limited and each of the US investors in the October and November 2009 private placement		10	10.27	January 6, 2010
10.28	Form of Subscription Agreement between Unilife Medical Solutions Limited and each of the Australian investors in the October and November 2009 private placement		10	10.28	January 6, 2010
10.29	2009 Share Purchase Plan Terms and Conditions		10	10.29	January 6, 2010
10.30	Offer Letter dated November 12, 2008 from Unilife Medical Solutions Limited to Daniel Calvert		10	10.30	February 1, 2010
10.31	Offer Letter dated November 20, 2008 from the Coelyn Group, on behalf of Unilife Medical Solutions Limited to Bernhard Opitz		10	10.31	February 1, 2010
10.32	Consulting Agreement between Unilife Medical Solutions Limited and Medical Middle East Limited		10	10.32	February 1, 2010
10.33	Option Deed, dated January 21, 2010 between Unilife Medical Solutions Limited and Edward Fine		10	10.33	February 1, 2010



## Table of Contents

Exhibit No.	Description of Exhibit	Included Herewith	Incorporated by Reference Herein		
			Form	Exhibit	Filing Date
10.34	Deed of Settlement and Release dated October 26, 2008 among Unilife Medical Solutions Limited and Craig Thorley, Joseph Kaal, Alan Shortall and Roger Williamson and notification related thereto dated October 27, 2009		10	10.34	February 10, 2010
10.35	Deed of Confirmation of Intellectual Property Rights and Confidentiality among Unilife Medical Solutions Limited, Unitract Syringe Pty Limited, Craig Thorley and Joseph Kaal		10	10.35	February 10, 2010
10.36	Form of Restricted Stock Agreement under the Unilife Corporation 2009 Stock Incentive Plan between Unilife Corporation and Alan Shortall		10	10.36	February 1, 2010
10.37	Form of Unilife Corporation Nonstatutory Stock Option Agreement between Unilife Corporation and Alan Shortall		10	10.37	February 1, 2010
10.38	Membership Interest Purchase Agreement, dated December 14, 2009 between Unilife Cross Farm LLC and Cross Farm, LLC.		10	10.38	February 1, 2010
10.39	Letter Agreement dated January 29, 2010 between sanofi-aventis and Unilife Medical Solutions.		10	10.39	February 1, 2010
10.40	Form of Restricted Stock Agreement Under the Unilife Corporation 2009 Stock Incentive Plan		10-Q	10.1	March 24, 2010
10.41	Form of Unilife Corporation Nonstatutory Stock Option Notice		10-Q	10.2	March 24, 2010
10.42*	Letter Agreement dated February 25, 2010 between sanofi-aventis and Unilife Medical Solutions Limited		10-Q	10.1	May 17, 2010
10.43	Employment Agreement, dated as of June 8, 2010 between Unilife Corporation and R Richard Wieland		8-K	10.1	June 14, 2010
10.44	Separation Agreement and General Release, dated as of June 28, 2010 between Unilife Corporation and Daniel Calvert		8-K	10.1	July 2, 2010
10.45	Employment Agreement, dated as of July 6, 2010 between Unilife Corporation and J. Christopher Naftzger		10-K	10.45	September 28, 2010
10.46	Employment Agreement, dated as of July 27, 2010 between Unilife Corporation and Dennis P. Pyers		10-K	10.46	September 28, 2010
10.47	Non-revolving Credit Agreement dated August 13, 2010 between Unilife Cross Farm LLC and Uninvest National Bank and Trust Co.		10-K	10.47	September 28, 2010
10.48	Non-revolving Promissory Note dated August 13, 2010 between Unilife Cross Farm LLC and Uninvest National Bank and Trust Co.		10-K	10.48	September 28, 2010
10.49	Surety dated August 13, 2010 between Unilife Corporation and Uninvest National Bank and Trust Co.		10-K	10.49	September 28, 2010

## Table of Contents

Exhibit No.	Description of Exhibit	Included Herewith	Incorporated by Reference Herein		
			Form	Exhibit	Filing Date
10.50	Security and Control Agreement Regarding Reserve Account dated August 13, 2010 between Unilife Corporation and Univest National Bank and Trust Co.		10-K	10.50	September 28, 2010
10.51	Loan Agreement between Metro Bank and Unilife Cross Farm LLC dated as of October 20, 2010		8-K	10.1	October 26, 2010
10.52	Term Note in the principal amount of \$14,250,000 dated as of October 20, 2010		8-K	10.2	October 26, 2010
10.53	Term Note in the principal amount of \$3,750,000 dated as of October 20, 2010		8-K	10.3	October 26, 2010
10.54	Guaranty and Suretyship Agreement dated October 20, 2010 (Unilife Corporation)		8-K	10.4	October 26, 2010
10.55	Guaranty and Suretyship Agreement dated October 20, 2010 (Unilife Medical Solutions, Inc.)		8-K	10.5	October 26, 2010
10.56	Form of Subscription Agreement between Unilife Corporation and each investor in the December 2010 Regulation S placement		8-K	10.1	December 2, 2010
10.57	Form of Option Agreement between Unilife Corporation and each investor in the December 2010 Regulation S placement		8-K	10.2	December 2, 2010
10.58	Form of Warrant issued to Keystone Redevelopment Group, LLC and L2 Architecture on December 2, 2010		POS AM	10.58	December 10, 2010
10.59	Form of Subscription Agreement (the Company entered into separate Subscription Agreements with the investors in substantially the same form set forth in Exhibit 10.1)		8-K	10.1	December 2, 2010
10.60	Form of Option Agreement (the Company entered into separate Option Agreements with the investors in substantially the same form set forth in Exhibit 10.2)		8-K	10.2	December 2, 2010
10.61	2010 Unilife Share Purchase Plan Terms and Conditions		8-K	10.1	January 6, 2011
10.62	Separation Agreement and General Release between Unilife Corporation and Bernhard Opitz		10-Q	10.5	February 14, 2011
10.63	Employment Agreement dated February 7, 2011 between Unilife Corporation and Ramin Mojdehbakhsh, Ph.D.		8-K	10.1	February 7, 2011
12.1	Statement regarding computation of Ratio of Earnings to Fixed Charges	X			
21	List of subsidiaries of Unilife Corporation	X			
23.1	Consent of KPMG LLP	X			
23.2	Consent of BDO Audit (WA) Pty Ltd	X			
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer	X			
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer	X			

## Table of Contents

Exhibit No.	Description of Exhibit	Included Herewith	Incorporated by Reference Herein		
			Form	Exhibit	Filing Date
32.1	Section 1350 Certification	X			
32.2	Section 1350 Certification	X			

- \* Confidential treatment has been requested for certain provisions of this Exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

# SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

## UNILIFE CORPORATION

By: /s/ Alan Shortall

Name: Alan Shortall

Title: Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Alan Shortall</u> Alan Shortall	Director and Chief Executive Officer (Principal Executive Officer)	September 13, 2011
<u>/s/ R. Richard Wieland II</u> R. Richard Wieland	Chief Financial Officer and Executive Vice President (Principal Financial Officer)	September 13, 2011
<u>/s/ Dennis P. Pyers</u> Dennis P. Pyers	Vice President, Controller and Chief Accounting Officer (Principal Accounting Officer)	September 13, 2011
<u>/s/ John Lund</u> John Lund	Director	September 13, 2011
<u>/s/ William Galle</u> William Galle	Director	September 13, 2011
<u>/s/ Jeff Carter</u> Jeff Carter	Director	September 13, 2011
<u>/s/ Slavko James Joseph Bosnjak</u> Slavko James Joseph Bosnjak	Chairman and Director	September 13, 2011
<u>/s/ Mary Katherine Wold</u> Mary Katherine Wold	Director	September 13, 2011
<u>/s/ Marc S. Firestone</u> Marc S. Firestone	Director	September 13, 2011

Calculation of Ratio of Earnings to Fixed Charges  
(In thousands)

	Fiscal Year Ended June 30,				
	2011	2010	2009	2008	2007
<b>Fixed Charges:</b>					
Interest expense	\$ 511	\$ 125	\$ 249	\$ 459	\$ 537
Capitalized interest	323	—	—	—	—
Estimate of interest within rental expense	217	184	228	194	216
<b>Fixed Charges</b>	<b>\$ 1,051</b>	<b>\$ 309</b>	<b>\$ 477</b>	<b>\$ 653</b>	<b>\$ 753</b>
<b>Earnings:</b>					
Add:					
Loss before income taxes	\$(40,682)	\$(29,748)	\$(517)	\$(8,537)	\$(8,969)
Fixed charges	1,051	309	477	653	753
Less:					
Capitalized interest	(323)	—	—	—	—
Deficiency of earnings to cover fixed charges	\$(39,954)	\$(29,439)	\$ (40)	\$(7,884)	\$(8,216)
<b>Ratio of earnings to fixed charges <sup>1</sup></b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>

<sup>1</sup> Earnings for the years ended June 30, 2011, 2010, 2009, 2008 and 2007 were inadequate to cover fixed charges and accordingly, no ratio to fixed charges is disclosed for those periods.

Entity	Jurisdiction of Formation
Unilife Medical Solutions, Inc.	Delaware
Unilife Cross Farm, LLC	Delaware
Unitract Syringe Pty Limited	Australia
Unilife Medical Solutions Limited	Australia



**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors  
Unilife Corporation:

We consent to the incorporation by reference on Form S-8 (Registration Statement No. 333-164964) and on Forms S-3 (Registration Statement Nos. 333-173195 and 333-167631) of Unilife Corporation of our report dated September 13, 2011, with respect to the consolidated balance sheets of Unilife Corporation and subsidiaries as of June 30, 2011 and 2010 and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for the years then ended and the effectiveness of internal control over financial reporting as of June 30, 2011, which reports appear in the June 30, 2011 annual report on Form 10-K of Unilife Corporation.

Our report dated September 13, 2011 contains an explanatory paragraph that states that the Company has incurred recurring losses from operations and estimates that its existing cash and cash equivalents will last only through the third quarter of fiscal 2012, which raises substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

/s/ KPMG LLP

Harrisburg, Pennsylvania  
September 13, 2011

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the registration statement on Form S-8 (No. 333-164964) and on Forms S-3 (Registration Statement Nos. 333-173195 and 333-167631) of Unilife Corporation of our report dated November 11, 2009 with respect to the statement of operations, statements of stockholders' equity and comprehensive loss and statements of cash flows for the fiscal year ended June 30, 2009, which report appears in Unilife Corporation's Annual Report on Form 10-K for the fiscal year ended June 30, 2011.

/s/ BDO Audit (WA) Pty Ltd

Perth, Western Australia  
September 13, 2011

**Certification of Chief Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Alan Shortall, certify that:

1. I have reviewed this Annual Report on Form 10-K of Unilife Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Alan Shortall

Name: Alan Shortall

Title: Chief Executive Officer

Date: September 13, 2011

**Certification of Chief Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, R. Richard Wieland II, certify that:

1. I have reviewed this Annual Report on Form 10-K of Unilife Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer( and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ R. Richard Wieland II

Name: R. Richard Wieland II

Title: Chief Financial Officer

Date: September 13, 2011

**Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to  
Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Annual Report of Unilife Corporation (the "Company") on Form 10-K for the year ended June 30, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Alan Shortall, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Alan Shortall

Name: Alan Shortall

Title: Chief Executive Officer

Date: September 13, 2011

**Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to  
Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Annual Report of Unilife Corporation (the "Company") on Form 10-K for the year ended June 30, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, R. Richard Wieland II, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ R. Richard Wieland II

Name: R. Richard Wieland II

Title: Chief Financial Officer

Date: September 13, 2011



**EXHIBIT D**

To the Unilife Board of Directors,

During my association with Unilife I have become aware of a number of actions which are questionable from either an ethical or regulatory perspective or both but had so far kept my silence with respect to yourselves. However, the events of the last week are so outrageous that I cannot in good conscience keep silent any longer. Below is a list of those violations of ethics or regulation that I believe are most serious and also easy to substantiate. There are certainly others that I feel would come out during a thorough investigation but that I am not close enough to feel comfortable leveling an accusation here.

The following are the issues that I am aware of:

1. Criminal conduct. On June 15<sup>th</sup>, Unilife terminated the employment of Massoud Samandi. Massoud subsequently suffered an anxiety attack and was taken to the hospital. In his absence, several Unilife employees witnessed CEO Alan Shortall directing other Unilife employees while they broke into and burglarized Massoud's personal vehicle. When Massoud returned that evening he found that his personal laptop had been taken along with personal records and evidence indicating his vehicle had been thoroughly searched. He subsequently filed a police report. Massoud was rumored to be in possession of information that was incriminating to Alan and to Ramin Mojdeh and the likely motive of the burglary was to retrieve and destroy this evidence.
2. Inappropriate relationship with a subordinate. It is considered common knowledge among employees that Ramin Mojdeh is or has been involved in an affair with Jyoti Gupta and possibly also with Sherry Fedorko. I can attest to only circumstantial evidence of an inappropriate relationship with Gupta (coming and leaving together in his vehicle, extreme favoritism shown to her, the way they interact in meetings, etc.), though there are many that claim to have seen more direct evidence. However, regardless of the actual facts of their relationship, Ramin has created the appearance of impropriety and thereby compromised his position as a senior executive of the company.
3. Stock fraud. In June and July of 2011, Unilife issued press releases indicating that the company had shipped validated, commercial Unifill product to Sanofi and to another unnamed pharmaceutical company (BMS). However, this information was false and misleading. In fact, the validation activities and the associated documentation required by the FDA were not completed and signed off until late March, 2012. There is an interesting problem here, for if Alan Shortall and Ramin Mojdeh wish to claim that the press release is truthful they must simultaneously admit to shipping "adulterated" product contrary to FDA regulations. Alternately, if they wish to claim that they complied with FDA regulations then they must admit to providing false information to shareholders.
4. Stock fraud and/or misuse of company resources. Ramin directed purchasing to buy 1,000,000 Unifill components per month in spite of the fact that there was no customer demand or manufacturing capacity to support this level of purchasing. His stated objective was to make suppliers believe that Unilife was producing at these volumes on the expectation that this would leak to the financial markets. This action resulted in a warehouse which is literally overflowing with millions of dollars of components that are now obsolete due to product design changes. In

spite of their obsolescence, Ramin and Jyoti will not allow these components to be disposed of. There is also approximately \$ 500,000 of Unifill barrels that were received defective from the supplier and due to Jyoti's inaction / poor decisions cannot be returned for credit.

5. Suppression of negative information. I am aware of at least one specific incident where Alan Shortall directed employees to suppress information that indicated that Unifill would not be profitable (or barely so) at the price that Sanofi was expected to be willing to pay. Unilife has also failed to disclose or even acknowledge internally that there are serious design and manufacturing issues with Unifill that likely preclude customer shipments in any volume and with any reasonable gross margin.
6. Compromise of the Quality System. There are numerous violations and questionable or high risk actions with respect to FDA regulation and product quality in general. These include:
  - a. Both Ramin and Jyoti have directed employees to ship unreleased or defective product to customers
  - b. Unitract product was provided to Jyoti for use in the RV tour this summer with the clear instruction that each piece be marked as not fit for human use (due to issues with the product). Jyoti failed to do this and the product was observed on the RV with only an identification as marketing samples on the cartons.
  - c. Jyoti directed Quality Control employees to falsify documents to give the appearance that certain test methods existed when they in fact did not.
  - d. Jyoti demanded to assume control for the NCR and CAPA process and ordered Quality to stop opening new NCR's, in violation of FDA rules.
  - e. The design review for Unifill was conducted by Ramin and Jyoti in such a way as to not allow those required to sign off ample time to review the information or the related data. Based on subsequent events, it is apparent that the activities necessary for sign-off were in fact not complete at the time the documents were signed, that a serious quality issue was covered up by Jyoti, and there is good reason to believe that falsification of records occurred. In at least one case Jyoti directed her team to conduct testing on old, defective batches with no lot traceability, in order to create data.
  - f. Jyoti attempted to have members of her team sort two of the PQ (validation) batches for Unifill subsequent to the design review above. This was an attempt to hide the fact that the needle shields on the syringes were falling off sometime after manufacture, a fact that was known to her during design review and should have precluded sign-off. Jyoti attempted to prevent manufacturing from following proper procedure to open an NCR and conduct a rework to address the issue. The rework ultimately rejected five out of six tubs of product as having at least one defect.
  - g. The reorganization and reduction in force orchestrated by Ramin and Jyoti on June 14<sup>th</sup> and 15<sup>th</sup> compromised the independence and authority of the quality system by making it subject to Jyoti and eliminating key positions such that there was no longer an appropriate number of people or level of skill to comply with FDA requirements. Given Jyoti's track record as noted above and general lack of understanding of the Quality System it is absolutely ludicrous to subordinate any portion of Quality to her.

- h. While it may be only circumstantial evidence, the layoffs of June 14<sup>th</sup> interrupted a fact finding meeting which had the potential to result in a recall of certain Unitract product. All those manufacturing and Quality Control personnel that had been involved in identifying and initially scoping the issue were terminated.
  - i. While not directly a Quality System violation, it should also be noted that all employees that had been trained to operate the Mikron line were terminated in the layoffs of the 14<sup>th</sup> and 15<sup>th</sup>. In fact, the layoffs combined with issues with the line and the product design render Unilife currently incapable of producing Unifill in any volume.
7. Retaliation against whistleblowers. In most of the cases noted above where employees were directed to violate FDA regulations (or at least Unilife SOP's), the employees refused to comply. Now, while a reduction in the workforce was likely needed to align with actual production volumes, the selection of the individuals terminated was tightly managed by Ramin and Jyoti in order to eliminate anyone that had ever expressed any reservation (whether based on ethics or regulation) as to their behavior or refused to comply with the orders above.

I strongly encourage the board to conduct a thorough investigation of these issues. Several key witnesses have been terminated; however it will be necessary to interview them to verify the truth of the above. I strongly recommend that the board conduct exit interviews with all managers / supervisors that have been terminated and/or have voluntarily terminated employment in the first half of this year.