

QUARTERLY UPDATE

Business Update and Recent Financial Results

Snapshot

February 7, 2011

Unilife Corp. (“Unilife” or “the Company”) develops and supplies innovative safety medical devices for pharmaceutical and healthcare markets that mandate the use of safety sharps. The Company is progressively launching its patented portfolio of prefilled and clinical syringes under two brands: (1) Unifill[®], glass-barreled, prefilled safety syringes; and (2) Unitract[®], a line of plastic-barreled, clinical safety syringes. The distinctive feature of all Unilife syringes is that needle retraction is both automatic and operator controlled within a fully integrated syringe—a combination of safety features that Unilife does not believe is available in any other technology marketed today. The Company’s syringes may virtually eliminate the risk of acquiring bloodborne infections, such as HIV or hepatitis C, via needlestick injuries or blood splatter. Unilife holds ISO 13485 certifications with FDA-registered state-of-the-art manufacturing facilities in Pennsylvania. Importantly, sanofi-aventis SA (SNY-NYSE), thought to be the world’s largest purchaser of prefilled syringes, is funding up to \$38.5 million (pre-sales) for the industrialization and exclusive right to buy the Unifill[®] Syringe in therapeutic areas such as vaccines and antithrombotics.



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Recent Financial Data

Ticker (Exchange)	UNIS (NASDAQ)
Recent Price (02/07/2011)*	\$4.85
Shares Outstanding	~63.4 million
Market Capitalization	~\$307 million
Average 3-month Volume	148,252
Insider Owners +5%	~11.4%
Institutional Owners	~5%
EPS (Qtr. ended 09/30/2010)	(\$0.14)
Employees	~155



* UNIS began trading on the NASDAQ in February 2010.

Key Points

- International healthcare and pharmaceutical markets are being driven by legislation to the mandatory use of safety syringes. However, since 2002, reported rates of needlestick injuries in U.S. healthcare facilities have remained largely stable, with safety syringes now causing the majority of injuries.
- Unilife has developed a full portfolio of syringes with novel safety and functionality features. All products are custom-designed to meet the specific market requirements of a target pharmaceutical or healthcare market.
- To the Company’s knowledge, the Unifill[®] Syringe is the world’s first and only known prefilled syringe with safety features integrated inside the glass barrel. Its non-commodity nature streamlines pharmaceutical industrial processes for the filling, packaging, and transport of prefilled syringes, optimizes product lifecycles, and serves as a brand differentiator in competitive therapeutic markets.
- Unilife has an approximately \$40 million validating partnership with sanofi-aventis to support industrialization of the product in exchange for the exclusive right to negotiate its purchase in select therapeutic drug classes. As well, Unilife reports that discussions with other pharmaceutical leaders are now accelerating.
- To meet projected market demand and stringent pharmaceutical standards for primary drug containers, Unilife emphasizes its operational capabilities and recently constructed, state-of-the-art facility in Pennsylvania. The Company has also built a highly experienced team with expertise in medical device and pharmaceutical markets.
- The Company plans to further increase production and possesses several near-to-mid-term revenue streams. Per its January 31, 2011, filing with the Australian Securities Exchange (ASX), Unilife held cash and cash equivalents of over \$39.5 million as of December 31, 2010.
- With an increasing convergence between therapeutic drugs and advanced, intuitive devices, Unilife believes that it is positioned to become a valuable partner for pharmaceutical companies in the delivery of injectable medications.

Financial Results and Recent Events

Presented in U.S. dollars, unless otherwise noted.

Unilife is currently in a period of significant business expansion necessary to develop the operational capabilities and other support resources to meet projected market demand for its proprietary products from pharmaceutical and healthcare customers. Key areas of expenditure for the Company have included the development of a new manufacturing facility, the completion of the industrialization program for the Unifill[®] syringe, the expansion of a network of component suppliers, and the development of new pipeline products. Expenditure has also been directed toward a subsequent expansion of Unilife's workforce, which has increased from 85 staff in December 2009 to approximately 155 staff at present.

Preliminary Second Quarter FY 2011 Financial Results

On January 31, 2011, Unilife filed an Appendix 4C ("Quarterly Report") for the three and six months ended December 31, 2010, with the Australian Securities Exchange (ASX). The Company's fiscal year ends on June 30. The Appendix 4C presents the Company's consolidated cash flows. Further quarterly financial results are scheduled to be released with the U.S. Securities and Exchange Commission (SEC) on February 14, 2011.

In its recent ASX filing, Unilife reported its receipts from customers for the second quarter fiscal 2011, ended December 31, 2010, as over \$2.8 million. For the six months ended December 31, 2010, the Company listed over \$5.2 million in receipts from customers. Net cash used for operations was nearly \$6.2 million for the second quarter fiscal 2011 and over \$12.6 million for the fiscal year to date due to payments for staff costs, advertising and marketing, research and development, leased assets, and other working capital of approximately (\$3.2 million) during the second quarter and (\$7.2 million) for the six months.

As of December 31, 2010, Unilife held cash, cash equivalents, and restricted cash of nearly \$42 million (which included \$2.4 million of restricted cash used to secure the mortgage on its York facility).

Liquidity

In October 2010, the Company secured an \$18 million mortgage from Metro Bank to support its new facility, and the U.S. Department of Agriculture (USDA) agreed to guarantee \$10 million of this loan. In addition, during December 2010, the Company obtained \$2.2 million of proceeds in a loan from the Commonwealth of Pennsylvania Building PA Program to support the cost of constructing the new facility. The proceeds from these financing arrangements, along with Unilife's investment of approximately \$10 million, provided sufficient funds for completion of the new facility with no further investment anticipated.

In December 2010, Unilife completed a private placement equity raise of A\$23.1 million (~US\$22.3 million) as well as an offer to eligible shareholders under a Share Purchase Plan of A\$12.8 million (~US\$13 million). The Company anticipates using the net proceeds from these capital raises for the purchase of additional capital equipment, for general operations including the development of other pipeline products, and to support the 2011 transition of Unilife into a commercial manufacturer and supplier of proprietary medical devices to pharmaceutical and healthcare companies.

Recent Events

An overview of the Company's recent announcements is provided below and on pages 3-4, referring the reader to Unilife's website for complete press releases (www.unilife.com).

- *On February 4, 2011*, Unilife announced that it intended to release its financial results for the fiscal 2011 second quarter ended December 31, 2010, after market trading ends on February 14, 2011.

- *On February 3, 2011*, Unilife announced that it appointed Dr. Ramin Mojdeh (biography on page 12), former vice president and general manager of Becton, Dickinson and Co.'s (BDX-NYSE) Pharmaceutical Systems, North America, and worldwide vice president of research and development, BD Medical, as Unilife's new chief operating officer (COO) and executive vice president.
- *On January 25, 2011*, the Company advised that it scheduled a special meeting of stockholders in Sydney, Australia, on February 8, 2011.
- *On December 31, 2010*, Unilife announced that its 2010 Share Purchase Plan, closed December 22, 2010, was oversubscribed. The Company received applications for roughly 15.1 million new CHESSE Depositary Interests (CDIs) at an issue price of A\$0.85 (each CDI representing an interest in one sixth of a share of the Company's Common Stock) with a value of approximately A\$12.8 million.
- *On December 20, 2010*, Unilife completed the relocation of its operations into its new, 165,000 square foot manufacturing facility and global headquarters in York, Pennsylvania (as pictured in Figure 1). All essential production equipment, including the automated assembly and packaging systems used to manufacture the Unitract[®] range of 1mL syringes, were transferred from Unilife's original Lewisberry, Pennsylvania, site into designated cleanrooms at the York facility on schedule.

Figure 1
Unilife Corp.
NEW MANUFACTURING FACILITY AND GLOBAL HEADQUARTERS



Source: Unilife Corp.

- *On December 3, 2010*, Unilife announced the completion of an A\$23.1 million private placement. Unilife issued 27,228,143 CDIs (Placement CDIs) at an issue price of A\$0.85 (each CDI representing an interest in one-sixth of a share of the Company's Common Stock) with free attaching unlisted options (Placement Options) to Australian investors.
- *On November 15, 2010*, Unilife announced its financial results for the first quarter of fiscal 2011, ended September 30, 2010. Unilife reported first quarter fiscal 2011 revenues of \$3.5 million versus \$3.1 million for the same period in fiscal 2010. The increase in revenues was attributable to an increase in contract manufacturing for B. Braun offset by a decrease in revenues under the industrialization agreement with sanofi-aventis. Net loss for the three months ended September 30, 2010, was \$7.2 million, or (\$0.14) per diluted share, versus a net loss of \$2.1 million, or (\$0.06) per diluted share, for the year-ago term. The increase in net loss was attributable to higher payroll and related expenses due to workforce increases, higher share-based compensation expense, and increased R&D expenses to finalize the product specifications of the Unifill[®] Syringe.
- *On November 15, 2010*, the Company commenced U.S. sales of its Unitract[®] range of 1mL safety syringes (as pictured in Figure 2 [page 4]). Unilife and Independent Medical Co-Op, Inc. (IMCO) entered into a preferred, non-exclusive marketing program for the sale of Unitract[®] 1mL syringes to U.S. healthcare facilities (as further described on page 11 under Commercialization Status).

Figure 2
Unilife Corp.

UNITRACT® RANGE OF 1ML SAFETY SYRINGES



Source: Unilife Corp.

- *On October 21, 2010*, Unilife announced that it secured U.S. government financial backing to support the construction of its new global headquarters and manufacturing facility in York, Pennsylvania. The USDA agreed to guarantee \$10 million of an \$18 million mortgage Unilife obtained from Metro Bank of Harrisburg to support construction of the 165,000 square foot facility.
- *On September 8, 2010*, the Company announced that it was included in the Standard & Poor's S&P/ASX 300® Index as of September 2, 2010.
- *On September 1, 2010*, Unilife announced that its Unitract® Tuberculin Syringe received 510(k) market clearance from the U.S. Food and Drug Administration (FDA).
- *On August 30, 2010*, the Company reported preliminary financial results for the fourth quarter and fiscal year ended June 30, 2010, as well as a number of corporate highlights from the 2010 fiscal year. Revenues for fiscal 2010 were \$11.4 million versus \$20.0 million in fiscal 2009. The decrease was largely due to a relative decline in revenues from Unilife's industrialization agreement with sanofi-aventis in 2010, caused by the accelerated receipt of milestone payments during 2009 because the industrialization program was ahead of its original schedule. The Company elected to prioritize its activities on the development and supply of its proprietary range of safety syringes, and consequently reduced business activities within the medical device contract manufacturing sector during this period.

Net loss for fiscal 2010 was \$29.7 million, or (\$0.64) per diluted share, versus net loss of \$0.5 million, or (\$0.02) per diluted share, in fiscal 2009. The increase in net loss was attributable to both the decline in revenues as well as higher payroll and related expenses due to an increase in workforce at the facility in Lewisberry, Pennsylvania. The Company also incurred an increase in legal and consulting fees in connection with its redomiciliation to the U.S.

- *On July 28, 2010*, Mr. Marc S. Firestone joined Unilife's Board of Directors as a new independent director. Mr. Firestone chairs the Nominating and Corporate Governance Committees and serves as a member of the Strategic Partnerships Committee. His biography is provided on page 13.
- *On July 7, 2010*, Mr. Christopher Naftzger was appointed as the Company's general counsel, corporate secretary, and chief compliance officer. He provides Unilife with counsel on all international, legal, and government matters as well as on corporate finance and U.S. Securities and Exchange Commission (SEC) regulations. His biography is provided on page 13.
- *On June 28, 2010*, Unilife announced that it was added to the Russell 3000®, Russell Microcap®, and Russell Global® indexes in the U.S.

Company Background

Unilife Corp. (“Unilife” or “the Company”) is a U.S.-based developer and supplier of innovative safety medical devices with U.S. Food and Drug Administration (FDA)-registered and International Organization for Standardization (ISO) 13485-certified manufacturing facilities in Pennsylvania. The Company’s core business focus is the commercialization of a proprietary range of prefilled and clinical retractable syringes suitable for the healthcare and pharmaceutical markets now transitioning to the mandatory use of needlestick prevention products. Primary target customers for Unilife’s safety syringes include pharmaceutical manufacturers, suppliers of medical equipment to healthcare facilities, and patients who self-administer prescription medication (e.g., insulin), although the syringes are also applicable to governmental harm reduction (needle exchange) programs and nongovernmental organizations’ (NGOs) vaccination efforts.

Unilife’s syringes are differentiated by a fully integrated passive (automatic) retraction mechanism that allows operators to control the speed of needle withdrawal directly from the body. This novel combination of features can help to virtually eliminate the risk of infection associated with potential transmission modes, such as needlestick injuries or aerosol (blood splatter). The Company has established exclusive agreements with global industry leaders, such as sanofi-aventis, as a result of the competitive strength of its products and associated manufacturing expertise.

Recent Corporate Focus

Unilife has recently focused on building its operational capabilities in order to meet projected demand for its syringes from pharmaceutical and healthcare companies. As a result of its efforts, the Company has recently completed a state-of-the-art new facility in York, Pennsylvania (detailed on page 12), and is nearing the end of the industrialization program for the Unifill[®] Syringe (addressed on pages 7-8). Unilife moved into the new facility in mid-December 2010, with commercial production and supply of the Unifill[®] Syringe scheduled to commence during the first half of calendar 2011.

In addition, in November 2010, Unilife began U.S. sales and shipments for its Unitract[®] range of 1mL syringes. To facilitate sales, the Company entered into preferred, non-exclusive marketing program with Independent Medical Co-Op, Inc. (IMCO), a national co-operative of independent medical device distributors, as described on page 11 under Commercialization Status.

Global Need for Improved Safety Syringe Products

Needlestick injuries are a serious and recognized occupational hazard for healthcare workers. The World Health Organization (WHO) estimates that three million healthcare workers (10%) are exposed to bloodborne pathogens annually due to needlestick injuries. Between 600,000 and 800,000 of those occur in the U.S. To reduce the risk of contracting disease from a needlestick, the U.S. Congress signed the Needlestick Safety and Prevention Act in 2000. U.S. healthcare facilities are now required to identify, review, and implement the use of sharps safety products where there is a risk of infection. Other international healthcare markets, including Europe, Canada, and Australia, are moving toward the mandatory use of sharps safety products as well. For instance, on February 11, 2010, the European Parliament approved a measure to prevent needlestick injuries that had been introduced by EU representatives of hospital employers and workers. As such, in the past decade, a number of medical device companies have introduced clinical and prefilled syringes designed to prevent unsafe injection practices. Several factors are driving this trend to safety syringes, as listed below.

- *Risk of Harm.* All healthcare personnel—from physicians to interns and cleaning staff—are at risk for harm from sharps. Disposable syringes cause more accidental punctures than any other device. Moreover, currently available safety syringes have not been shown to adequately protect those at risk. Although laws are now in place mandating the use of safety syringes, numbers of reported needlestick injuries have remained relatively stable. In some cases, safety syringes now represent the majority of all reported needlestick injuries. Unilife believes that some of this is because the current generation of retractable safety syringes does not meet the requirements of healthcare workers from both a functional and a safety point of view; thus, the syringes’ safety features are being activated improperly or not at all.

- **Enforcement.** In countries such as the U.S., where the use of safety syringes is mandated, government agencies responsible for occupational health and safety conduct random inspections of healthcare facilities and issue citations and heavy fines for noncompliance. From 2002 to 2007, the number of citations issued annually by the Occupational Safety and Health Administration (OSHA) to U.S. healthcare facilities for noncompliance in the use of sharps safety products doubled, with nearly one in every five federal OSHA inspections leading to a citation by 2007 (Source: *Medical Laboratory Observer [MLO]* Special Feature, March 2008).
- **Costs of Testing and Treatment.** Direct costs for initial testing and follow-up treatment of a needlestick injury (even if an infection does not occur) can range between \$500 and \$3,000 or more per injury (Source: U.S. Centers for Disease Control and Prevention [CDC]).
- **Staff Retention and Litigation.** Fear of contracting a bloodborne disease is one of the greatest workplace concerns for healthcare workers. Employees who incur a needlestick injury may choose to take legal action against employers who have not provided a safe working environment.

Limitations of Existing Clinical Syringes

For therapeutic drugs and vaccines that must be loaded from a vial, cartridge, or ampoule into a plastic syringe at the point of dose delivery (i.e., clinical syringes), safety syringes typically use either a manual guard that operators must slide over the needle after use, or a retractable syringe. However, many retractable syringes require operators to exert additional pressure on the plunger to activate the safety mechanism, which fires the needle into the barrel at a rapid, uncontrolled rate. Because this application of additional force to activate the safety mechanism inside the body may exacerbate venous tissue damage, it has been reported that healthcare workers often first remove the needle from the body of the patient. However, while potentially less painful for the patient, activating the safety mechanism in the open air may not only exacerbate the risk of needlestick injuries to the operators and their colleagues, but may also increase the risk of infection via the generation of aerosol (blood splatter) that can occur due to the uncontrolled rate of needle retraction.

Limitations of Existing Prefilled Syringes

Prefilled syringes come with a glass barrel and are filled with a measured dose of injectable medication by the pharmaceutical company before being shipped to the customer. Due to their relative ease of use and removal of dose wastage during the filling process, prefilled syringes are now a preferred drug delivery device for at least 50 injectable medicines and vaccines. A number of current pipeline injectable drugs and vaccines are also expected to be launched in a prefilled syringe format. Between two and three billion prefilled syringes are used annually, with the market valued at approximately \$1.5 billion and believed to be growing by 15% per year. To comply with sharps safety legislation, many drugs available in a prefilled syringe format are commonly supplied with a needlestick prevention feature.

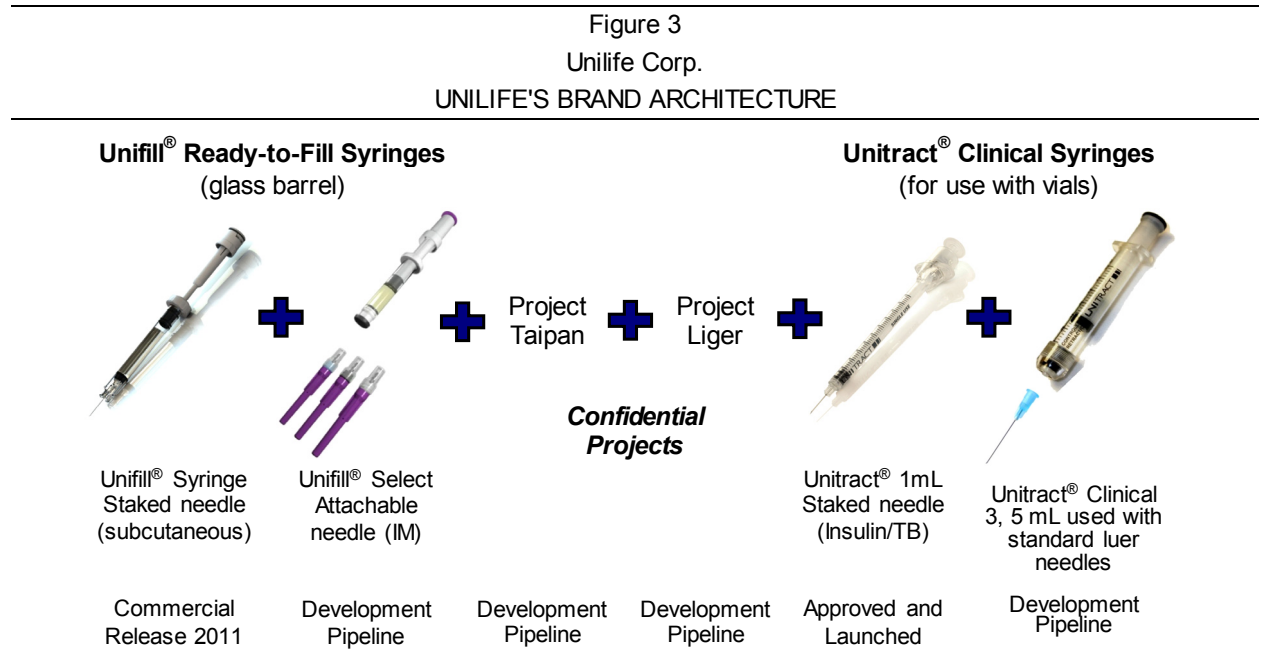
However, to Unilife's knowledge, there is no prefilled syringe with a safety mechanism integrated within the glass barrel. Many pharmaceutical companies purchase safety devices, such as a needle guard or external sheath, for attachment onto the prefilled syringe after dose filling but prior to shipment. The attachment of these ancillary safety products onto a prefilled syringe may increase the filling, packaging, and shipment volumes of a pharmaceutical company by up to 70%. The bulky size of these products also makes them relatively cumbersome to handle and may increase the incidence of needle phobia in some patients.

Unilife's Safety Syringe Technology

To promote procedural compliance and encourage retraction of a needle directly from the body rather than in the open air, Unilife's proprietary clinical and prefilled safety syringes incorporate an integrated, automatic safety mechanism by which operators control the speed of needle retraction directly from the body. Activation of the automatic needle retraction occurs during full dose delivery while the needle is still inside the body. The operator is able to control the speed of needle retraction directly from the body into the barrel of the syringe by relieving thumb or finger pressure from the top of the plunger. Hence, retraction begins immediately after the injection is completed while the needle is still inside the body with

no additional action required by the administrator. Upon the full withdrawal of the needle into the barrel, the plunger is automatically locked to prevent re-exposure or reuse. Thus, the risk of a needlestick injury or aerosol may be essentially eliminated as the needle never comes into contact with the open air.

Unilife believes that its safety syringes can help to virtually eliminate the risk of acquiring bloodborne infections, such as HIV or hepatitis C, via potential transmission modes, including needlestick injuries and aerosol. Unilife's range of approved and pipeline syringes includes the Unifill[®] Syringe, the Unifill[®] Select Syringe, the Unitract[®] 1mL Insulin, Tuberculin, and Safe Syringes, and the Unitract[®] Clinical Range, as illustrated in Figure 3, plus other confidential projects.



Source: Unilife Corp.

Unifill[®] Syringe

The prefilled syringe market represents one of the fastest growing and more profitable sectors of the international market for syringes. Prefilled syringes are continuing to gain popularity as this technology improves patient compliance, facilitates efficient production and delivery of therapeutic drugs, and enhances patient and caregiver safety. The cost of biologicals in particular has created interest in prefilled syringes as a method to reduce the expense and waste associated with vial-packaged drugs. This has led to partnerships between device designers and drug developers—relationships that have become an essential element in the success of prefilled devices.

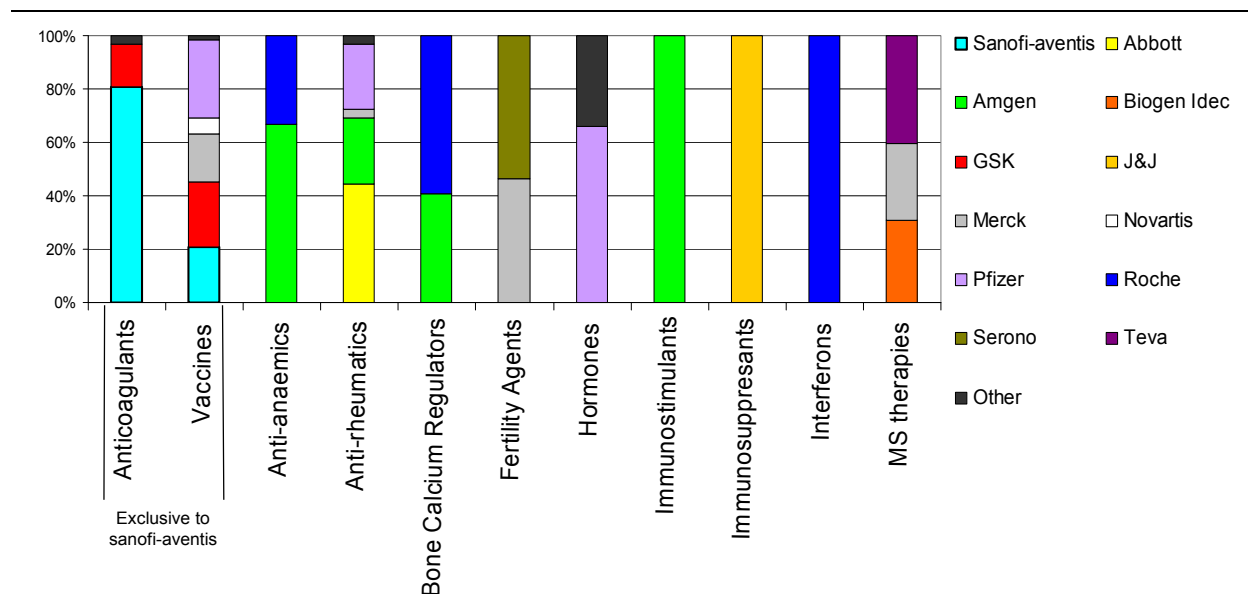
Unilife has partnered with a global leader in the prefilled syringe space and one of the world's largest pharmaceutical groups, sanofi-aventis, for approximately seven years. This relationship has led to the development of the Unifill[®] Syringe, for which sanofi-aventis has paid Unilife approximately \$40 million in industrialization payments and exclusivity fees in exchange for the exclusive right to negotiate the purchase of this syringe. This \$40 million comprises a \$13 million (€10 million) exclusivity fee as part of an agreement signed in July 2008, and a \$23.6 million Industrialization Agreement signed in July 2009 (described below).

Unilife and sanofi-aventis entered into an Industrialization Agreement in June 2009, under which Unilife is receiving up to \$23.6 million (€17 million) in quarterly milestone payments for the development of production systems to manufacture and supply Unifill[®]. Industrialization has proceeded a year ahead of schedule, after which Unilife expects to commence the supply and sale of the Unifill[®] Syringe to sanofi-aventis. Pages 12-14 of the base Executive Informational Overview[®] (EIO[®]), published April 16, 2010, and available at www.crystalra.com, provide greater details of Unilife's partnership with sanofi-aventis and

overview how production risks have been mitigated through the engagement of Mikron Group, which has demonstrated successful product assembly of the Unifill[®] Syringe at desired speeds using the same assembly station as is planned to be employed for the commercial and high-volume assembly platforms.

In March 2010, Unilife announced that it had agreed to a list of therapeutic drug classes within which sanofi-aventis has the exclusive right to purchase the Unifill[®] Syringe. The pharmaceutical leader secured exclusivity for the product within the full therapeutic classes of antithrombotic agents and vaccines until June 30, 2014. As depicted in Figure 4, sanofi-aventis is believed to be a market leader in both of these therapeutic classes. Combined, these two classes represent more than half of all prefilled syringes consumed globally.

Figure 4
INDICATIVE GUIDE BASED ON DISCLOSED REVENUES FOR APPROVED DRUGS AVAILABLE IN PREFILLED FORMATS



Source: Unilife Corp.

Sanofi-aventis has also secured product exclusivity in four smaller subgroups that fall within other therapeutic classes that Unilife believes represent new market opportunities for the pharmaceutical use of prefilled syringes. The scope of the Exclusivity List allows Unilife to commence formal discussions with further pharmaceutical companies relating to the potential use of the Unifill[®] Syringe within a number of significant therapeutic classes that fall outside of those areas retained by sanofi-aventis. To this extent, the Company is currently pursuing discussions with interested pharmaceutical companies in parallel across several therapeutic markets.

Key Market Opportunities

Unilife is tracking more than 80 marketed and pipeline drugs and vaccines that are considered potential candidates for the Unifill[®] syringe. The Company believes that key market opportunities for the Unifill[®] syringe include those summarized below and on page 9.

- Extending the lifecycle of blockbuster drugs.** There are several prefilled blockbuster drugs approaching patent expiration or coming under threat from biosimilar or generic competition. Conversion of these blockbusters to unique proprietary devices, such as the Unifill[®] Syringe, that are controlled within a particular therapeutic class and restricted to competitors, may provide an opportunity to extend product lifecycles and maximize revenues.

- Upgrading the delivery of marketed drugs. Pharmaceutical companies routinely seek to maximize the lifecycle of marketed drugs by upgrading the delivery device. Converting marketed drugs into the Unifill[®] Syringe can potentially result in increased market share (e.g., patient self-administration), improve brand differentiation in competitive markets, or increase unit selling prices. Some drugs already available in a prefilled format may also need to be converted to a safety prefilled format to comply with needlestick prevention laws within regions such as North America, Europe, and parts of Asia-Pacific. Other prefilled drugs already supplied with an ancillary safety product may also be upgraded into a proprietary device, such as the Unifill[®] syringe.
- Pipeline products. More than 20 pharmaceutical companies have products in development pipelines that are expected to be suitable for launch in a prefilled syringe format. The launch of many of these pipeline drugs following approval will likely not only expand the number of products supplied in a prefilled syringe format but may also extend the array of therapeutic classes in which they are used.

Competitive Device Design

Unilife is not aware of any prefilled syringe other than its Unifill[®] Syringe that possesses an automatic needle retraction feature fully integrated into the barrel. In addition to offering considerable improvements in safety, this device design makes the syringe compact and simple to use with convenient, cost-effective disposal. Unifill[®] syringes are virtually the same size as conventional (non-safety) prefilled syringes and are designed for compatibility with the drug validation and manufacturing systems currently used to fill and package standard prefilled syringes. By eliminating the need to use bulky clip-on safety attachments, pharmaceutical companies may be able to save up to 70% in filling, transportation, and packaging volumes through the use of the Unifill[®] Syringe. Figure 5 illustrates a comparison between three current plastic safety products (left and middle of Figure 5), which are clipped onto a prefilled syringe by a pharmaceutical manufacturer between the filling and packaging processes, and the Unifill[®] Syringe (on the right side of Figure 5). Unilife expects that the syringe’s intuitive use, compact design, and convenience for disposal also makes it suitable for use by patients who self-administer prescription medication outside of a healthcare setting—a growing trend as the healthcare industry seeks to contain costs and improve patient care.

Figure 5
Unilife Corp.
COMPETITIVE DEVICE DESIGN



Source: Unilife Corp.

Combined, the syringe’s innovative design attributes may create opportunities for pharmaceutical companies to improve brand differentiation within competitive therapeutic markets or potentially to extend product life cycles, particularly when established drugs experience pressure from generic or biosimilar products.

Targeted Production Capacities

The first Unifill[®] commercial line—scheduled for installation in early 2011—is anticipated to have a target production capacity of approximately 60 million units per year, which is a 50% increase over forecasted capacity from when the Company initiated the Industrialization Program in July 2008. Additional higher volume assembly lines to be progressively installed are expected to have an annual production capacity of 150 million units per year. These high-volume lines use the same assembly platform employed for both the initial 60-million unit line, as well as the line used to successfully manufacture the Unifill[®] Syringe during proof-of-principle testing undertaken in conjunction with Unilife during 2009. Under a project plan developed by Unilife, annual production volumes for the Unifill[®] Syringe are intended to increase to more than 400 million units beyond 2014 and 850 million units beyond 2016—fueled by the modular design platform and greater capacity of the high-volume assembly system. The Company expects that this system can enable it to increase production capacities at a more rapid and cost-effective rate than was originally envisioned as well as to quickly ramp-up production if market demand exceeds projections.

Unifill[®] Select

In late 2009, Unilife introduced a new prefilled syringe to its pipeline called the Unifill[®] Select. While the Unifill[®] Syringe is optimized for use in subcutaneous injections, the Unifill[®] Select syringe has been designed for intramuscular injections, such as vaccines, which require attachable needles. In intramuscular injections, healthcare workers require a variety of needle gauge and length options, as the needle employed is selected based on the patient's age, gender, and size, as well as the location of the muscle being injected. To Unilife's knowledge, its Unifill[®] Select syringes could become the first prefilled safety syringe with automatic and fully integrated safety features that are designed with attachable needles suitable for intramuscular injections.

The intellectual property for the Unifill[®] Select is separate to, and not covered by, previously signed agreements with pharmaceutical partners. Thus, this pipeline product is not constrained by the existing agreement with sanofi-aventis; rather, the Unifill[®] Select complements the existing Unifill[®] Syringe being launched in conjunction with sanofi-aventis. By adding the Unifill[®] Select to its proprietary portfolio of ready-to-fill syringes, Unilife expects to expand its relationships with pharmaceutical companies and further establish a significant presence across therapeutic drug markets where prefilled safety syringes are in demand.

Unitract[®] 1mL Syringes

Unlike the Unifill[®] prefilled syringes, the Unitract[®] 1mL syringes require healthcare workers or patients to draw up a dose from a vial or ampoule immediately prior to the injection. The Unitract[®] range of products includes a 1mL Insulin Syringe designed for use in healthcare facilities and by patients who self-administer insulin at home. Unilife anticipates having U.S. production capacity for Unitract[®] of approximately 40 million units annually and has commenced launching these syringes across key international markets, as further described under Commercialization Status.

The Unitract[®] line also includes the Unitract[®] 1mL Safe Syringe designed to enhance the effectiveness of harm reduction (needle exchange) programs in more than 65 countries. Under these programs, syringes are supplied to injecting drug users (IDUs) with the intent of minimizing HIV and hepatitis C epidemics associated with the reuse, sharing, and unsafe disposal of non-sterile syringes. In addition to automatic, operator-controlled needle retraction, the Safe Syringe also has an independent non-reuse feature that prevents the operator from being able to pull back the plunger and draw up a second dose once the initial dose administration has commenced. Unilife believes that this product is well positioned to support governments that seek to implement socioeconomic healthcare policies targeted toward preventing syringe reuse and sharing by IDUs.

Commercialization Status

In March 2010, Unilife announced an agreement with Stason Pharmaceuticals, Inc., a California pharmaceutical company, for the exclusive distribution of the Unitract[®] 1mL syringes in Japan, China, and Taiwan. In return for exclusivity, Stason committed to the minimum purchase of one million units per year. Stason (in conjunction with its local Asian affiliates, including Standard Chem. and Pharm. Co., Ltd) is responsible for regulatory approval and marketing activities within the designated Asian regions.

In April 2010, the Company announced an agreement with Clinicare, a Mumbai-based supplier of safety medical devices, to serve as Unilife's exclusive local partner to Indian healthcare facilities and pharmaceutical companies as well as the Company's authorized national representative to secure the registration of the Unitract[®] 1mL syringes with Indian regulatory authorities.

To help introduce the Unitract[®] 1mL syringes to U.S. healthcare facilities, Unilife entered into an agreement with Independent Medical Co-Op, Inc. (IMCO) in November 2010. As a national co-operative of independent medical device distributors, IMCO's member distributors supply medical equipment to healthcare facilities across the U.S. and Canada. Many of these distributors focus primarily on the physician and long-term care segments—healthcare sectors characterized by considerable use of 1mL safety syringes. As such, the Company believes that IMCO is well positioned to act as a preferred, non-exclusive partner in support of Unilife's Unitract[®] launch activities. Unilife has already begun processing initial purchase orders and commenced sales for shipment to a number of IMCO member distributors.

Regulatory Clearances

Unilife holds 510(k) clearances from the FDA for its Unitract[®] 1mL Insulin and Tuberculin syringes for their sale and marketing within the U.S. Globally, the Company has also secured regulatory approvals for its 1mL range in Canada, Europe (the CE Mark), and Australia.

The Unitract[®] Clinical Range

Currently at the advanced design and prototype stage, the Unitract[®] Clinical Range project has been slowed in order to focus the Company's efforts on developing the Unifill[®] Syringe. Yet, ultimately, the Unitract[®] Clinical Range products are expected to be available in 3mL and 5mL sizes with attachable needles suitable for intramuscular injections.

Headquarters and Employees

Founded in 2002, Unilife is headquartered in Pennsylvania and employs over 150 full-time staff globally. In October 2009, Unilife accepted a revised \$5.2 million offer of assistance from Pennsylvania to support the creation of 240 additional new jobs within York County.

Unilife trades on the NASDAQ stock exchange as "UNIS" and its CHES Depository Interests (CDIs) trade on the Australian Securities Exchange (ASX) as "UNS." The Company began trading on NASDAQ on February 16, 2010, and was formally welcomed to the exchange at NASDAQ Closing Bell ceremony on February 22, 2010 (as illustrated in Figure 6 via an image from NASDAQ's live webcam of the seven-story MarketSite Tower in New York City's Times Square).

Listing on a U.S. exchange was part of Unilife's strategy for relocating from Australia to the U.S. The Company completed its redomiciliation from Australia to Delaware on January 27, 2010, in a transaction whereby Unilife Corp. (incorporated in Delaware in July 2009) became the parent company of Unilife Medical Solutions Ltd. (UMSL), the Australian entity.

Figure 6
Unilife Corp.
NASDAQ'S MARKETSITE TOWER IN NYC



Source: NASDAQ.

Construction of New Global Headquarters and High-volume Production Plant

Since the initial ground breaking in December 2009, Unilife has completed the construction of a 165,000 ft² global headquarters and manufacturing facility in York, Pennsylvania, with an annual capacity to manufacture up to 400 million units of Unilife's range of safety syringes in its first phase. The Company has also secured pre-approval for the production of a second-stage, 100,000 ft² extension that could increase the capacity of the facility to approximately one billion units per year.

The construction of this new facility occurred in parallel with the Company's relocation from Australia to the U.S. The York production plant is intended to help Unilife meet anticipated demand for its products and become a preferred, long-term supplier to a number of pharmaceutical companies.

Unilife relocated and consolidated staff from its Lewisberry, Pennsylvania, sites to the new facility during mid-December 2010. The transfer and installation of the Unitract[®] automated assembly line into the York facility also occurred in December. Production and supply of Unitract[®] syringes from the York facility are anticipated to re-commence during the first quarter 2011. The Unifill[®] automated assembly line is scheduled to be installed into the York facility in the first quarter of calendar 2011, with initial commercial supply expected to occur during the second quarter of calendar 2011.

This location is intended to leverage the expanded production capacities of Unilife's assembly lines and the ability for Unilife, under the Industrialization Agreement, to sell to pharmaceutical companies other than sanofi-aventis. In addition, it is anticipated to reduce operational costs, optimize supply chain activities, and place Unilife in a favorable international location from which to supply its products.

The York facility incorporates eight Class 8 and three Class 7 clean rooms where environmental factors such as temperature, humidity, and particulate matter are tightly controlled. An advanced Water-for-Injection (WFI) system meets pharmaceutical standards of water purity required for production of the Unifill[®] Syringe. Additional amenities include a product development center, a microbiology laboratory, quality inspection and control rooms, and a fully segregated warehouse for efficient inventory management. Within the plant, 54,000 ft² are designated to become the Company's global offices.

Unilife evaluated financial and operational factors before determining that developing its own custom-built facility in York, Pennsylvania, could be more cost-efficient than leasing and retrofitting an existing warehouse. Unilife has invested approximately \$10 million in the project, and does not expect being required to lay out any additional cash to finance the completion of the York facility. In October 2010, the Company secured an \$18 million mortgage from Metro Bank to support the new facility and the U.S. Department of Agriculture (USDA) agreed to guarantee \$10 million of the loan.

Recent Additions to Unilife's Corporate Leadership and Board of Directors

Unilife has augmented its executive team and Board of Directors in line with the Company's U.S. expansion. Biographies for key recent additions to Unilife are included below and on page 13.

Ramin Mojdeh, Ph.D., MBA, Chief Operating Officer (COO) and Executive Vice President

Dr. Mojdeh has over 25 years of business leadership experience, including 18 years in the design, development, manufacturing, sale, and marketing of therapeutic and diagnostic medical devices for several multinational companies, including Becton, Dickinson and Co., GE Healthcare, and Boston Scientific (formerly Guidant Corp.). He has developed and maintained relationships with many pharmaceutical manufacturers that utilize prefilled syringes for injectable drugs and vaccines. At BD, Dr. Mojdeh served as vice president and general manager of BD Medical, Pharmaceutical Systems, North America, from 2008 to 2010. He has also served as a key Board member of the Business Strategy Council that led the worldwide business growth strategy for BD Pharmaceutical Systems, for which annual revenues exceeded \$1 billion. He further led the creation of an innovative new growth business for BD Pharmaceutical Systems in advanced drug delivery. Formerly, Dr. Mojdeh has been worldwide vice president of research and development for BD Medical; a Board member of BD Ventures Inc., the venture capital arm of BD; chairman of the Advanced Drug Delivery Council; and business director, invasive cardiology at GE Healthcare; among other positions. Dr. Mojdeh received a Ph.D. in computer science from the University of Minnesota, and an MBA from Kellogg Graduate School of Management, Northwestern University.

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

Mr. Wieland has over 30 years of senior financial experience with U.S.-based public and private companies. He has served as the chief financial officer (CFO) of four NASDAQ-listed companies within the life sciences industry, and as a senior executive of two NYSE-listed companies. Most recently, Mr. Wieland served as the CFO of Cytochroma Inc., a closely held specialty pharmaceutical company. From 2004 to 2008, he served as executive vice president and CFO of Advanced Life Sciences Holdings, Inc. (ADLS-OTC). Prior to that, Mr. Wieland served as a senior executive of other life science and healthcare companies, including Option Care, Inc., where he was a Board member, president, and chief operating officer (COO). Mr. Wieland received an MBA from Washington University in St. Louis, Missouri, and a B.A. in accounting and economics from Monmouth College in Monmouth, Illinois, where he later served as a member of the Board of Trustees. Mr. Wieland is a past member of the National Investor Relations Institute, Financial Executives International, and the U.S. Army Signal Corps.

Christopher Naftzger, J.D., General Counsel, Corporate Secretary, and Chief Compliance Officer

Mr. Naftzger previously served as assistant general counsel and assistant secretary of Chesapeake Corporation, a supplier of packaging to the pharmaceutical, healthcare, and consumer industries. While at Chesapeake, Mr. Naftzger participated in all Board of Directors and Board Committee meetings as well as coordinated with the global sales team on negotiations for multi-year/multi-product supply contracts with a number of leading pharmaceutical and healthcare companies. Mr. Naftzger has also served as the senior counsel at Koch Industries, Inc., one of the largest closely held companies in the U.S. with revenues of approximately \$98 billion in 2008, and as a partner at Blank Rome LLP, a full-service international law and government affairs firm. He holds a J.D. from Willamette University College of Law in Oregon and a Bachelor's degree from Hampden-Sydney College in Virginia.

Marc S. Firestone, J.D., Director

Mr. Firestone leads the department responsible for legal, corporate affairs, government affairs, compliance, and corporate governance for Kraft Foods Inc. (KFT-NYSE). In his current position, he oversees 450 people around the world. He worked in Europe for seven years and, more recently, has represented Kraft Foods before the U.S. Senate, UK Parliament, European Commission, and in meetings with public interest groups, community organizations, and the media. He has also handled various matters for Kraft Foods before major U.S. regulatory agencies. Additionally, Mr. Firestone advised the Kraft Foods Board and executive management team on the legal, governance, and communications aspects of numerous multibillion dollar transactions and acquisitions, including the recent acquisition of Cadbury plc for approximately \$19 billion. Previously, Mr. Firestone held senior executive positions for Philip Morris Companies and subsidiaries, including as senior vice president and general counsel, Philip Morris International Inc. (PM-NYSE), and senior vice president of regulatory affairs, Phillip Morris Companies. Mr. Firestone is also a frequent public speaker on international competition law, diversity, and in-house practice, and has received several awards, including the Distinguished General Counsel Award. He holds a J.D. from Tulane University School of Law and a Bachelor's degree from Washington & Lee University in Virginia. He is proficient in English, French, and Italian.

Mary Kate Wold, J.D., Director

Ms. Wold spent seven years at Wyeth (now part of Pfizer Inc. [PFE-NYSE]), serving as senior vice president of finance from 2007 to 2009 and senior vice president of tax and treasury from 2005 to 2007. She was responsible for Wyeth's global treasury, tax, and procurement operations and assumed a major transformational role in each function. She was also responsible for Wyeth's Global Business Process Outsourcing initiative. She served on a number of executive management committees that cut across most areas of Wyeth's operations, and appeared as the spokesperson at various investor and healthcare conferences. Prior to that, Ms. Wold spent 17 years with Shearman & Sterling, a preeminent international law firm based in New York. Made a partner in 1988, Ms. Wold specialized in international tax planning for multinational corporations and in the tax aspects of mergers and acquisitions, capital markets, and private equity transactions. She served as chair of its Global Tax Group from 1995 to 2000, and as deputy chair from 1993 to 1995. Ms. Wold also worked for the U.S. Department of the Treasury as an attorney advisor for the Office of International Tax Counsel. She received a law degree from the University of Michigan, where she graduated *cum laude*. She received a B.A. from Hamline University in St. Paul, Minnesota, where she was Phi Beta Kappa and graduated *summa cum laude*.

Key Points to Consider

- Unilife believes that it is well positioned, as it possesses a disruptive technology for a marketplace that is driven by legislation. Unilife has developed and patented a portfolio of prefilled and clinical retractable syringes with an automatic, user-controlled needle retraction system that is fully integrated within the device. The Company aims to supply a best-in-class range of safety syringes into target healthcare and pharmaceutical markets that increasingly mandate the use of such devices. Specifically, Unilife is working to secure a competitive position within the pharmaceutical market for prefilled syringes—one of the most profitable and fastest-growing sectors of this industry.
- Although legislation exists, reported needlestick injuries remain stable. Unilife believes one key reason is that the current generation of safety syringes does not meet the functional and safety requirements of healthcare workers. These devices may instead put workers at an increased risk of infection from needlesticks or splatter due to an incorrect use or non-activation of safety mechanisms.
- Unilife believes that nearly all of its competitors have been *technology driven*. What differentiates Unilife in this market is that rather than being technology driven, the Company considers itself to be *market driven*, where it enters each syringe market segment to discover the users' specific needs and then creates targeted syringe designs to achieve new levels of desired functionality and safety.
- Unifill[®] is engineered for high-volume production and designed for compatibility with standard filling and packaging systems. All safety features are contained within the glass barrel to ensure the product is compact in size for cost-effective shipment, improved operator ease of use, and reduced waste. By removing the need to purchase and attach clip-on safety products, Unilife can significantly reduce pharmaceutical companies' costs in areas such as assembly, packaging, storage, and transport.
- Sanofi-aventis—one of the world's largest purchasers of prefilled syringes—has committed up to \$38.5 million (pre-sales) to the Unifill[®] Syringe. Up to \$23.6 million (€17 million) is for production of Unifill[®] under an Industrialization Agreement, and \$13.9 million (€10 million) was for five-year exclusivity to purchase the Unifill[®] Syringe within agreed therapeutic drug classes, such as vaccines and antithrombotic agents. The Company expects initial manufacturing capacity for Unifill[®] to be 60 million units by late 2011, with annual production reaching 450 million units beyond 2014.
 - Unilife has the right to supply Unifill[®] to other third parties for use in therapeutic drug classes that are not retained exclusively by sanofi-aventis under the Exclusivity List signed in March 2010. Unilife is currently holding discussions with a number of interested pharmaceutical manufacturers relating to the use of the Unifill[®] Syringe within therapeutic classes outside of those retained by sanofi-aventis, or for other related proprietary products in its pipeline.
- Unilife has received regulatory clearances for its Unitract[®] 1mL Syringes in the U.S., Canada, Europe, and Australia. Production began in August 2009 at the Company's FDA-registered and ISO 13485-certified Pennsylvania facility, with commercial launch across key global markets during 2010.
- Unilife has attracted world-class medical device and pharmaceutical experts to its team. It has also invested significant resources expanding and developing its operational capabilities in the design, development, production, inspection, certification, and supply of medical devices, including primary drug containers to pharmaceutical customers. This includes recent construction of and opening a \$31 million, 165,000 ft² state-of-the-art manufacturing facility and global headquarters in Pennsylvania.
- The Company has 32 issued patents in 16 countries (including four issued patents in Australia and two in the U.S.), as well as other pending patent applications in the U.S., Australia, and under the Patent Cooperation Treaty (PCT), registered trademarks, and trade secrets. Patents expire at various dates between 2018 and 2028, with patents relating to the Unifill[®] expected to expire by 2028.
- As of December 31, 2010, Unilife held cash, cash equivalents, and restricted cash of nearly \$42 million (which included \$2.4 million of restricted cash used to secure the mortgage on its York facility). The Company secured an \$18 million mortgage in October 2010, for which \$10 million is guaranteed by the USDA. In December 2010, Unilife completed a private placement for proceeds of A\$23.1 million (~US\$22.8 million) and a share purchase plan for A\$12.8 million (~US\$13 million).

Risks

Some of the information in this Quarterly Update relates to future events or future business and financial performance. Such statements can only be predictions and the actual events or results may differ from those detailed due to risks addressed in Unilife's statements filed with the U.S. Securities and Exchange Commission (SEC) and the Australian Securities Exchange (ASX) as well as other forms filed from time to time. The content of this report with respect to Unilife has been compiled from information available to the public released by the Company through news releases, Annual Reports, forms filed with the SEC and ASX, and other filings. Unilife is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by the Company. Certain summaries of activities have been condensed to aid the reader in gaining a general understanding. For more complete information about Unilife, please refer to the Company's website at www.unilife.com. Additionally, please refer to Crystal Research Associates' base report, the Executive Informational Overview[®] (EIO[®]) dated April 16, 2010, and located on Crystal Research Associates' website at www.crystalra.com for more comprehensive details of Unilife's risk factors.

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