EXECUTIVE INFORMATIONAL OVERVIEW

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Designer and Supplier of Next-Generation Safety Syringe Technology

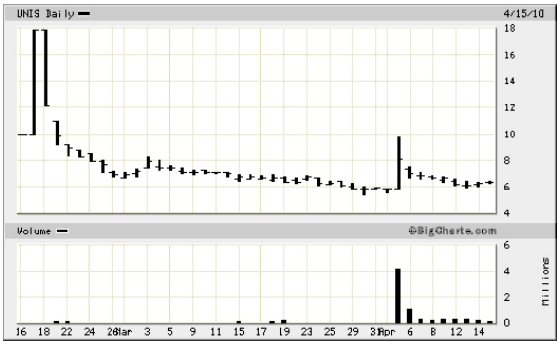
Snapshot

April 16, 2010

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™, a glass-barreled, prefilled safety syringe; and (2) Unitract™, a line of plastic-barreled, clinical safety syringes. The distinctive feature of Unilife's products 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 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 industrialization and exclusive right to buy the Unifill™ Syringe in therapeutic areas such as vaccines and **antithrombotics**. Unilife also aims to establish agreements with other pharmaceutical companies in areas not reserved for sanofi-aventis. Unilife began trading on NASDAQ on February 16, 2010.

Recent Financial Data

Ticker (Exchange)	UNIS (NASDAQ)
Recent Price (04/15/2010)	$6.30
Shares Outstanding	~54.3 million
Market Capitalization	~$342 million
Average 3-month Volume	201,776
Insider Owners +5%	~21%
Institutional Owners	~5%
EPS (Qtr. ended 12/31/2009)	($0.13)
Employees	~120



Key Points

- In March 2010, Unilife and sanofi-aventis agreed to an Exclusivity List specifying the therapeutic classes where sanofi-aventis has an exclusive right to purchase the Unifill™ Syringe. These include the full therapeutic classes of antithrombotics and vaccines, and six smaller subgroups that may represent new market opportunities for pharmaceutical prefilled syringes.
- Unilife is building a new global headquarters and commercial production facility in York, Pennsylvania. The custom-designed, 165,000 ft^2 facility is scheduled for completion in late 2010. Thus, supply of the Unifill™ Syringe to sanofi-aventis could begin in early 2011 (one year ahead of schedule), with high-volume manufacturing likely to be in place by the end of 2011.
- In August 2009, Unilife began manufacturing the Unitract™ 1mL Insulin Syringe, intended for diabetics who self-inject insulin at home. Unilife is preparing for commercial launch of its Unitract™ 1mL clinical syringes in the first half of 2010 and, in February 2010, donated the first shipment of Unitract™ syringes to Doctors Without Borders in support of Haiti's earthquake relief efforts.
- The Company holds 26 issued patents in 14 countries as well as a number of patent applications pending in the U.S., Australia, and under the **Patent Cooperation Treaty (PCT)**.
- To date in 2010, Unilife has redomiciled from Australia to the U.S. and commenced trading on NASDAQ. The Company has also attracted world-class medical device and pharmaceutical experts to its team and believes that it is well positioned both operationally and financially.
- At December 31, 2009, Unilife had cash of over $41 million after raising ~$47.5 million in U.S. and Australian markets during November 2009 and securing a $5.2 million offer from the Pennsylvania government in October 2009.

†**BOLD** WORDS ARE REFERENCED IN THE GLOSSARY ON PAGES 70-71.

Table of Contents

Executive Overview

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.

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. each year. To reduce the risk of contracting a bloodborne disease from a needlestick injury, 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, as listed below, are driving this trend to safety syringes.

- *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 and, in some cases, are on the rise. 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 can 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 under the **Bloodborne Pathogens Standard (BPS)** doubled, with nearly one in every five federal OSHA inspections entailing a BPS 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: 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 pharmaceuticals that must be loaded from a vial, cartridge, or ampoule into a plastic syringe at the point of dose delivery (i.e., clinical syringes), a safety syringe with an integrated spring-activated needle retraction mechanism is commonly used. 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 less painful for the patient, activating the safety mechanism in the open air not only creates 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, prefilled syringes are commonly supplied with a needlestick prevention feature.

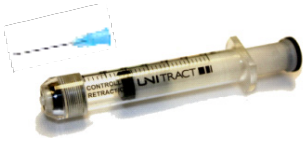
However, to Unilife's knowledge, there is no prefilled syringe with a safety mechanism integrated within the barrel. Many pharmaceutical companies purchase safety devices, such as a needle guard or external sheath, for attachment onto the prefilled syringe after dose filling but prior to shipment. The 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 withdrawal of the needle into the barrel, the plunger is automatically locked and the needle is tilted to one side 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 may 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 syringes comprises the Unifill™ Syringe, the Unifill™ Select Syringe, the Unitract™ 1mL Insulin, Tuberculin, and Safe Syringes, and the Unitract™ Clinical Range. Figure 1 (page 5) summarizes the Company's product lines.

Figure 1
Unilife Corp.
UNILIFE'S BRAND ARCHITECTURE

UNITRACT® Sharps Safety Devices		UNIFILL	
Clinical Syringes (plastic barrel for use with vials)		Ready-to-Fill (Prefilled) Syringes (glass barrel)	
			
1mL Insulin, Tuberculin (TB), and Safe Fixed Needle	Clinical Range 3mL and 5mL Luer Needles	Unifill™ Syringe Fixed Needle	Unifill™ Select Attachable Needles
U.S. Production	**Pipeline**	**Industrialization Program**	**Pipeline**

Source: Unilife Corp.

Unifill™ Syringe

The prefilled syringe market continues to thrive as this technology improves patient compliance, facilitates efficient delivery of high-priced biologicals, and enhances patient and caregiver safety. The cost of biologicals 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 six years. This relationship has led to the development of the Unifill™ Syringe, for which sanofi-aventis paid Unilife $13.9 million (€10 million) in July 2008 for the exclusive right to negotiate the purchase of this syringe for a period of five years. 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. Combined, these two therapeutic classes represent more than half of all prefilled syringes consumed globally.

Sanofi-aventis has also secured product exclusivity in an additional six smaller subgroups that fall within other therapeutic classes that Unilife believes represent new market opportunities for pharmaceutical use of prefilled syringes. The scope of the Exclusivity List allows Unilife to commence formal discussions with other 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.

In addition, 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™. To date, the Company has received milestone payments from sanofi-aventis of €13 million. Furthermore, industrialization is proceeding a year ahead of schedule and is likely to conclude by the end of 2010, after which Unilife expects to commence the supply and sale of the Unifill™ Syringe to sanofi-aventis. Pages 12-14 provide greater details of Unilife's partnership with sanofi-aventis as well as 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.

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. Unilife expects that the syringe's intuitive use 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. Combined, the syringe's 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 late 2010—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. Subsequently, Unilife anticipates installing a high-volume assembly line by the end of 2011 with an annual production capacity of 150 million units. Under a project plan developed by Unilife, annual production volumes for the Unifill™ Syringe are intended to increase in excess of 450 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. The Unifill™ Syringe described above is optimized for use in **subcutaneous** injections; however, 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. Unilife is manufacturing the Unitract™ 1mL syringes at its FDA-registered, ISO 13485-certified manufacturing facility in Lewisberry, Pennsylvania. 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. Production of the Unitract™ 1mL Insulin Syringe began in August 2009. In December 2009, Unilife completed its required product aging studies for the Unitract™ 1mL syringes. Unilife anticipates having U.S. production capacity for Unitract™ of approximately 40 million units annually and intends to launch these syringes across key international markets during 2010.

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 re-use and sharing by IDUs.

Commercialization Status

Unilife is working toward the full commercial launch of its 1mL Insulin Syringe during the first half of 2010. In February 2010, the first shipment of these syringes was donated to Doctors Without Borders in support of Haiti's earthquake relief efforts. 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. Unilife is also in discussions with a number of other pharmaceutical companies and healthcare distributors regarding the Unitract™ 1mL syringes for use within North America, Europe, and Asia-Pacific.

Unilife holds **510(k) clearance** from the FDA for Unitract™ 1mL Insulin Syringes manufactured in China (secured in August 2008) and at its FDA-registered Lewisberry facility (secured in April 2010). Globally, the Company has secured regulatory approvals for its 1mL range in Canada, Europe (the **CE Mark**), and Australia. In addition, the Company announced in April 2010 the submission of a subsequent 510(k) to the FDA seeking clearance for the Unitract™ Tuberculin (TB) syringe, which is a variant of the Unitract™ Insulin Syringe intended to be marketed for use within healthcare settings.

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 Lewisberry, Pennsylvania, and employs over 120 full-time staff globally, which is expected to increase to 200 individuals by the end of 2010. In October 2009, Unilife accepted a revised $5.2 million offer of assistance from Pennsylvania to support the creation of 241 additional new jobs within York County.

Unilife trades on the National Association of Securities Dealers Automated Quotation (NASDAQ) stock exchange as "UNIS" and its CHESS Depositary Interests (CDIs) are traded 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 2 via an image from NASDAQ's live webcam of the seven-story MarketSite Tower in New York City's Times Square).

Figure 2

Unilife Corp.

NASDAQ'S MARKETSITE TOWER IN NYC

Source: NASDAQ.

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.

In April 2010, following FDA clearance of the Unitract™ Insulin syringes assembled at its Lewisberry facility, Unilife shifted manufacturing activities to a four-shift, 24-hour, 7-day per week (24/7) manufacturing cycle. This 24/7 manufacturing cycle is expected to maximize annual production capacities for the Unitract™ 1mL syringes and further improve manufacturing cost-efficiencies.

Construction of New Global Headquarters and High-volume Production Plant

As part of its move to the U.S., Unilife is constructing a 165,000 ft^2 global headquarters and manufacturing facility capable of a first-stage manufacturing capacity of up to 360 million syringes annually in York, Pennsylvania. 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 is scheduled to be ready for operations by late 2010 to support the completion of the industrialization program for the Unifill™ Syringe and the supply of the product to sanofi-aventis. Within the plant, 54,000 ft^2 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. The Company has projected the total cost for its new facility to be $26 million, with only up to $9 million likely be funded out of existing cash. Unilife believes that the remaining amounts can be financed from a commercial bank or other U.S. lending institution and from the Commonwealth of Pennsylvania and other U.S. federal and state entities. Pages 46-48 of the Core Story detail the new facility, including its timeline for completion and financing.

Growth Strategy

Whereas in 2009 Unilife was focused on positioning its business for expansion, 2010 is in many ways about delivery—establishing a presence within the drug delivery market as an emerging leader in the design, development, and supply of innovative safety medical devices. Unilife is no longer merely a technology company; it is now an industrial manufacturer as well.

To this extent, the Company has been increasing its advertising within the drug delivery market and has been attending industry events, such as the Parenteral Drug Association's (PDA) Universe of Pre-filled Syringes and Injection Devices, Conference and Exhibition (October 27-30, 2009, in Venice, Italy), and PharmaPack 2010 (February 1-2, 2010, in Paris, France).

Business Priorities

At present, Unilife's chief priorities are bringing the Unifill™ Syringe to high-volume production and supply to sanofi-aventis while continuing to expand the number of long-term supply agreements that the Company has for its products with other pharmaceutical companies.

Key tenets of Unilife's growth strategy are summarized below.

- Continue to build a strong relationship with sanofi-aventis, which includes supplying the Unifill™ Syringe to sanofi-aventis for use within defined therapeutic drug classes, including vaccines and antithrombotics, upon completion of the industrialization program.

- Enter into business relationships with additional pharmaceutical companies that are industry leaders within their respective therapeutic areas of expertise. By pursuing this strategy, Unilife believes that its products can be marketed within a significant number of large therapeutic drug classes outside of those retained by sanofi-aventis where prefilled and clinical syringes are commonly used.

- Expand its proprietary product portfolio to include the commercialization of current pipeline products (Unifill™ Select; Unitract™ Clinical Range). Additionally, Unilife may evaluate opportunities to acquire other complementary technologies or products on a case-by-case basis.

- Continue to expand operational capabilities within central Pennsylvania, as Unilife believes that the U.S. represents the largest and most mature market for safety syringes.

- Manufacture and supply the Unitract™ 1mL Syringes for international markets while continuing to expand the customer base (pharmaceutical companies, healthcare distributors, **group purchasing organizations**, and government harm reduction programs) for these syringes. Unilife has secured FDA and other regulatory approvals for the Company's Unitract™ 1mL syringes. The Company desires to follow the launch of its prefilled and 1mL syringes with its full clinical range, with the objective of ensuring that healthcare personnel view Unilife's technology as a new benchmark for safety sharps.

Intellectual Property

Unilife's intellectual property portfolio includes 26 issued patents in 14 countries; a number of patent applications pending in the U.S., Australia, and under the Patent Cooperation Treaty (PCT); registered trademarks; and trade secrets.

Unilife classifies its patents and patent applications as they relate to certain product categories: (1) 1mL Insulin and Safe Syringes with an attached needle; (2) clinical syringes that include larger sizes and interchangeable **luer** needles; and (3) the Unifill™ Syringe. Many of the features claimed in the Insulin and Safe Syringes patents also apply to other of Unilife's products, such as the mechanism allowing for automatic and controlled needle retraction within an integrated medical device. Unilife's patents expire at various dates between 2018 and 2028. Some of the key patents are noted in Table 1 (page 11).

In addition, the Company possesses **Freedom to Operate (FTO)** reports regarding the likelihood of a technology infringing a third party's patent. Unilife obtained an FTO report from one of its patent attorneys in January 2008 that gave the Company confidence that its patents filed for the Unifill™ Syringe did not infringe on identified U.S. and European patents and patent applications. Unilife has also created an Intellectual Property Management Committee to manage and strengthen its intellectual property portfolio.

Patent Cooperation Treaty (PCT)

Many of the Company's international patent applications are pending under the PCT, which enables an entity to seek patent protection simultaneously in over 140 countries. The PCT does not grant an "international patent," which does not exist, but rather facilitates the process of obtaining a patent in each member country and bestows additional benefits to the applicant, including priority over more recent third-party applications. Unilife's PCT applications are currently moving through various national phases in jurisdictions around the world. Additionally, the Company has filed (and been granted) international patent applications in some non-PCT countries, such as Taiwan and Thailand.

Registered Trademarks

"Unitract" is a registered trademark in Australia, the U.S., Mexico, New Zealand, Canada, India, Indonesia, South Africa, and Brazil, and "Unitract Safe Syringe" is a registered trademark in Australia. "Unitract" is also a registered trademark in 22 countries under the Madrid Protocol Agreement established in 1891 for the international registration of marks. Commonly known as the Madrid system, this agreement allows an entity to protect its trademark in numerous countries while only filing an application in that entity's own national or regional trademark office. The Company has also commenced applications to register trademarks for its name "Unilife" and its prefilled syringe brand name "Unifill" across a number of target territories, including the U.S., Canada, Europe, Australia, Taiwan, and Japan.

Table 1

Unilife Corp.

INTELLECTUAL PROPERTY SNAPSHOT

Filing Date	Title Global Status	PCT Number	WIPO* Number
	Insulin and Safe Syringe		
09/22/1998	Retractable syringe Granted in Australia and the U.S.	—	—
04/20/2001	Single use syringe Granted in Australia, China, New Zealand, Russia, Singapore, South Africa, and South Korea Pending in Brazil, Canada, Europe, India, Indonesia, Hong Kong, Japan, Mexico, Norway, and the U.S.	PCT/AU2001/000458	WO2001/080930
03/19/2004	Syringe spring retainer Granted in New Zealand, Singapore, and Taiwan Pending in Australia, Canada, China, Hong Kong, Europe, India, Indonesia, Japan, Mexico, South Africa, the U.S., Malaysia, Thailand, Peru, Chile, Argentina, and Venezuela	PCT/AU2004/000354	WO2004/082747
	Clinical Syringe		
01/28/2005	Retractable syringe with plunger disabling system Granted in Taiwan Pending in Australia, Canada, China, Europe, the U.S., Malaysia, and Thailand	PCT/AU2005/000107	WO2005/072801
05/11/2006	Improved controlled retraction syringe and plunger therefor Pending in Australia, Canada, China, Europe, India, Indonesia, South Africa, the U.S., Malaysia, Taiwan, and Thailand	PCT/AU2006/000618	WO2006/119570
	Unifill™ Syringe		
04/18/2006	Controlled retraction syringe and plunger therefor Pending in Australia, Canada, China, Europe, India, Indonesia, Japan, South Africa, and the U.S.	PCT/AU2006/000516	WO2006/108243
07/02/2008	Prefilled retractable syringe, plunger, and needle assembly	PCT/AU2008/000971	

** WIPO is the World Intellectual Property Organization.*

Sources: Crystal Research Associates, LLC, Unilife Corp., IP Australia <www.ipaustralia.gov.au>, the World Intellectual Property Organization <www.wipo.int>, and the U.S. Patent and Trademark Office <www.uspto.gov>.

Strategic Relationships

Unilife has leveraged the competitive strength of its patented technology and operational expertise to secure exclusive industry partnerships with global healthcare and pharmaceutical leaders.

Unilife's Six-year Relationship with Sanofi-Aventis for the Unifill™ Syringe

Sanofi-aventis is a world leader within the pharmaceutical industry. It is among the largest purchasers of prefilled syringes in the world, a global leader in vaccines, one of the largest pharmaceutical groups in Europe, and one of the top five pharmaceutical groups in the world. Sanofi-aventis has primary business activities in the development and marketing of injectable drugs across five core therapeutic areas: anti-coagulants (**deep vein thrombosis [DVT]**), the central nervous system (**multiple sclerosis**), metabolic disorders (diabetes), vaccines, and oncology (cancer).

Sanofi-aventis approached Unilife roughly six years ago after conducting a global search of all safety syringe technologies beyond those in the prefilled arena. Sanofi-aventis asked Unilife to create a prefilled safety syringe in a glass barrel that would fit sanofi-aventis' filling system and maintain biocompatibility with target injectable drug products. For five years, Unilife worked to develop this prefilled safety syringe in conjunction with sanofi-aventis. After three years of development, in April 2006, Unilife demonstrated its concept to sanofi-aventis—automatic and user-controlled retraction in the prefilled format—in a glass barrel prototype. In December 2006, this relationship was formalized under a Memorandum of Understanding (MOU) with product design specifications agreed to by both parties in July 2007.

The MOU was signed between Unilife and sanofi-aventis on the basis that sanofi-aventis would provide A$500,000 to Unilife for the development process, and that over the period of the MOU (which was to be for 12 months), Unilife would provide sanofi-aventis with 3,000 prototypes. In addition to the A$500,000 initial payment to Unilife, sanofi-aventis agreed to exclusivity with Unilife. During the MOU, sanofi-aventis decided that in order to move the requirement from a prototype to a plan of production, the partners would need to extend the MOU for an additional six months, indicating to Unilife that sanofi-aventis agreed with the Company's direction at this stage of prototype development.

Exclusive Licensing Agreement

In July 2008, Unilife signed an Exclusive Licensing Agreement with sanofi-aventis, under which sanofi-aventis paid Unilife $13.9 million (€10 million) for the exclusive right to negotiate the purchase of Unifill™ for a period of five years. Unilife is also receiving a further $20.8 million to $23.6 million (€15 million to €17 million) in quarterly milestone payments for the development of production systems to manufacture and supply Unifill™ as part of an Industrialization Agreement (described in greater detail on page 14).

In March 2010, Unilife agreed to a list of therapeutic drug classes within which sanofi-aventis has the exclusive right to purchase the Unifill™ ready-to-fill syringe. Sanofi-aventis secured exclusivity for the Unifill™ syringe within the full therapeutic classes of antithrombotic agents and vaccines until June 30, 2014. These two therapeutic classes together are believed to represent the majority of all prefilled syringes consumed globally. Sanofi-aventis also secured exclusivity in an additional six smaller subgroups that fall within other therapeutic classes that Unilife believes represent new market opportunities in the pharmaceutical use of prefilled syringes.

Under the agreement, sanofi-aventis receives a 10-year extension on its period of exclusivity within a designated therapeutic class if it purchases commercial quantities of the product before July 1, 2014. This extension is reduced on a per therapeutic class basis to five years if sanofi-aventis does not sell a minimum of 20 million units of the Unifill™ syringe for use with an injectable drug product to be marketed in such therapeutic class in at least one of the first five years of the extension period.

During the period of exclusivity, sanofi-aventis may also nominate additional therapeutic subgroups to be placed onto the Exclusivity List if Unilife has not already signed a commercial arrangement within this subgroup with a third party. Before an additional therapeutic class can be added to the Exclusivity List, both parties must be reasonably satisfied that a target drug suitable for use with the Unifill™ syringe is likely to generate a commercial order.

Unilife Retains the Right to Enter into Agreements with Additional Pharmaceutical Companies

The scope of the Exclusivity List allows Unilife to commence formal discussions with other 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. Now that these drug classes are agreed upon with sanofi-aventis, the Company can begin to review the signing of agreements for the supply of Unifill™ to other interested pharmaceutical companies in therapeutic areas not included on the Exclusivity List. The Company hopes to progress or finalize a number of these other Unifill™ agreements during 2010. Table 2 summarizes key terms of Unilife's agreements with sanofi-aventis.

At present, Unilife is aware of more than 20 pharmaceutical companies that supply injectable drugs in a prefilled syringe format (many of which are listed in Tables 8 and 9 [pages 36-37]), and the Company has received interest in its Unifill™ syringe from a number of these companies. The market for prefilled syringes is over $1.5 billion globally and is expected to expand as greater numbers of products are being designed as injections that are suitable for a prefilled syringe format.

Table 2

Unilife Corp.

KEY TERMS OF THE EXCLUSIVE LICENSING AND INDUSTRIALIZATION AGREEMENTS

Period of Exclusivity	Sanofi-aventis has the exclusive right until June 30, 2014, to negotiate for purchase of the Unifill™ Syringe, subject to extensions of up to 10 years for products for which sanofi-aventis has placed orders.
Exclusivity List	Under an Exclusivity List agreed to in March 2010, sanofi-aventis retains the exclusive right to negotiate for the purchase of the Unifill™ Syringe for use with injectable drug products in the full therapeutic classes of antithrombotic agents and vaccines until June 30, 2014. Sanofi-aventis also secured exclusivity in an additional six smaller subgroups that fall within other therapeutic classes. In each therapeutic class, sanofi-aventis receives a 10-year extension on its period of exclusivity if it purchases commercial quantities of the product before July 1, 2014; however, the extension is reduced to five years if sanofi-aventis does not sell a minimum of 20 million units of the syringe for use with an injectable drug product in such therapeutic class in at least one of the first five years of the extension period.
Supply to Other Pharmaceutical Companies	Unilife can enter into agreements with other pharmaceutical companies for use of the Unifill™ Syringe with injectable drug products marketed in Unilife Therapeutic Drug Classes. Sanofi-aventis receives a 5% royalty on revenue generated from these sales to other entities. Royalty payments to sanofi-aventis cease when Unilife's total revenues from these other pharmaceutical companies reaches €340 million.
Therapeutic Exclusivity and Other Pharmaceutical Companies	Unilife may seek an Access Fee from other pharmaceutical companies for the right to negotiate for the purchase of the syringe for use with a Unilife Therapeutic Drug Class. Sanofi-aventis is given 70% of any Access Fees received until the earlier of either €14.286 million in total Access Fee revenue or June 30, 2014. Thereafter, if not already expired, sanofi-aventis is given 30% of the Access Fees generated by Unilife during the remainder of the period of exclusivity.
Supply Agreement	If both parties sign a Supply Agreement before July 1, 2014, sanofi-aventis receives a 10-year extension of its exclusive right to purchase the Unifill™ Syringe for a designated therapeutic class. This extension is reduced to five years if sanofi-aventis does not sell a minimum of 20 million units of the syringe for use with an injectable drug product for this therapeutic class in at least one of the first five years of the Supply Agreement. Each therapeutic class on the exclusivity list is treated separately for this purpose.
Access to Production Capacities	Unilife is not required to commit >30% of its annual production capacity for Unifill™ to sanofi-aventis, thereby allowing adequate capacity for other customers. Sanofi-aventis must order 24 months in advance to receive a greater portion of Unilife's annual capacity.

Source: Unilife Corp.

Industrialization Agreement for the Unifill™ Syringe

On June 30, 2009, Unilife and Sanofi Winthrop Industrie, a wholly owned subsidiary of sanofi-aventis, formally entered into an Industrialization Agreement for commercialization of the Unifill™ Syringe. Unilife received the first quarterly payment under the industrialization program of €1.5 million in October 2008. From October 2008 through March 2010, the Company received milestone payments of €13 million. The industrialization program, which has a total budget of €17 million, is proceeding a year ahead of schedule and is likely to conclude by the end of 2010.

The program is being coordinated by Unilife under its ISO 13485-certified quality management systems. The program includes the finalization of design and biocompatibility testing, noting that although Unilife has already performed biocompatibility testing and has received notification that the materials meet all of the requirements, testing must be performed again under specific conditions in order to apply for regulatory approval. Importantly, Unilife is not responsible for obtaining regulatory approvals for the completed combination drug delivery device; these are under the control of sanofi-aventis. Unilife and sanofi-aventis intend to work in good faith toward the signing of Supply Agreements to specify commercial orders for the Unifill™ Syringe for products targeted for use within retained therapeutic drug areas. When Unilife supplies the prefilled syringes to sanofi-aventis, sanofi-aventis is expected to then fill, package, and deliver these syringes to the marketplace. Thus, Unilife does not incur significant regulatory, marketing, or distribution costs, but only minimal administration and transport costs.

Targeted Production Capacity

The first Unifill™ commercial line is anticipated to have a target production capacity of approximately 60 million units per year, which is a 50% increase over Unilife's forecasted capacity from when the Company initiated the industrialization program in July 2008. A commercial line is scheduled for installation into Unilife's new global production facility at York in late 2010. Subsequently, Unilife and Mikron Group (the Company's supply partner, as overviewed below) expect to develop a high-volume assembly line with a targeted annual production capacity of 150 million units, which could be ready by the end of 2011. Combined, these two assembly lines could manufacture more than 200 million syringes per year.

Under a project plan developed by Unilife, annual production volumes for the Unifill™ Syringe may increase to an excess of approximately 450 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 quicker and more cost-effective rate than was originally envisioned as well as to quickly ramp-up production if market demand exceeds projections. Figure 3 (page 15) depicts Unilife's anticipated future production capacity in relation to total forecasted growth within the prefilled syringe market.

Mikron Group

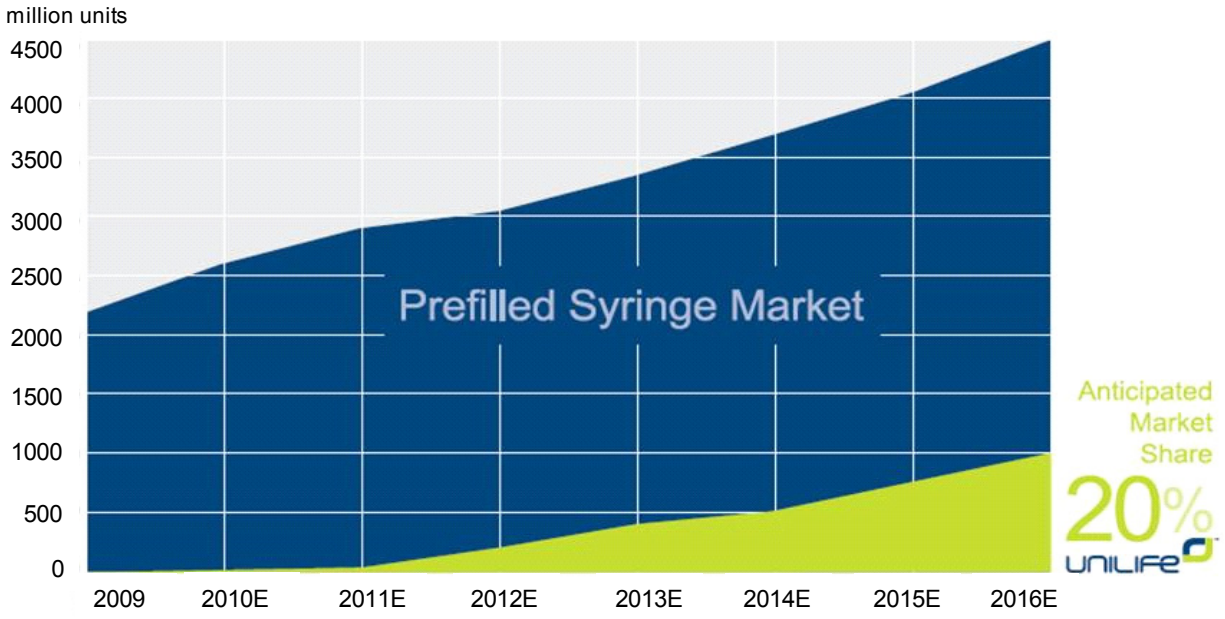
Unilife executed comprehensive due diligence for nearly 12 months to identify an appropriate partner to develop and supply automated assembly systems for commercial manufacturing of the Unifill™ Syringe. In November 2009, Unilife appointed Mikron Group (www.mikron.com) as its contracted supply partner. With 1,000 global staff, Mikron is a Swiss-based global provider of manufacturing technology and assembly automation. Mikron specializes in high-performance assembly and test solutions for the medical device, pharmaceutical, automotive supply, and electronics markets.

The development of the automated assembly system began in December 2009, with completion and installation into Unilife's York, Pennsylvania, manufacturing facility scheduled for the fourth quarter 2010. Proof-of-principle activities that occurred prior to Mikron being engaged 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 line platforms referenced above. Unilife believes that the use of an already proven Mikron assembly system platform has helped to mitigate risks associated with the path toward high-volume commercial production of the Unifill™ Syringe, with it now being more of a scheduled process of replication rather than a complex technical challenge.

Figure 3

Unilife Corp.

UNILIFE'S SCHEDULED ANNUAL PRODUCTION VOLUMES AS A PERCENTAGE OF THE TOTAL PROJECTED GROWTH IN THE PREFILLED SYRINGE MARKET



Note: Prefilled syringe market growth 2009-2012 estimated by Greystone Associates' Prefilled Syringes, May 2009. (Average annual growth trend beyond 2012 continued to 2016.)

Source: Unilife Corp.

Supply Chain Partners

Where possible, Unilife is adopting a minimum dual-source supply for components and related services for the Unifill™ syringe to de-risk its supply-chain. The Company is in the process of negotiating with a number of quality approved suppliers for materials, components, and services. These suppliers for which Unilife is currently in discussions are already established and recognized suppliers within the pharmaceutical market for devices relating to the delivery of injectable drugs and vaccines. Greater information regarding Unilife's dual-source supply strategy is provided in the Company's Form 10 filed with the U.S. Securities and Exchange Commission (SEC) on November 12, 2009.

While Unilife is responsible for producing the majority of its Unitract™ 1mL syringes at its own facility in Lewisberry, Pennsylvania, the Company also has a strategic partnership with China's Shanghai Kindly Enterprise Development Group Co., Ltd ("KDL") for the production of its Unitract™ 1mL syringes in China. This relationship with KDL was primarily utilized for the production of sufficient quantities of stock to support international regulatory applications, initial marketing endeavors, and discussions with interested healthcare and pharmaceutical companies. Unilife may continue to secure Chinese-assembled stock from KDL on a per order basis; however, the majority of its products will likely be manufactured internally at the Company's U.S. facilities. As such, Unilife has a supply relationship with Tessy Plastics, Corp., a New York-based producer of medical device components. Tessy supplies the majority of plastic component requirements for the Unitract™ 1mL syringes to Unilife's facility in Pennsylvania.

Company Leadership

Since the relocation of operational and commercial functions from Australia to the U.S., Unilife has significantly expanded its engineering, quality, and marketing capabilities to support the Company's core projects, such as the Unifill™ Industrialization Program. Unilife has doubled in size since 2008 and has added over 40 managers and professionals. Members of its management team have an average 23 years of experience, which include working with multinational medical device and pharmaceutical leaders, such as Baxter International Inc. (BAX-NYSE), Medtronic, Inc. (MDT-NYSE), Teva Pharmaceutical Industries Ltd (TEVA-NASDAQ), Safety Syringes, Inc., ResMed Inc. (RMD-NYSE), MEDRAD, Inc. (part of Bayer HealthCare), and Boston Scientific Corporation (BSX-NYSE). Additionally, Unilife's vice president of scientific and international affairs, Dr. Gerald Verollet, was previously the head of medical devices responsible for developing global standards for single-use syringes at the WHO. The experience of this team is believed to reflect the type of business that Unilife intends to become and the status of the customers with which it intends to build long-term relationships. The Company is continuing to hire new skilled employees, with the aim of employing nearly 200 people by the end of 2010.

Unilife's corporate leadership team and Board of Directors comprise individuals with extensive global experience in key functions, such as medical device development and commercialization, regulatory affairs, quality control, international development, and Australian and U.S. reporting requirements, among other areas. In addition to the members listed in Table 3, the Company is led by a senior management team that fulfills further manufacturing, engineering, scientific, legal, human resources, technology, finance, supply chain, operations, and product development positions. These individuals have medical device experience that ranges from the start-up stage to global leaders in the healthcare equipment and pharmaceutical markets. Greater details of Unilife's senior management are available at www.unilife.com.

Executive Management

Table 3 summarizes Unilife's key executives, followed by detailed biographies.

Table 3
Unilife Corp.
EXECUTIVE MANAGEMENT

Alan Shortall	Chief Executive Officer and Director
Daniel Calvert, CMA, MBA, M.S.	Chief Financial Officer
Eugene Shortall	Senior Vice President of RTFS
Bernhard Opitz, M.S.	Senior Vice President of Operations
Mark Iampietro	Vice President of Quality and Regulatory Affairs
Stephen Allan	Vice President of Marketing and Communications
Tim Spang, B.Sc., MBA	Vice President of Manufacturing and Supply Chain
Dave Watson, MSME	Vice President of Engineering
Cynthia Lighty, J.D.	Director of Human Resources and Legal Services
Mark Hassett	Director of Sales and Marketing
Gerald Verollet, Ph.D.	Vice President of Scientific and International Affairs
Tom Westbye	Director of Product Development

Source: Unilife Corp.

Alan Shortall, Chief Executive Officer (CEO) and Director

Mr. Shortall has served as CEO and director of Unilife Medical Solutions Ltd. (UMSL) since September 2002 and of Unilife Corp. since its incorporation in July 2009. He is an experienced entrepreneur who co-founded Unilife in July 2002 and has guided the growth and international development of the Company since then. Mr. Shortall operates in partnership with the Board and is responsible for the executive management team, with responsibility for the effective leadership and business development of Unilife worldwide. Mr. Shortall has a solid understanding of the characteristics and advantages of the Company's products as well as substantial marketing and commercial experience. In 2008, the trade magazine *Medical Device and Diagnostic Industry (MD&DI)* named him as one of 100 Notable People in the worldwide medical device industry. Mr. Shortall has recently relocated from Sydney, Australia, to Pennsylvania to support the continued global expansion of Unilife.

Daniel Calvert, CMA, MBA, M.S., Chief Financial Officer (CFO)

Mr. Calvert has served as CFO of UMSL since December 2008 and of Unilife Corp. since July 2009. He is experienced in SEC reporting requirements for publicly listed companies, Sarbanes-Oxley compliance, merger and acquisition activities, investor relations, and tax planning. He has over 25 years of financial, strategic, and operational management experience in diversified national and international companies. From September 2006 to November 2008, Mr. Calvert served as executive vice president and chief accounting officer of Standard Management Corp. (SMAN-OTC.PK), a national institutional pharmacy and home healthcare company. From May 2004 to March 2006, he was the CFO of MBT International Inc., a division of a publicly held company. Mr. Calvert is a certified management accountant (CMA), holds an MBA in finance from Michigan State University, and received an M.S. in taxation from the University of Baltimore.

Eugene Shortall, Senior Vice President of RTFS

Mr. Shortall has served as the senior vice president of the ready-to-fill syringe ([RTFS] the Unifill™ Syringe) of UMSL since February 2009 and of Unilife Corp. since November 2009. He is responsible for the development and implementation of the Industrialization Program for the Unifill™ RTFS. From October 2007 to February 2009, he served as Unilife's RTFS project director. Mr. Shortall is an experienced manager for major construction projects in Europe and the Middle East. From June 2003 to October 2007, he was a consultant for the Public Institute for Social Security in Kuwait and previously served as a consultant for Behbehani National Construction. Specifically, in Kuwait, he has had a key role in the rebuilding of more than a dozen major government and private facilities following the liberation of the country in 1991. Mr. Shortall is the brother of Mr. Alan Shortall, the Company's CEO and director.

Bernhard Opitz, M.S., Senior Vice President of Operations

Mr. Opitz has served as senior vice president of operations of UMSL since December 2008 and of Unilife Corp. since November 2009. Mr. Opitz has almost 30 years of medical device and biotechnology experience and has held senior leadership positions with global industry leaders, including Bayer AG (BAYRY-OTC). His core specialties include device innovation and productivity improvement initiatives. From August 2007 to June 2008, Mr. Opitz served as vice president, manufacturing at Nanosphere, Inc. (NSPH-NASDAQ). From December 2002 to July 2006, he was the vice president, engineering/operations at Wells' Dairy, Inc., a large manufacturer of ice cream. From September 2000 to April 2002, he was senior vice president of operations at Ikonisys, Inc., a cell-based diagnostics company. From 1980 to 2000, Mr. Opitz held various positions at Bayer, including project engineer, manager of plant engineering, manager of engineering, production manager, vice president of operations, and senior vice president of engineering. While at Bayer, he was responsible for capital investment programs valued at up to $1 billion a year, the launch of several major new products, the management of operations and global engineering divisions employing more than 2,000 staff, and the design, construction, and on-time start-up of a $60 million greenfield production facility in re-unified Germany. Mr. Opitz holds an M.S. in mechanical/process engineering from Technical University Graz in Austria.

Mark Iampietro, Vice President of Quality and Regulatory Affairs

Mr. Iampietro has served as vice president of quality and regulatory affairs of UMSL since October 2008 and of Unilife Corp. since November 2009. He has more than 30 years of quality experience across global pharmaceutical, biologics, and medical device markets. Mr. Iampietro has extensive experience building quality systems to FDA and CE Mark (Europe) standards as well as other specific skills sets such as quality assurance, statistical analysis, stability programming, and total quality systems. He has successfully launched two ISO 9000/13485 quality programs and implemented quality programs for new operations leading to pre-approval inspections, with no observations by the FDA. 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. Previously, Mr. Iampietro has held senior quality and regulatory positions at Cynosure, Inc. (CYNO-NASDAQ), MedChem Products, a division of C.R. Bard, Inc. (BCR-NYSE), Summit Technology Inc., and Tambrands Inc. Mr. Iampietro holds American Society for Quality (ASQ) certifications as both a quality and reliability engineer and holds a B.S. in life sciences with a minor in engineering from Worcester Polytechnic Institute.

Stephen Allan, Vice President of Marketing and Communications

Mr. Allan has served as vice president of marketing and communications of UMSL since October 2008 and of Unilife Corp. since November 2009. He served as the Company's director of communications from November 2007 to October 2008 and as manager of communications from July 2002 to November 2007. Mr. Allan has more than 15 years of media, government, and public relations experience and is responsible for all communications, public relations, and public affairs activities undertaken by the Company on a global level. Prior to joining Unilife, he 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. Mr. Allan also spent five years as a journalist for various Sydney-based newspaper groups. He holds a Bachelor's of Communications from Charles Sturt University.

Tim Spang, B.Sc., MBA, Vice President of Manufacturing and Supply Chain

Mr. Spang is an experienced leader in international business and product development. His expertise is in operations excellence with over 17 years of progressive experience in high-tech manufacturing across both Europe and the U.S. for medical devices and related industries. He was previously with MEDRAD, where he was executive director of new product development. Other prior roles have included director of global operations for Ariba, Inc. (ARBA-NASDAQ) and managing director-Europe for the JPM Company. He has expertise and experience in successfully building and directing LEAN manufacturing, using Six Sigma to drive process improvement, demand flow manufacturing, and e-sourcing operations globally. Mr. Spang has lived and worked in Germany, Belgium, Czech Republic, and Pennsylvania (U.S.).

Dave Watson, MSME, Vice President of Engineering

Mr. Watson is a senior level manager with almost 30 years of engineering experience with multinational information technology (IT) and life science industry leaders, including Biotronik, Inc., Fujitsu Ltd. (6702-TSE), and International Business Machines Corp. (IBM-NYSE). He has expertise in business LEAN, with the distinction of changing manufacturing into profitable best-in-class operations. At Biotronik, as director of manufacturing and director of advanced manufacturing technology, he developed and put in place new technologies and automated high-volume lines to produce Class III implantable medical devices. At Fujitsu, as director of engineering, he introduced laptop computers to the U.S. market that were manufactured in the U.S. At IBM for 15 years, Mr. Watson held many technical and senior management positions, including strategist at IBM Technology Products Division headquarters where he developed plans and corporate development budgets for the $11 billion division. Mr. Watson has patents in the fields of automated equipment and technology products. He has an MSME from the University of Texas and a BSME from California Polytechnic State University in California. At Unilife, Mr. Watson is responsible for the introduction of new products, technologies, and automation into production, as well as enhancing the efficiency of current operational activities.

Cynthia Lighty, J.D., Director of Human Resources and Legal Services

Ms. Lighty has 23 years of experience as a practicing attorney as well as managing human resource departments with large organizations. Her specialty is litigation, labor, and employment law. Between 1991 and 2008, she held a number of roles with Hershey Company (HSY-NYSE) institutions, including assistant senior counsel, manager of training and policy in the Hershey Law Department; manager of employee relations at Hershey's largest manufacturing facility, and director of employee and labor relations at the Milton Hershey School. The institution is the largest private K-12 school in the U.S. At Hershey, she managed a department that provided a number of services, such as labor relations, employee services, organizational development and training, security, employee safety, health services, and traditional personnel functions to 2,000 employees. Ms. Lighty also has extensive experience in litigation management, a broad range of corporate legal issues, outside counsel management, preventive law, compliance, and compliance training. She graduated from Franklin and Marshall College in Pennsylvania, *cum laude*, Phi Beta Kappa, in 1983 and from the University of Pennsylvania Law School in Philadelphia, *cum laude* in 1986.

Mark Hassett, Director of Sales and Marketing

Mr. Hassett has more than 25 years of experience in the sales and marketing of medical device and pharmaceutical products that entail the acute care, alternate site, pharmaceutical, and biotechnology markets. He also has significant experience coordinating the development of strategic business partnerships with multinational healthcare, pharmaceutical, and IT companies. Prior to joining Unilife, Mr. Hassett coordinated the licensing of a next-generation auto-injector device to a leading pharmaceutical company. Between 2004 and 2008, he was the executive vice president of sales, marketing, and business development at California-based Safety Syringes, Inc. At Safety Syringes, he led major account development activities and managed key account relationships with more than 12 large pharmaceutical companies in the U.S., Europe, and Asia-Pacific. Between 1990 and 1999, he served as vice president of sales and marketing for three start-up medical device companies: Venetec International, Inc. (now a subsidiary of C.R. Bard, Inc.), Medication Delivery Devices, and Block Medical Inc. (purchased by Hillenbrand Industries Inc.), all based in Southern California. At these companies, he increased medical device product sales and established new account relationships with large suppliers within the acute care and alternative care markets. Mr. Hassett has a B.S. in communications from Georgia State University.

Gerald Verollet, Ph.D., Vice President of Scientific and International Affairs

Dr. Verollet is the former head of the WHO's medical device division. In this position, he had a key role in the development of the injection safety policies and international regulations now adopted by international non-governmental organizations (NGOs) as well as national government agencies. He was responsible for the creation and adoption of new International Organization for Standardization (ISO) standards for **auto-disable** syringes. Dr. Verollet also helped create an alliance with the World Bank for worldwide access to safe injection technologies. He established relations with NGOs, such as the United Nations Children's Fund (UNICEF), and worked closely with nations, including China, on the successful implementation of healthcare projects. Prior to joining the WHO, his medical device expertise encompassed almost 20 years of experience in the health industry, ranging from sales to international marketing management. Dr. Verollet was previously medical device product manager at the international European headquarters of Johnson & Johnson (JNJ-NYSE) and later at Nycomed International Management GmbH. His decision in 2003 to join the Company as vice president of scientific and international affairs was made to attain the same injection safety policies that he developed during his career at the WHO.

Tom Westbye, Director of Product Development

Mr. Westbye has more than 30 years of executive experience in all aspects of medical device manufacturing. Between 2000 and 2009, he was vice president of product development and then vice president of technology integration at Safety Syringes. In roles at Safety Syringes, he led dedicated design teams to develop current leading passive safety devices used in prefilled glass syringes, co-developed the first re-usable auto-injector, and managed the development of product-specific automation for a number of major pharmaceutical companies. During this time, he lodged a significant number of patents covering passive safety devices, tamper-evident devices, reconstitution devices, and dental safety syringes. Prior to his time at Safety Syringes, Mr. Westbye worked with an eye care solutions company managing the construction and validation of a major new production facility and obtaining FDA approval of several products. He was also director of manufacturing support for a San Diego-based infusion therapy device manufacturer in managing the development, selection, and procurement of molding, product mixing, and Water for Injection (WFI) process equipment. Mr. Westbye has a B.S. in polymer engineering from Chalmers University in Sweden.

Board of Directors

The Board of Directors oversees the conduct of and supervises the Company's management. Table 4 provides a summary of Board members, followed by detailed biographies.

Table 4
Unilife Corp.
BOARD OF DIRECTORS

Jim Bosnjak, OAM	Chairman and Director
Alan Shortall	Director and Chief Executive Officer
John Lund, CPA	Director
William Galle	Director
Jeff Carter, M.App.Fin.	Director

Source: Unilife Corp.

Jim Bosnjak, OAM, Chairman

Mr. Bosnjak has served as a director of UMSL since February 2003 and of Unilife Corp. since November 2009 and as chairman of the Board of UMSL since April 2006 and of Unilife Corp. since November 2009. Since 2002, he has been a co-owner and director of the Le Meridian Lav Hotel in Split, Croatia, a $150 million resort and casino that opened in 2007 and was named Europe's Leading Conference Hotel in 2008, and is presently chairman and co-founder of Ultimate Outdoor Ltd., an Australian outdoor advertising company. Mr. Bosnjak was a director of Westbus Pty Ltd. from 1975 to 2001 and the chairman of Westbus between 1990 and 2001. He has also held positions on Commonwealth and New South Wales advisory bodies, including the Greater Western Sydney Economic Development Board and the GROW Employment Council. Mr. Bosnjak further served as the chairman of the Tourism Council of Australia and Bus 2000, which coordinated bus services for the Sydney 2000 Olympic Games. Mr. Bosnjak holds an honorary doctorate from the University of Western Sydney for his services related to employment growth and economic development, and has been awarded the Medal of the Order of Australia for his services to road transport and the community and an Order of Merit from the New South Wales Olympic Council.

Alan Shortall, Director and CEO

Biography provided on page 17.

John Lund, CPA, Director

Mr. Lund has served as a director of UMSL and Unilife Corp. since November 2009. He has also served as managing partner of M&A Holdings, LLC, a closely held 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 was vice president and controller of Nexstar Broadcasting Group, Inc. (NXST-NASDAQ) from March 2008 to November 2008, vice president of finance and corporate controller of LQ Management, LLC (which owns the La Quinta hotel brand) from November 2006 to March 2008, and corporate controller of ExcellerateHRO Corp. (the human resources outsourcing business of Hewlett-Packard Co. [HPQ-NYSE]) from January 2005 to October 2006. Prior to that, Mr. Lund held controller and CFO positions for various companies and was a manager at KPMG LLP.

William Galle, Director

Mr. Galle has served as a director of UMSL since June 2008 and of Unilife Corp. since November 2009. He has also served as the managing director of American Marketing Complex, a New York City-based group that implements balance sheet enhancement strategies and develops strategic business plans for public and private companies, since October 2007 and as president of Diversified Portfolio Strategies LLC in Washington, D.C. since 1993. Diversified Portfolio Strategies 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, M.App.Fin., Director

Mr. Carter has served as a director of UMSL since April 2006 and of Unilife Corp. since November 2009. From February 2005 until December 2008, he served as CFO of UMSL. He has also served as company secretary since March 2007. From March 2003 to November 2004, Mr. Carter was the CFO and company secretary of the former Ambri Ltd. (currently Diversa Ltd. [DVA-ASX]). He is a chartered accountant with more than 25 years of experience in financial and senior management roles in both Australia and the U.S. and he holds a Master's degree in applied finance from Macquarie University of Sydney.

Core Story

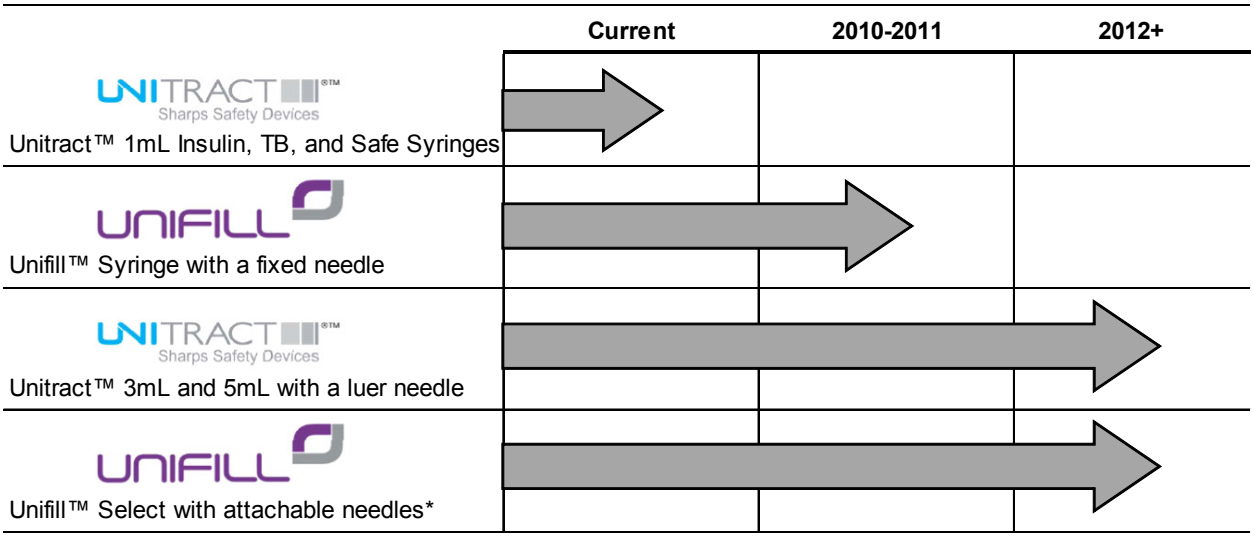
Unilife Corp. ("Unilife" or "the Company") is working to commercialize a proprietary range of innovative retractable syringes that incorporate automatic and fully integrated safety features. The Company has designed and incorporated safety features that it believes can protect people from needlestick injuries and other unsafe injection practices. To Unilife's knowledge, it is the only company developing a portfolio of prefilled and clinical syringes that share the same technology platform for automatic, integrated safety features. This characteristic may provide Unilife with a competitive advantage since healthcare facilities prefer to employ standardized, routine procedures; thus, the Company believes that its core technology could become a new standard for safety syringes.

Unilife's lead product is the Unifill™ prefilled or ready-to-fill syringe (RTFS). Unifill™ syringes are designed for supply to pharmaceutical manufacturers where they can be filled with the manufacturer's injectable pharmaceutical products before being distributed to the end users. The Unifill™ Syringe has been optimized for use with medications that require subcutaneous (under the skin) injections. Under an industrialization program funded by sanofi-aventis, Unilife expects to commence production and supply of the Unifill™ Syringe in late 2010. The Company has recently begun developing a Unifill™ Select syringe as well, which is an RTFS with integrated safety features but is suited for use with vaccines or other products that require injection intramuscularly (into the muscle).

In addition to the prefilled Unifill™ and Unifill™ Select syringes, Unilife has created a line of clinical syringes branded Unitract™. The Company's Unitract™ 1mL syringes are designed primarily for use in healthcare facilities and by patients who self-administer prescription medication, such as insulin. Unilife began production of a Unitract™ 1mL Insulin Syringe in August 2009 and expects to release this product commercially during the first half of 2010. Additional Unitract™ pipeline products include 1mL Tuberculin (TB) and Safe Syringes and 3mL and 5mL syringes for intramuscular injections.

Figure 4 summarizes Unilife's product portfolio, followed by a description of the safety syringe market on pages 23-30. The Company seeks to capitalize on an expanding global market for sharps safety devices fueled by government legislation mandating the use of these products. An overview of Unilife's core technology platform is provided on pages 31-33, accompanied by greater details of the Unifill™ and Unitract™ brands on pages 34-45 and the Company's U.S. manufacturing facilities on pages 46-48.

Figure 4
Unilife Corp.
UNILIFE'S SAFETY SYRINGES



* Development is subject to the completion of a strategic agreement with an interested pharmaceutical company.

Source: Unilife Corp.

Industry Overview

Globally, it is estimated that as many as 35 billion syringes are used annually (half of which are used in developed healthcare markets, such as North America, Europe, Japan, and Australia), which is believed to represent a $4 billion to $5 billion market (Source: International Association of Safe Injection Technology). In the U.S. alone, approximately six billion syringes are thought to be used each year. The greatest consumers of syringes are healthcare facilities. As well, patients who self-administer medication (e.g., insulin), government agencies that sponsor harm reduction (needle exchange) programs, and non-government organizations conducting vaccination programs also represent considerable volumes.

The syringe market contains a variety of products. These include the traditional needle and syringe design, which has no mechanism to prevent the needle's reuse or shield to protect the needle from pricking people after it has been used, as well as newer safety sharps that are rendered unusable after a single injection and/or that have safety features designed to protect users from accidental needlestick injuries.

Prefilled syringes are now a preferred drug delivery format for at least 50 injectable medicines and vaccines—a number that is expected to grow considerably going forward. Prefilled syringes are filled with a measured dose of injectable medication by the pharmaceutical company. The completed drug delivery device is then packaged for shipment to end users, such as patients who self-administer prescribed treatments at home and healthcare personnel.

At present, it is estimated that 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, prefilled syringes are also now commonly supplied with an ancillary needlestick prevention feature. The prefilled syringe market and the limitations of the current generation of safety features available for these syringes are addressed in greater detail on pages 35-38.

The Risks of Injections Having Little to No Safety Mechanism

The Unsafe Reuse of "Dirty" Needles

The World Health Organization (WHO) estimates that over 1.3 million people die each year as a result of unsafe injection practices. While in countries such as the U.S., safe immunization processes are well established, the majority of developing countries cannot afford an adequate amount of needles, especially the more modern and costly needles that prevent reuse. As a result, healthcare workers in these areas reuse unsterilized syringes to immunize local populations, resulting in considerable problems where vaccines and other treatments are administered with dirty needles.

Likewise, many disposable syringes are also being reused and shared by injecting drug users (IDUs). The reuse and sharing of standard syringes is a prime accelerant in HIV and hepatitis C epidemics worldwide, accounting for roughly one-third of new HIV infections globally outside of sub-Saharan Africa. The issue is not restricted to developing or transitional countries. In the U.S., approximately 12% of the IDU population is HIV-positive with the majority also having hepatitis C, according to the CDC. The supply of cost-efficient safety sharps that do not require skilled administration and do not permit reuse could help improve the safety of injections in developing countries and among IDUs, thereby also helping to reduce disease transmission.

Needlestick Injuries

Needlestick wounds entail any accidental punctures by exposed needles or other like sharps that result in contact with blood or other bodily fluids. These injuries are not limited to nurses and physicians. They include injuries to cleaning staff, housekeeping, emergency medical services (EMS)/paramedics, law enforcement officials, correctional officers, and firefighters. Even the disposal of non-sterile standard syringes by IDUs and patients who self-administer prescribed medication at home can place garbage personnel and other members of the community at risk for a needlestick injury. The smallest needle prick that contacts bodily fluid carries the risk of transmitting dangerous infectious diseases.

The conventional syringe design leaves patients, practitioners, and the general population prone to accidental needlestick injuries. Worldwide, the WHO estimates that three million healthcare workers (10%) are exposed to bloodborne pathogens annually due to needlestick injuries. In the U.S., between 600,000 and 800,000 needlestick and other similar injuries are reported annually among healthcare workers (Source: Johns Hopkins). Over one million needlestick injuries are estimated to occur in Europe each year (Source: the EU's Employment and Social Affairs Committee). Moreover, the actual incidence of sharps injuries is believed to be higher, as these numbers may not include injuries at non-hospital institutions, such as home healthcare, long-term care, and private practice. As well, the CDC estimates that up to 50% of healthcare personnel do not report occupational **percutaneous** wounds.

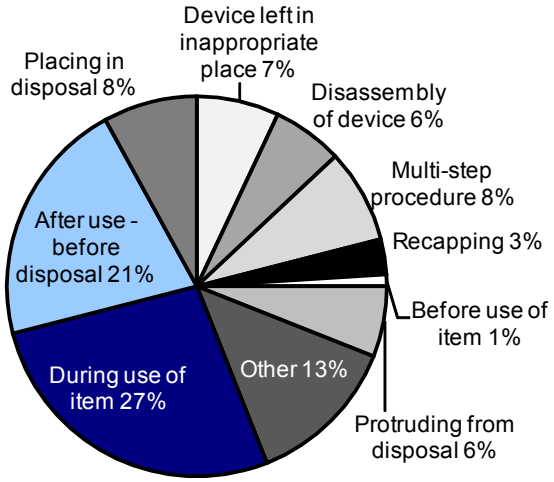
In a study of medical students/interns at 17 medical centers, researchers from Johns Hopkins found that nearly 60% of respondents had sustained one or more needlestick injuries as a medical student. Many had been stuck more than once. Of those residents whose most recent needlestick injury was during medical school, 47% did not report the incident (Source: *Academic Medicine* December 2009).

The majority of sharps injuries occur when individuals are performing five general activities: (1) needle disposal; (2) administering injections; (3) drawing blood; (4) recapping needles; and (5) handling trash and dirty linens. While sharps injuries can occur at any time, preventing these five types of wounds could lower the rate of injuries materially. To this extent, recapping needles in the U.S. is now against the law (except under very rare conditions). The left side of Figure 5 highlights the times when needlesticks are most likely to occur. The right side of Figure 5 lists some of the infections that have been transmitted via sharps injuries. The most common pathogens contracted by individuals who have been accidentally stuck with an exposed sharp are hepatitis B, hepatitis C, and HIV, although it is possible to transmit more than 20 known infections through unsafe injection practices.

Figure 5

NEEDLESTICK INJURIES

Most Common Instances When Needlesticks Occur



Infections Transmitted Via Sharps Injuries During Patient Care and/or Laboratory/Autopsy

- Blastomycosis
- Cryptococossis
- Diphtheria
- Ebola
- Gonorrhea
- Hepatitis B
- Hepatitis C
- HIV
- Herpes
- Leptospirosis
- Malaria
- *M. tuberculosis*
- Rocky Mountain spotted fever
- Scrub typhus
- *Strep. pyogenes*
- Syphilis
- Toxoplasmosis

Sources: Greystone Associates' Retractable Safety Syringes 2007 and the CDC 2004.

The direct costs associated with treating needlestick injuries can range from $500 to $3,000 or more per patient, depending on the treatment required (Source: CDC). There are also non-monetary impacts that are harder to quantify, such as the emotional burdens of fear and anxiety that result from worrying about disease exposure, the social stigma associated with contracting one of these infectious pathogens, lost time from work, and litigation expenses. In the U.S., these injuries remain one of the main occupational concerns of healthcare workers and are a key issue in the employment and retention of staff.

At times, the cost of testing and treating employees exposed to bloodborne pathogens may exceed the annual cost of procuring safety syringes. Consequently, organizations that recognize this incongruity may be willing to pay higher costs for medical supplies that emphasize safety and reduce or eliminate needlestick injuries to potentially minimize overall costs (Source: Greystone Associates' *Retractable Safety Syringes* January 2007).

Needle Phobias and Patient Anxieties

While many patients dislike needles—with reactions including anxiety, fear, and avoidance—between 7% and 22% of the general population has an injection phobia that makes injectable treatments difficult or impossible (Source: the *Journal of Neuroscience Nursing* 2006). Phobias and needle anxiety are more common in pediatric patients and those individuals whose therapy requires frequent shots.

A report of the American Association of Diabetes Educators (AADE) released in August 2008 found that 20% of diabetic patients surveyed had skipped insulin injections and 43% of individuals had altered their eating schedules in order to avoid injections (Source: *Injection Impact Report* 2008). For this patient population, noncompliance to insulin injections can lead to severe and costly complications, including heart disease, blindness, renal failure, and hypertension (high blood pressure), among many other conditions. As a result, the provision of a safety syringe with the capability to minimize patient discomfort, such as that enabled by Unilife's technology, may benefit this injection-averse patient population. It is important to note that patient comfort with Unilife's retraction system is relative to other spring-fired non-controlled retractable syringes, not standard syringes.

Global Transition to Safety Medical Devices

Beginning in the 1990s, pharmaceutical and medical device companies began incorporating safety mechanisms onto syringes. This trend has accelerated in the past decade across many healthcare markets, such as the U.S., the EU, Canada, and Australia, in response to the passage of legislation mandating the use of safety syringes.

U.S. Regulation

With the passage of the Needlestick Safety and Prevention Act in 2000, the U.S. was the first country to adopt and actively enforce legislation requiring healthcare facilities to use safety syringes. Prior to the passage of this act, in 1992, the U.S. Occupational Safety and Health Administration (OSHA) had implemented a Bloodborne Pathogens Standard (BPS) designed to protect employees at hospitals, funeral homes, nursing homes, clinics, and research laboratories, as well as law enforcement and emergency responder personnel from the occupational transmission of bloodborne pathogens. However, following the implementation of the BPS in the 1990s, exposure to bloodborne pathogens from accidental sharps injuries in healthcare and other job settings continued to be a pervasive risk (Source: OSHA).

In 1999, California was the first U.S. state to place more stringent requirements on employers to protect healthcare workers by preventing needlestick injuries. Following pressure from U.S. healthcare groups, such as the American Nurses Association, to replicate the California legislation on a national scale, the U.S. Congress signed the Needlestick Safety and Prevention Act into law in November 2000 as an update and improvement of the BPS. In 2003, the legislation was modified further by the Medicare Modernization Act, which stipulated that hospitals that were not previously covered by the federal OSHA act, such as public hospitals in states without an OSHA-approved state plan, were now also required to comply with the BPS. To comply with the BPS, healthcare facilities are required to establish sharps safety committees, evaluate new products annually, and report needlestick injuries, among other aspects.

Through the Needlestick Safety and Prevention Act, the revision of the BPS, and subsequent interpretations, OSHA has defined safety-engineered sharp devices as either a non-needle sharp or a needle device that is used to withdraw bodily fluids, access a vein or artery, or administer medications/fluids and that includes a built-in safety feature or mechanism to effectively minimize the risk of exposure. In addition to standards already in place, new legislation incorporates four requirements to reduce the occupational transmission of bloodborne pathogens (as summarized below and on page 26).

(1) Wherever possible, utilize safer devices (e.g., retractable needles) that have engineered safety characteristics;

(2) Maintain an updated exposure control log that adapts to changes in technology to minimize exposure to bloodborne pathogens, and that documents the annual consideration and use of commercially available and safer medical devices;

(3) Retain a detailed sharps injury log, including the type and brand of the device involved, the department or work area of the incident, and an explanation of the incident itself; and

(4) Involve non-managerial employees—those who are responsible for direct patient care and are at risk for contaminated needlestick injuries—in the implementation, selection, and evaluation of safety devices.

While the law does not provide a formal list of approved or endorsed products, in a "Hospital eTool," OSHA makes reference to the use of safety needle devices with passive and integrated safety features. The agency defines passive safety features as those remaining in effect before, during, and after use, and elaborates that an integrated safety design is one that is constructed as an integral part of the device and cannot be removed. In contrast, accessory safety devices are external to the device and must be temporarily or permanently fixed to the point of use. As accessory devices depend on operator compliance, OSHA notes that the integrated design feature is usually preferred. Furthermore, the agency recommends the use of certain safety device selection criteria, as developed by the U.S. Food and Drug Administration (FDA) and summarized in Table 5.

Table 5

SAFETY DEVICE SELECTION CRITERIA AS RECOMMENDED BY THE FDA

- Provide a barrier between the hands and the needle after use, as the safety feature should allow or require the worker's hands to remain behind the needle at all times
- Be an integral part of the device and not an accessory
- Be in effect before disassembly (passive) and remain in effect after disposal to protect users and trash handlers as well as for environmental safety
- Be as simple as possible, requiring little or no training to use effectively

Source: OSHA's Hospital eTool.

By not mandating specific sharps brands, the U.S. places the responsibility with employers to determine which engineering controls are appropriate for specific hazards presented by the medical procedures being conducted, what is feasible, and what is commercially available. The reason for this broad standard is that OSHA is not concerned with cost but rather with what provides the safest device for healthcare workers, particularly because it has been determined in the past that most needlestick injuries result from unsafe needle devices rather than carelessness by healthcare workers (Source: OSHA).

Worldwide Regulation

Organized healthcare worker unions in several European countries—including France, England, Germany, and Italy—seek to make safety a higher priority in hospitals and government agencies through the use of safer medical devices. To this effect, 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. The measure allows member states to continue to adopt additional measures as well. Moreover, several areas in Asia and Africa are considering the use of safety syringes and other safety sharps products to minimize the transmission of bloodborne diseases in their communities.

Enforcing Compliance with Sharps Safety Legislation

In many countries, including the U.S., healthcare facilities are required to conduct annual evaluations of new sharps safety products to assess which devices are best positioned to deliver a safe working environment. Healthcare facilities that select sharps safety products on the basis of price rather than employee protection place themselves at risk for fines or litigation. Unilife believes that this regulatory pressure is likely to bode well for its technology, which entails fully integrated and automatic safety features.

OSHA enforces U.S. standards through monetary penalties for infractions. Fines are issued based on the severity of the situation (how likely the violation is to result in serious harm to employees) and whether or not the incident is isolated. OSHA has taken action against a number of U.S. healthcare facilities and other entities for noncompliance with the BPS. One in every five healthcare facilities to receive an OSHA hospital inspection between 2002 and 2007 was cited for noncompliance with the use of safety engineering controls (sharps safety devices). The total number of BPS citations for noncompliance in the use of safety devices went from 77 in 2001 to 270 in 2007. OSHA's citations demonstrate the organization's seriousness in seeking full compliance with the requirement to use safety-engineered medical devices and its willingness to impose fines when these devices are not implemented facility-wide.

Example of an OSHA Violation

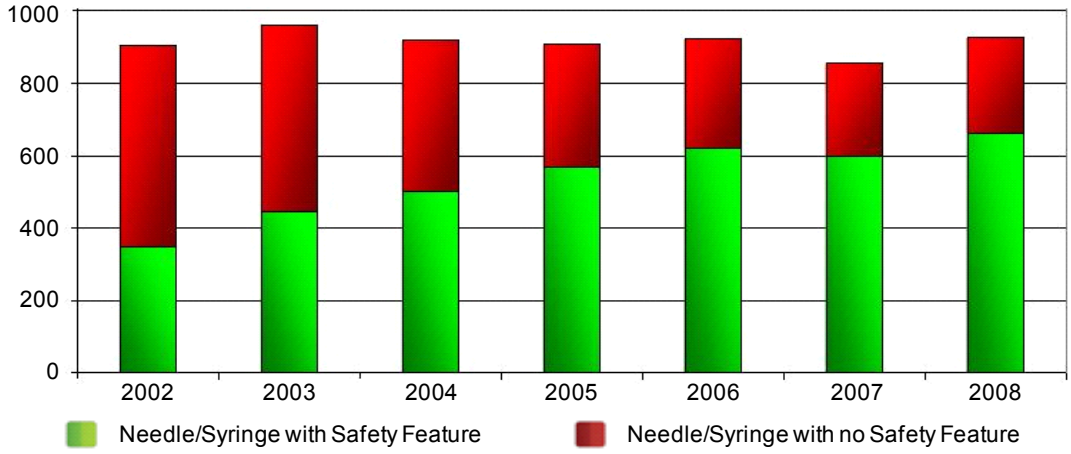
In 2008, the California Division of Occupational Safety and Health (Cal/OSHA) was alerted to the sale in California and nationwide of prefilled syringes with fixed needles containing a seasonal influenza vaccine, Fluvirin® manufactured by Novartis AG (NVS-NYSE). The needles did not have engineered sharps injury protection and were not able to be removed and replaced with safety needle products that had sheaths or shields. Cal/OSHA standards require needles used by healthcare workers who administer flu vaccinations to have built-in anti-stick protection, unless there is no acceptable alternative available on the market. In response, Novartis replaced the fixed needle syringes provided to public health departments in California and offered replacement Fluvirin® products to its direct customers; contacted its distributors and provided replacement products for their customers; provided Cal/OSHA with a list of distributors so that Cal/OSHA could make direct contact with them to provide information to their customers; and obtained "add-on" safety devices that could be attached to the fixed needle syringe prior to administering the vaccine. In California, these "add-on" devices can only be used if there is no acceptable needleless or engineered sharps injury protection device available, including vaccine products from other manufacturers.

TARGET MARKETS AWAIT PREMIUM PRODUCTS

Even with the introduction and enforcement of U.S. legislation, the current generation of safety syringes continues to leave many healthcare workers at risk of acquiring a bloodborne disease from a needlestick injury. Although laws are in place mandating the use of safety syringes, reported needlestick injuries are relatively stable and, in some cases, are on the rise. Unilife believes that 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. In many ways, these devices may instead put workers at increased risk. Figure 6 illustrates data from the Massachusetts Sharps Injury Surveillance System suggesting that existing safety syringes have not yet solved the issue of needlestick injuries.

Figure 6

REPORTED NEEDLESTICK INJURIES IN MASSACHUSETTS HEALTHCARE FACILITIES WITH SAFETY VERSUS STANDARD (NON-SAFETY) SYRINGES



Sharps injuries among hospital workers in Massachusetts 2002-2008 reports.

Source: Massachusetts Sharps Injury Surveillance System, Massachusetts Department of Public Health.

One key reason for the continued risk is that many current safety syringe products require healthcare workers to undertake a secondary action to engage the safety mechanism. Numerous needlestick injuries involving the present generation of safety syringes occur after use but prior to disposal, indicating that existing safety mechanisms are either being activated incorrectly or not at all. To this effect, the Premier Safety Institute (a provider of safety resources and tools that promote a safe healthcare delivery environment) has noted that, in hospitals having adopted safety devices, continued needlestick injuries are often due to non-activation of the safety mechanism. Thus, many hospitals are influenced to select products that have passive safety features integral to the device, as is recommended by the FDA and OSHA (Source: Premier Safety Institute).

Further, other existing types of safety syringes with a spring-fired (non-controllable) retraction mechanism may leave healthcare workers to retract the needle after it has been removed from the body in order to minimize patient discomfort. In addition to the continued risk of needlestick injury, this may also create a risk of infection from a bloodborne disease via aerosol (blood splatter) (Source: Emergency Care Research Institute [ECRI Institute] www.ecri.org).

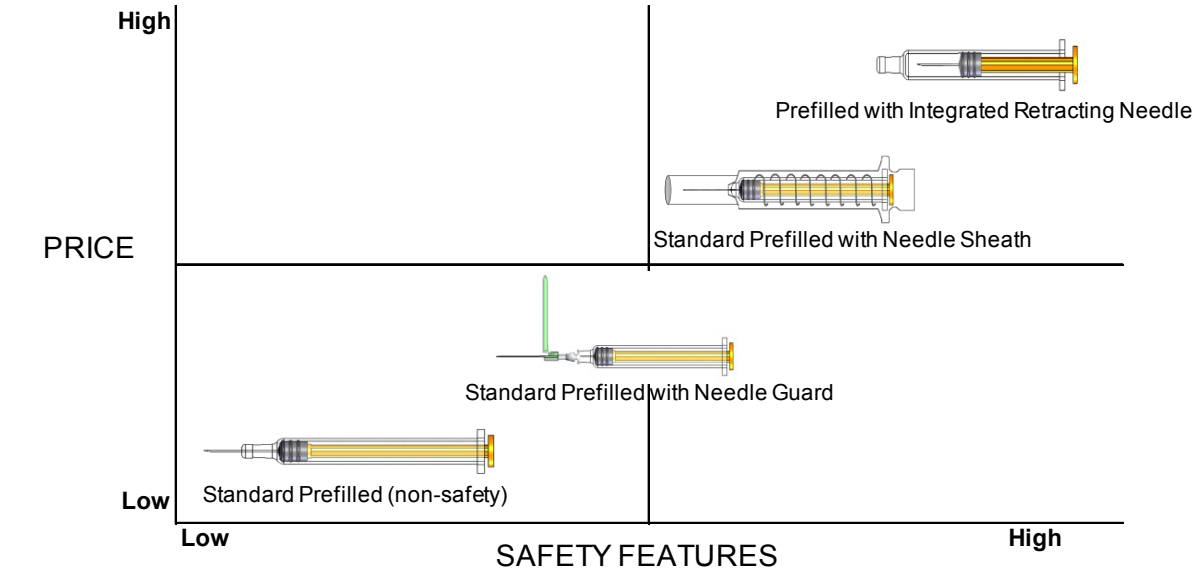
Current Types of Safety Syringes

There are several types of safety syringes currently in use, including those accompanied by a type of needlestick protection device, auto-disable (non-reuse) syringes, and retractable syringes. Excluding the cost of medication, a manually disabled safety syringe can range from $0.14 to $0.31 per injection and retractable safety syringes can cost $0.30 to $0.50 per injection versus a traditional disposable syringe, which is estimated at $0.05 to $0.18 each (Source: Greystone Associates' *Prefilled Syringes* 2008).

Prefilled syringes are often supplied with an ancillary clip-on safety device as well. Unilife approximates the final cost of a prefilled syringe with a clip-on external needle sheath safety device (which is attached onto the device after filling and prior to packaging) at the point of shipment (excluding the drug) to be between $0.55 and $1.30 per unit, depending upon the volume of units purchased. Figure 7 highlights a pricing comparison among several prefilled safety syringe options.

Figure 7

PREFILLED SYRINGES—INDICATIVE PRICING CHART FOR SAFETY FEATURES



Source: Unilife Corp.

Safety Syringes with a Needlestick Protection Device

Needlestick prevention devices can be supplied preattached to a syringe or as an ancillary, clip-on product. They differ in how the mechanism is activated and the extent to which the safety feature is integrated into the device. Figure 8 (page 29) summarizes two common safety approaches—needle guards and needle sheaths—as well as retractable needles (which are further described on page 30).

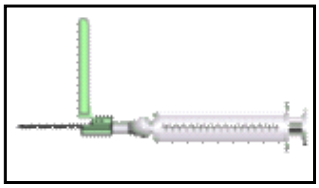
Auto-disable (Non-reuse) Syringes

Due to the consequences of needle reuse, the WHO requires auto-disable syringes in many applications. At present, auto-disable syringes are most common in developing countries and in the immunization programs of nongovernmental organizations (NGOs), such as the United Nations Children's Fund (UNICEF). In 2008, UNICEF procured over 480 million auto-disable syringes with $34 million spent on safe injection supplies, including auto-disable syringes and safety boxes (Source: UNICEF July 2009). However, auto-disable syringes do not necessarily protect individuals from needlestick injuries.

Figure 8

COMMONLY USED SAFETY DEVICES

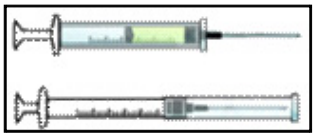
Needle Guard



- A guard slides over the needle to cover it after use
- Can be supplied separately as an add-on needle or preattached to the syringe
- Requires operator activation after removing the needle from the patient
- Typically requires two hands to activate this safety mechanism
- May create an increase in waste volume
- Procprocedure interference, syringe reuse, and tampering are all possible

Needle Sheath

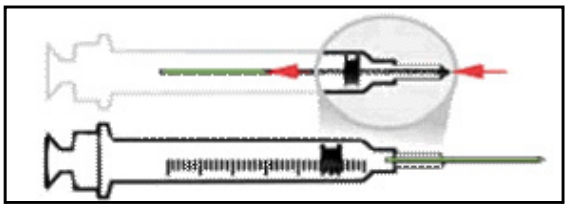
Before Use



After Use

- An external sheath slides over both the needle and syringe after use
- The sheath is supplied preattached to the syringe
- Requires operator to undertake secondary action after dose delivery
- May create an increase in waste volume
- May be bulky in size, causing interference with procedures in confined areas
- Not tamper proof

Retractable Syringes



Hand-drawn Retracting Needle Syringe

- This syringe requires operators to use their hands to retract the needle by pulling back on the plunger after use
- Supplied as a fixed needle, although a preattached version may also be available
- Some versions require the operator to snap off the plunger after use to reduce waste
- Requires operator activation after removing the needle from the patient
- Typically requires two hands to activate the safety mechanism

Spring-based, Non-controlled Retracting Needle Syringe

- A coiled spring fires the needle into the barrel after full dose delivery or after additional pressure by the operator
- Supplied as a syringe with a fixed or preattached needle
- The operator is unable to control the rate of needle retraction
- Activating the retraction mechanism in the body may cause discomfort or user fatigue in multiple injections
- Has the potential to create aerosols (blood splatters) if retracted outside the body

Sources: the CDC, Crystal Research Associates, LLC, and Unilife Corp.

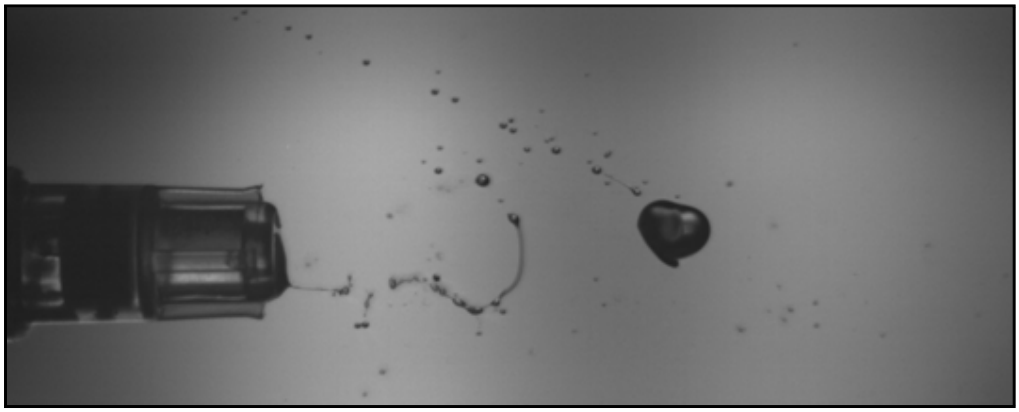
Retractable Needles

Retractable syringes have a fully integrated safety mechanism designed to withdraw the needle into the barrel of the syringe after the full delivery of a dose. There are two main types of retractable syringes: (1) products that require the operator to manually pull back on the plunger after the injection to retract the needle into the barrel; and (2) spring-based, non-controlled retractable needles that function on the basis of a compressed spring situated at the tip of the syringe barrel. With this technology, the operator loads the syringe as normal and then expels the liquid to complete the injection process. When the liquid is expelled, in order to make the needle retract, the operator must apply additional pressure (in some cases up to 10 pounds [nearly 5 kilograms]) to the plunger to break the seal and retract the needle into the syringe. The needle then retracts into the barrel of the syringe very quickly.

This uncontrolled needle retraction mechanism is not considered ideal by many healthcare authorities. According to evaluations conducted by groups such as the ECRI, needle retraction is often not performed while the needle is still in the patient. This is because the practitioner must leverage the needle toward the patient, which may inflict additional and unnecessary pain or discomfort on the patient. Due to the inability to control the speed of needle retraction, industry bodies, such as ECRI, have reported that healthcare workers often first remove the device from the patient before activating the safety mechanism in the open air, which puts practitioners at immediate risk for needlestick injury and exposure from the blood, tissue, or residue that remains on the needle. According to ECRI and the CDC, the rapid, uncontrolled retraction of the needle into the barrel of these retractable syringes may create the risk of infection via the generation of aerosol (blood splatter) as well (depicted in Figure 9). For example, the Australian government had to cancel a trial of retractable syringes for use by IDUs once it was identified that the products under trial caused visible splatter.

Figure 9

POTENTIAL BLOOD SPLATTER



Source: Unilife Corp.

It is possible that, in emergencies, retraction may not be activated at all following removal of the needle from the patient. When the patient is attended to as a priority, the non-sterile syringe with the exposed needle may turn up in other places (e.g., among the bed linens), creating the risk of needlestick injury to personnel downstream, such as cleaning staff.

Thus, as identified by both the ECRI and the CDC, clinical challenges relating to the use of spring-activated retractable syringes include non-activation of the safety mechanism *in situ*, generation of aerosol from needle retraction in open air, and potential discomfort for patients as the operator applies considerable downward plunger force to activate the safety mechanism.

Due to the aforementioned limitations of the current generation of retractable syringes, there is a resistance from healthcare workers to embrace these technologies. In addition, at up to triple the price (or more) of a traditional syringe, current retractable syringes also require healthcare workers to change their procedures (which these individuals prefer not to do), and may actually increase the risk of transferring a bloodborne virus should the device not be activated according to manufacturers' recommendations. All of these factors contribute to the market's need for improved safety syringes.

Unilife's Safety Syringe Technology

Unilife believes that it possesses a truly automatic retractable syringe technology, which could lead the next generation of safety devices, benefitting from OSHA's broad regulations of the BPS (as described on pages 25-27). The BPS states that all healthcare facilities must provide safety syringes and amplifies the importance of engineering controls (e.g., sharps with engineered injury protection mechanisms) in healthcare and similar settings.

Unilife's research suggests that an improved safety syringe should have the following design components incorporated, noting that one device is not yet on the market that integrates all of these features. Unilife believes that its technology is capable of meeting each of these needs in a fully integrated device.

- *Passive Design*. Safety syringes with a passive safety feature that is engaged automatically as part of the standard injection process are necessary to virtually eliminate the risk of needlestick injuries. Many types of safety syringes have an 'active' design, which requires the manual activation of the safety mechanism by the operator after the completion of an injection.

- *Operator-controlled Needle Retraction*. To the Company's knowledge, the ability to automatically retract the needle into the barrel upon full dose activation is available in some retractable syringes but not in any known prefilled format. Further, Unilife does not believe that there is a retractable syringe of any kind that gives operators full control over the speed of needle withdrawal from the body to minimize the risk of infection from splatter and help reduce patient discomfort.

- *Integrated Safety*. The integration of a device's safety features into the core design within the barrel can reduce transport and packaging costs, improve operator handling, and reduce waste volumes.

- *Complies with Standard Procedures*. The device entails single-handed use and requires minimal changes to standard injection procedures.

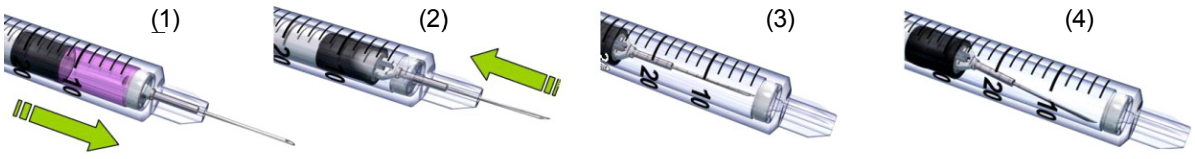
- *Auto-disable (Tamper Resistant)*. Upon retraction of the needle into the barrel, the plunger is automatically locked in place, preventing any opportunity for product re-use or tampering.

Unilife's proprietary prefilled and clinical safety syringes incorporate an integrated safety mechanism that allows operators to control the speed of automatic needle retraction directly from the body. This feature may 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 syringes comprises both prefilled (in a glass barrel) and clinical (plastic) product candidates. These are the Unifill™ and the Unifill™ Select syringes, which are prefilled, and the Unitract™ 1mL Syringes and Unitract™ Clinical Range, which are clinical syringes. Each of the Company's products employs a core platform of innovative technological features, as illustrated in Figure 10 and described on the accompanying pages.

Figure 10

Unilife Corp.

KEY ADVANTAGES OF UNILIFE'S SAFETY SYRINGES



Integrated Design | Automatic (Passive) Retraction | Controlled Retraction | Auto-disable

Source: Unilife Corp.

Competitors are Technology Driven, Unilife is Market Driven

There is a requirement in the marketplace to provide safety syringes. As listed in Table 6, Unilife has identified sectors of the global syringe market that are transitioning toward the use of safety syringes. The Company is targeting fast-growing and non-crowded markets that it believes are pre-conditioned to demand premium safety devices.

Table 6
Unilife Corp.
KEY TARGET MARKETS

	Unilife Target Market	Volumes (billions)*	Annual Growth Rates	Capacity for Premium Devices	Market Transition to Safety	Level of Competition
Pharmaceutical	High	2.7	High	High	Mature	Low
Mature Healthcare**	Moderate	12.0	Medium	High	Mature	Moderate
Patient Self-injection	Moderate	6.0	Medium	Moderate	Emerging	High
Harm Reduction	Moderate	0.4	Medium	Moderate	Emerging	Low
Emerging Healthcare	Low	12.0	Low	Low	Poor	High
Immunizations	Low	2.0	Medium	Low	Emerging	Moderate

**Internal Unilife estimates based upon the International Association of Safe Injection Technology's (IASIT) 2004 estimate of 35 billion syringes used globally ** Includes healthcare facilities for North America, the EU, Japan, and Australia*

Source: Unilife Corp.

Unilife believes that nearly all of its competitors have been *technology driven* in the development of safety syringes designed to either protect those at risk of needlestick injury or prevent the reuse and sharing of non-sterile equipment. What differentiates Unilife in this market is that rather than being technology driven, the Company considers itself to be *market driven*. To develop its products, Unilife went directly to the market to discover its needs and subsequently identified that each market had specific injection safety and product functionality requirements. The Company has sought to apply its core technology into the development of a range of products, each of which is custom-designed to address its specific target audience requirements.

Integrated Design

All safety features contained in Unilife's safety syringe products, including automatic, user-controlled retraction, are fully integrated (built-in) within the barrel of the device and are in no way external to the actual syringe. Integrated safety features facilitate comfortable handling and intuitive use and also encourage convenient, compact disposal. In particular, Unilife maintains that its Unifill™ syringes can be marketed as a true safety medical device, rather than as an ancillary safety product.

Automatic and User-controlled Retraction

One of the key pieces of information the Company learned as a result of its market research is that medical practitioners prefer not to invoke unnecessary pain or fear in their patients, even to the extent that many would rather put themselves at risk. For instance, when using spring-based retractable needles, healthcare workers may elect to remove the syringe from the patient in order to trigger the retraction externally rather than apply pressure (up to 10 pounds [nearly 5 kilograms]) on the plunger while the needle is still in the patient. However, this action, while meant to prevent pain to the patient, unnecessarily increases the risk of needlestick injury and aerosol exposure to the healthcare professional. Furthermore, the current generation of retractable syringes is equipped with an automatic retraction rate that is rapid and cannot be adjusted. This is reported to cause blood splatter—potentially exposing the operator to dangerous bloodborne pathogens—and can also inflict damage on the patient's tissue or veins, causing unnecessary pain and discomfort.

To promote procedural compliance and encourage retraction of the needle directly from the body rather than in the open air, Unilife has incorporated an automatic, user-controlled retraction mechanism—one that does not require significant added pressure while in the patient. Once a Unilife syringe has been used to deliver an injection, the operator is signaled by an audible click to indicate that the safety mechanism has been activated. The retraction mechanism is then initiated relatively effortlessly as the operator's thumb or finger is released from the top of the plunger following an injection. 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. The risk of infection via needlestick injuries or splatter is thus virtually eliminated as the non-sterile needle never comes into contact with the open air. Upon withdrawal of the needle into the barrel, it is automatically locked and tilted to one side to prevent re-exposure or reuse. Thus, the risk of a needlestick injury may be virtually eliminated as the operator never sees the needle following dose delivery.

Moreover, by varying the rate at which the finger is released from the top of the plunger, the rate of needle retraction can be adjusted to optimize safety for the operator and comfort for the patient relative to other spring-fired non-controlled retractable syringes, as slower retraction minimizes damage to the venous tissue.

All of Unilife's Syringes Share a Common Technology Platform

Another key finding from Unilife's market research is that medical practitioners are averse to changing their procedures. Healthcare facilities prefer to employ standardized, routine procedures. To this effect, each of Unilife's syringes share the same core technology, which the Company believes is a competitive advantage that may lead to its syringes becoming a new standard in sharps safety. To Unilife's knowledge, it is the only company developing a full range of prefilled and clinical safety syringes based on a shared technology platform of automatic, integrated safety features.

The Unifill™ Brand (Prefilled Syringes)

At present, Unilife's Unifill™ brand encompasses two product lines: (1) the Unifill™ Syringe (formerly referred to as the Ready-to-Fill Syringe [RTFS] or Unilife Prefilled Syringe), which has been optimized for subcutaneous injections; and (2) the Unifill™ Select syringe, a pipeline product that is intended to facilitate intramuscular injections. The Company's primary focus is commencing production and initial sales of the Unifill™ Syringe, an automatic, fully integrated, glass barrel, prefilled safety syringe targeted toward pharmaceutical manufacturers that have adopted the prefilled syringe format as a preferred delivery device for injectable drugs and vaccines.

The Unifill™ Syringe

To Unilife's knowledge, the Unifill™ Syringe is the world's first and only known ready-to-fill syringe with automatic safety features that are fully integrated within the glass barrel. It is supplied ready for integration into the standard fill-finish systems used by pharmaceutical manufacturers to fill and package an equivalent standard (non-safety) syringe. Due to the device's compact size, packaging and logistical volumes are also similar to equivalent standard syringes and may be up to 70% less than products with attached ancillary safety features. The automatic, operator-controlled needle retraction mechanism of the Unifill™ Syringe can help to virtually eliminate the risk of infection from needlestick injuries and splatter, with the device's functionality enabling it to be suitable for intuitive use by both healthcare workers and patients who self-administer injectable medication at home. Key industrial and marketing benefits of the Unifill™ Syringe are outlined below.

Industrial

- It is a fully integrated safety medical device and primary container for injectable drugs and vaccines.
- It is suitable for doses up to 1mL in size that are administered via subcutaneous injection.
- It is supplied per standard pharmaceutical handling systems for the filling and packaging of injectable medications, in three pieces (barrel subassembly, plunger seal, and plunger subassembly).
- The barrel subassembly is supplied sterile in tub and trays for direct loading onto pharmaceutical filling lines that can automatically fill up to 160 syringes at a time with a measured dose.
- The glass barrel is formed at only one end, allowing the use of glass vials (cartridges) from a wide range of suppliers instead of only five international suppliers of glass barrels for prefilled syringes (which must be formed at both ends).
- Its shipping volume is similar to standard non-safety prefilled syringes.
- It can reduce packaging, transport, and storage volumes by up to 70% compared to prefilled syringes supplied with an ancillary safety product, as well as reduce the industrial footprint required by a pharmaceutical manufacturer to fill and package a drug and comply with needlestick prevention laws.
- Components in the fluid path are U.S. pharmacopeia (USP) compliant to facilitate drug biocompatibility.

Marketing

- It offers a virtual elimination of infection risk from needlestick injuries and aerosol (splatter).
- It meets OSHA guidelines for devices with passive, integrated safety features.
- Device functionality makes it intuitive for use by healthcare workers and patients.
- Its compact size may reduce patient fear of the device and make it portable to carry outside of healthcare facilities.
- Its compact volume after use is similar to standard prefilled syringes.
- It offers opportunities to extend product lifecycles and help protect or retain market share.
- Its product differentiation may become synonymous with a pharmaceutical company's brand image.

The Unifill™ delivery device offers pharmaceutical companies a novel way to promote their injectable products in competitive arenas—particularly for the launch of new pipeline drugs or for use when a currently available drug is approaching patent expiry or is under pressure from generic competition. Moreover, the safety benefits and ease-of-use of the Unifill™ Syringe may allow pharmaceutical companies to better promote the self-injection of current and pipeline drugs by patients at home. The costs of self-administration by the patient is significantly lower than the equivalent costs of receiving treatment by a trained clinician within a healthcare facility.

The Company expects that a number of new pipeline drugs can benefit from a launch with the Unifill™ Syringe. Being the first and only known technology to offer pharmaceutical companies the opportunity to market a prefilled syringe with fully integrated and passive safety features without the need to change standard drug filling and packaging procedures provides a considerable advantage and a marketing opportunity that may disrupt the status quo in the global market for prefilled syringes. By eliminating the need to attach an ancillary safety product to the prefilled syringe, Unifill™ has the potential to reduce the packaging, transportation, and storage volumes of pharmaceutical companies by up to 70%.

As described on pages 12-14, Unilife and sanofi-aventis have entered into an Exclusivity Agreement for the right to negotiate the purchase of Unifill™ for five years as well as an Industrialization Agreement for the development of the Unifill™ syringe, which sanofi-aventis is funding. Collectively, sanofi-aventis' total investment in Unilife may equal $38.5 million. Unilife believes the alliance validates its technology and competency developing and operating automated assembly systems. It is also important to note that under these agreements, Unilife is still in a position to do business with other companies for the supply of Unifill™ in certain therapeutic drug classes that are not designated as exclusive to sanofi-aventis. The signing of an Exclusivity List with sanofi-aventis in February 2010 specifying those therapeutic areas, where sanofi-aventis has the exclusive right to purchase the Unifill™ syringe within defined therapeutic classes, such as vaccines and antithrombotics, until mid-2014 now allows Unilife to enter into formal discussions with other pharmaceutical companies for additional Unifill™ agreements.

Page 41 describes the Unifill™ Select syringe, which has completed the prototype stage of development. The Company is seeking a pharmaceutical partner to facilitate further development and commercialization of this pipeline product.

The Market for Prefilled Syringes

Similar to how the drug delivery space has been transitioning to the use of safer injections over the past decade, pharmaceutical and biotechnology companies have also been increasingly offering prefilled syringes as an alternative to vial disposable syringes. Today, prefilled syringes are the preferred delivery format for at least 50 injectable medications and vaccines, collectively supplied by over 20 pharmaceutical companies (Source: ONdrugDelivery Publishing's *Prefilled Syringes: New Ideas for the New Decade* 2010). Total annual sales of these 50 prefilled products are approximately $50 billion. Going forward, many new products are expected to be launched in a prefilled format as well, due to the considerable advantages of this delivery method (as outlined in Table 7 [page 36]).

Prefilled syringes have been most commonly used for anti-coagulants and vaccines but are now employed across an array of therapeutic sectors. Table 8 (page 36) lists the indications where these syringes are in use and marks which companies hold significant market share for prefilled syringes in each therapeutic sector. In particular, the use of prefilled delivery devices in hematology, multiple sclerosis, arthritis, oncology, and human growth hormones (HGH) is expected to increase in the future (Source: ONdrugDelivery 2010).

Table 7

KEY ADVANTAGES OF PREFILLED SYRINGES

Market Driver	Possible Benefits of Prefilled Syringes	Who Benefits	
		Pharma	*End User*
Reduces Drug Waste	Virtually eliminates the need for overfill; in contrast, vials may be overfilled by up to 20% to 30% in order to account for potential waste	✓	
Competitive Differentiation	Differentiates from drugs delivered in vials/generic versions	✓	
Productivity	Improves productivity by integrating assembly/packaging in a single unit	✓	
Re-launch Aging Drugs	Improves drug marketability when patent expiry is approaching or to boost sales within a drug arena	✓	
Procedural Kits	Pre-packed procedural kits are increasingly used to cover a range of procedures and favor the use of prefilled syringes	✓	✓
Self-administration	User friendly delivery improves patients' at-home use	✓	✓
Reduced Drug Errors	Reduces risk of administering the wrong dose or drug type because the syringe is clearly labeled and prefilled	✓	✓
Ease of Use	Convenient to administer and simple to use; eliminates several of the steps required for vials		✓
Accurate Dose Delivery	Ensures the correct dosage per patient for every injection		✓
Improved Efficiency	Reduces the time required to draw up a dose from a vial, especially in intensive care areas		✓
Drug Volume	Accommodates volumes ranging from 0.25mL to 5.0mL, making them appropriate for products administered subcutaneously or intramuscularly	✓	

Sources: Unilife Corp. and Crystal Research Associates, LLC.

Each of the therapeutic sectors listed in Table 8 is highly competitive, with multiple products aggressively marketed against each other by the major pharmaceutical companies. Following Table 8, Table 9 (page 37) lists a selection of some products that are currently administered in a prefilled syringe.

Table 8

INDICATIVE PHARMACEUTICAL SHARE OF KEY PREFILLED THERAPEUTIC MARKETS

	Anti-coagulants	Vaccines	Anti-Infectives	Anti-inflamatory	Hema-tology	Multiple Sclerosis	HGH	Obstetrics	Other	Oncology
Sanofi-aventis	■									
Sanofi-pasteur		■								
GSK	■	■								
Novartis		■								
Wyeth		■		■						
Roche			■		■				■	
Merck		■				■				
Amgen					■					
TEVA						■				
Pfizer							■	■		
J&J								■		
Serono								■		
Abbott				■						
Biogen-Idec						■				
Others	■	■		■		■	■		■	■

Sources: Unilife Corp. and ONdrugDelivery Publishing's Prefilled Syringes: New Ideas for the New Decade.

As noted in Table 9, there are a number of "blockbuster" prefilled products, with annual sales of over $1 billion. Needlestick prevention features are available in virtually all of the main therapeutic sectors where prefilled syringes are in use. Many of these products in Table 9 require regular injections (e.g., daily or weekly); thus, prefilled syringes suitable for self-administration by patients are increasingly preferred. Note that this is not an exhaustive listing of prefilled medications, as there are at least 50 known products administered in this format.

Table 9

A SELECTION OF PRODUCTS CURRENTLY AVAILABLE IN A PREFILLED DELIVERY DEVICE

Anti-infective	**Central Nervous System (Multiple Sclerosis among other indications)**
*Hoffmann-La Roche Inc.'s Pegasys®	*Biogen Idec Inc.'s Avonex®
Cardiovascular (Antithrombotic)	*EMD Serono, Inc. and Pfizer's Rebif®
*Sanofi-aventis SA's Lovenox®	*Teva Pharmaceutical Industries Ltd. and sanofi-aventis' Copaxone®
GlaxoSmithKline plc's Arixtra®	Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Risperdal® CONSTA®
Fragmin® (trademark of Pfizer Health AB and licensed to Eisai Inc.)	
Hematology	**Musculoskeletal (Rheumatoid Arthritis)**
*Amgen, Inc.'s Aranesp®, Neulasta®, and Neupogen®	*Abbott Laboratories' Humira®
Roche's Mircera®	*Wyeth's (now part of Pfizer) Enbrel®
*Centocor Ortho Biotech Products, L.P.'s Procrit®	Roche's Boniva® Injection
Oncology	**Human Growth Hormone (HGH) Deficiencies**
*Roche's NeoRecormon®	Pfizer's Genotropin®
AstraZeneca's Faslodex®	Tercica, Inc.'s (an affiliate of the Ipsen Group) Somatuline® Depot
Abbott's Lupron Depot®	
Obstetrics	**Vaccines**
EMD Serono's Ovidrel® and Cetrotide®	*Wyeth's Prevnar®
	Sanofi Pasteur's Fluzone® and Menactra®
** Annual sales of over $1 billion*	*GlaxoSmithKline's Infanrix®/Pediarix®

Source: Unilife Corp., Crystal Research Associates, LLC, and manufacturer web sites.

Specialty Pipeline Drugs Targeted for Use with Prefilled Syringes

In addition, many medications in development are being optimized for administration as an injection rather than orally and thus may be candidates for delivery in a prefilled syringe format. This is largely due to the harsh environment that stomach acids present for protein-based pharmaceuticals, an area of development that has increased significantly in recent years. Many proteins given orally are absorbed by the digestive system and metabolized by the liver before they reach the desired site of action in the body. In some cases, treatments are so extensively broken down by the liver that only a small amount of medication enters the systemic circulation, reducing the bioavailability and efficacy of the drug. Further, the gastrointestinal tract's acidic environment, digestive enzymes, and permeable membranes may hinder the delivery of proteins, sequestering or altering these products in the stomach or another organ.

However, intramuscular or subcutaneous injections can bypass many of these issues, thereby improving absorption, systemic dose accuracy, and time until onset of action. More than two-thirds of all therapeutic proteins for chronic diseases are supplied in an autoinjector or injection pen format, and many biologic products are likely to continue to be injected (Source: Greystone Associates May 2008). Unilife anticipates that in general the trend toward a greater use of injections will likely also fuel market demand for efficient, convenient, safe, and cost-effective injection systems using prefilled syringes, such as the Company's Unifill™ syringe.

Table 10 describes several pipeline products in either Phase II or Phase III clinical trial stages, or awaiting regulatory approval, that are or may be designated for targeted delivery in a prefilled syringe format.

Table 10

PIPELINE PRODUCTS THAT MAY BE SUITABLE FOR INCLUSION IN A PREFILLED SYRINGE

- Zalbin™ from Novartis AG and Human Genome Sciences, Inc. for the treatment of chronic hepatitis C
- Apixaban from Pfizer and Bristol-Myers to prevent and treat a broad range of venous and arterial thrombotic conditions, such as DVT
- Prolia™ (denosumab) from Amgen, for which clinical trials of prefilled syringes are underway to evaluate its use in osteoporosis, treatment-induced bone loss, bone metastases, rheumatoid arthritis, and myeloma
- AVE5026 from sanofi-aventis to replace Lovenox® in preventing DVT in patients undergoing surgeries

Sources: Crystal Research Associates, LLC and manufacturer websites.

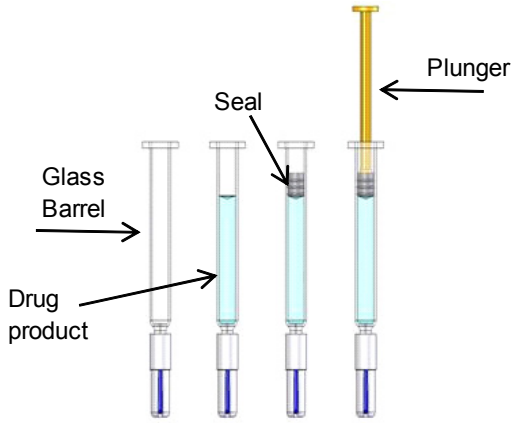
Production of Standard Prefilled Syringes

Prefilled syringes are provided to pharmaceutical companies "ready to fill" in three separate pieces—a glass barrel, a seal, and a plunger—as illustrated in the left side of Figure 11 under Filling and Packaging. Barrels of prefilled syringes are generally made of glass due to biocompatibility and shelf-life issues. Glass is a more stable material than plastic, which can leach or become porous, allowing oxygen to affect the medication. The drug must have a shelf life in the syringe of over two years in order to receive regulatory approval, thus biocompatibility is key. Unilife's Unifill™ syringes are developed using component materials that are currently used with standard prefilled syringes or vials in order to maximize biocompatibility with target injectable drug products.

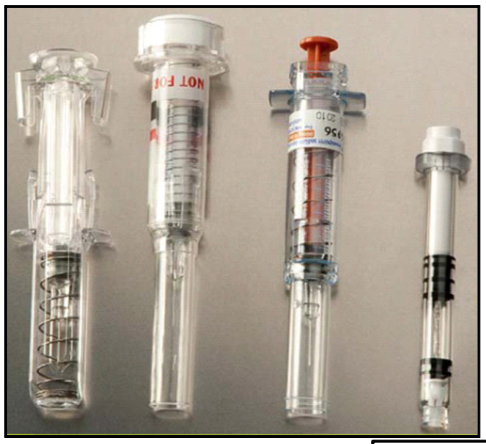
Figure 11

PREFILLED SYRINGES

Filling and Packaging



Competitive Size Comparison



Ancillary safety products attached onto standard prefilled syringes

the Unifill™ Syringe

Sources: Unilife Corp. and Crystal Research Associates, LLC.

In the filling of standard prefilled syringes, tubs of up to 160 jets or more glass barrels are automatically loaded onto a sterile filling line, before being filled with a measured dose of drug. High-volume systems are capable of filling hundreds of glass barrels per minute with high rates of precision. A rubber seal is then inserted into the glass barrel to create a sterile, air-tight, and leak-proof barrier between the drug and outside contaminants. Finally, the plunger is screwed into the seal, making it ready for packaging and shipment. Should a pharmaceutical company seek to attach a safety product onto the standard prefilled syringe, this typically occurs following the insertion of the plunger but prior to packaging and shipment.

Manufacture of the Unifill™ Syringe

To deliver full compatibility with existing drugs and their filling systems, the Unifill™ Syringe is a similar size to standard non-safety prefilled syringes and is supplied in the three standard sub-assembly pieces. The design compatibility minimizes the time and cost required by pharmaceutical companies to integrate the product onto current filling lines. This characteristic was key to Unilife's agreement with sanofi-aventis (detailed on pages 12-14). As all safety features in the Unifill™ Syringe are fully integrated into the core device design—making the product compact and simple to use and offering convenient, cost-effective disposal—the Unifill™ Syringe may also generate production and transport savings for companies that would have otherwise had to attach bulky clip-on safety products (as illustrated in Figure 11 [page 38]). Clip-on products increase costs related to packaging, shipping, and storage as well as require an investment in the automated assembly systems needed to attach these devices to the syringes.

Dual-source Supply Strategy

Unilife is presently in negotiations with a number of established supply partners for various components of its syringes, such as rubber seals and glass barrels. The Unifill™ Syringe's glass barrel can be sourced from ampoule suppliers. Glass barrels used in the production of standard prefilled syringes require forming at both ends. Given the limited number of global manufacturers of glass barrels for prefilled syringes, Unilife has designed its barrel for the Unifill™ Syringe to require forming at only one end. This allows Unilife to enter into supply contracts with any of up to 30 suppliers of glass vials and cartridges.

The Company intends to have, at a minimum, a dual-source supply process for each component, raw material, and related services. Unilife is evaluating potential suppliers of various materials and components that pharmaceutical companies may desire for use in a Unifill™ Syringe provided to them for filling with target drugs and vaccines. Thus, if the pharmaceutical customer wants a particular material for use with the glass barrel, Unilife aims to have a relationship with a glass manufacturer that can support this need. The Company views this strategy as important in giving it the flexibility to meet the drug compatibility requirements of its customers.

Establishment of a High-volume Production Facility in York, Pennsylvania

Following a review of opportunities within Europe, Unilife has opted to centralize its manufacturing operations in Pennsylvania. This location leverages the expanded production capacities of Unilife's assembly lines and the ability for Unilife, under its Industrialization Agreement with sanofi-aventis, 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 the Unifill™ Syringe.

Unilife began initial pilot production of the Unifill™ Syringe at the Company's Lewisberry, Pennsylvania, facility in 2008. The industrialization program for high-volume Unifill™ manufacture at the Company's York, Pennsylvania, facility is underway and is proceeding a year ahead of schedule. Supply of the Unifill™ Syringe to sanofi-aventis could begin in late 2010, with a high-volume automated assembly system expected to be established by the end of 2011.

The first Unifill™ commercial line is anticipated to have a target production capacity of approximately 60 million units per year, which is a 50% increase over Unilife's forecasted capacity from when the Company initiated the industrialization program in July 2008. Subsequently, Unilife and Mikron Group (the Company's supply partner, as overviewed on page 14) expect to be able to achieve a high-volume annual production of 150 million units. Under a project plan developed by Unilife, annual production capacity for the Unifill™ Syringe may exceed 450 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. Page 14 provides details of the Unifill™ Syringe's industrialization program, and pages 46-48 detail the York facility, which is being built.

Regulatory Status

Unilife intends to file a Type III **Drug Master File** for Unifill™ with relevant regulatory authorities, such as the FDA. However, it is the ultimate responsibility of the pharmaceutical customer to obtain final approval of the Unifill™ Syringe in combination with the pharmaceutical manufacturer's drug product.

Attachment of Safety Features

To Unilife's knowledge, there are not currently any prefilled syringes with an integrated safety feature in development or marketed, since biocompatibility requirements thwart most concepts for needle retraction into the glass barrel. As pharmaceutical companies must provide a safety feature for the prefilled syringes in order to comply with government regulation, these entities typically opt for a clip-on safety device that attaches onto the entire syringe and thus does not present biocompatibility challenges. The two main safety products attached onto standard prefilled syringes are external sheaths and needle shields.

- *External Sheaths.* These products are clipped onto the syringe after it is filled and assembled but prior to final packaging. Pharmaceutical companies devote considerable time and resources to assemble these clip-on devices at filling facilities. As shown in the right side of Figure 11 (page 38), the bulky size of clip-on devices also means they can add up to 70% to the volume of the final product, in turn adding costs to packaging, storing (which is significant as many drugs must be stored in cool rooms, which can be costly), and transporting the prefilled syringes.

- *Needle Shields.* These products may be either attached by the pharmaceutical company prior to shipment or purchased and stored by hospitals separately. For the latter scenario, healthcare workers clip the shields onto the prefilled syringe at the point of use. To activate the safety mechanism, the operator manually slides an external guard over the needle with the thumb or finger—often requiring a two-handed technique. This method cannot guarantee that the healthcare worker actually uses or activates the clip-on device according to the manufacturer's recommendations.

Unilife approximates the final cost of a prefilled syringe with a clip-on safety device at the point of shipment (excluding the drug) to be between $0.55 and $1.30 per unit, depending upon the volume of units purchased.

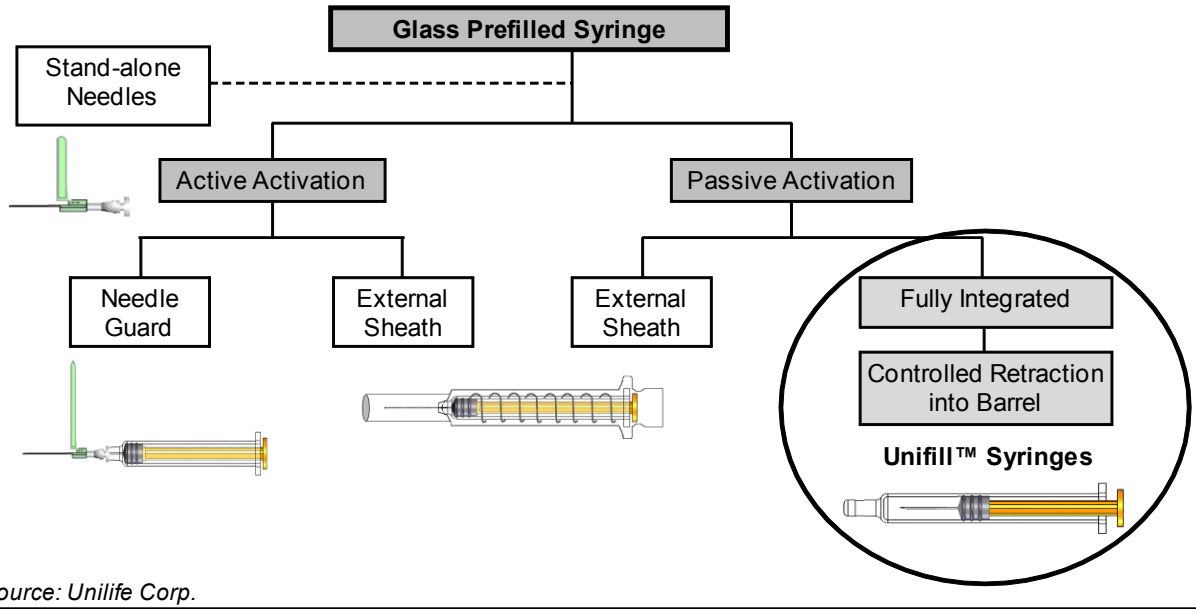
Moreover, the size of a syringe with a clip-on device may create additional fear in patients due to its invasive and onerous look. As a result, these approaches are believed to have a low acceptance rate in the marketplace. Yet, because of the biocompatibility issues, people had accepted that clip-on devices were the only viable solution. As such, to the Company's knowledge, no new technology has come onto the market in the past five years. Figure 12 depicts the market sector where Unilife participates relative to other manufacturers of ancillary safety products for standard glass-barrel prefilled syringes.

Figure 12

Unilife Corp.

THE UNIFILL™ SYRINGE'S COMPETITIVE POSITION

Unifill™ is believed to be the only primary syringe container with the safety mechanism inside the glass barrel.



Source: Unilife Corp.

Unifill™ Select

In late 2009, Unilife introduced a new ready-to-fill syringe to its pipeline called the Unifill™ Select (a rendering of which is shown in Figure 13). This syringe is targeted primarily for use with vaccines, which commonly require intramuscular injections. This distinct new pipeline product complements the existing Unifill™ Syringe being launched in conjunction with sanofi-aventis. The Unifill™ Select syringe incorporates attachable needles suited for use with intramuscular injections where healthcare workers require a variety of needle gauge and length options. For these injections, the length and gauge of the needle employed is selected based on the patient's age, gender, and size, as well as the location of the muscle being injected. The Unifill™ Select product allows healthcare workers to affix needles that are up to 1.5 inches in length to the syringe, which is the longest size typically used for intramuscular injections. Keeping with Unilife's commitment to providing safe syringes, the Unifill™ Select includes a needle retraction mechanism that is automatically activated upon full dose delivery. The operator can control the speed of needle withdrawal directly from the body into the glass barrel.

Figure 13
Unilife Corp.
UNIFILL™ SELECT

Source: Unilife Corp.

To Unilife's knowledge, its Unifill™ Select syringes could become the first prefilled safety syringe with automatic and fully integrated safety features inside the barrel that is designed with attachable needles suitable for intramuscular injections. Unifill™ Select syringes have the potential for marketing by pharmaceutical companies in convenient kit formats ready for injection by healthcare workers and are compatible with the drug filling systems now used by pharmaceutical companies for comparable standard prefilled syringes. Further, Unilife is not aware of any existing ancillary safety product that can be attached onto a standard prefilled syringe that has a 1.5-inch needle. In November 2009, the Company filed U.S. patent applications for the Unifill™ Select, and has initiated discussions with pharmaceutical parties regarding this new syringe. This pipeline product is not constrained by the existing agreement with sanofi-aventis.

Market Opportunity

To Unilife's knowledge, virtually all injectable medications and vaccinations that are currently available in a prefilled syringe format are administered as either a subcutaneous or intramuscular injection. As the Unifill™ Syringe encompasses subcutaneous applications, Unilife believes that the addition of the Unifill™ Select syringes, optimized for intramuscular injections, to its portfolio can help further penetrate the prefilled syringe market.

Unilife has found that of the more than 50 injectable products currently available in a prefilled syringe format monitored by the Company, roughly half are indicated for intramuscular injection and the majority of those are vaccines. Vaccine sales are forecast to double within five years from $19 billion in 2008 to approximately $39 billion by 2013 (Source: Kalorama Information). Greystone Associates has estimated that as many as 75% of vaccinations could be performed with a prefilled syringe by 2012. The largest single application is likely to be flu shots. Further sectors that may benefit from the supply of a safety prefilled intramuscular injection are antivirals, HGH products, and anti-inflammatories (e.g., for arthritis).

Sanofi Pasteur, GlaxoSmithKline, Wyeth, and Merck & Co., Inc. (MRK-NYSE) compete for the largest share of the vaccine market. Some of the highest selling vaccines available in a prefilled syringe format have included Wyeth's Prevnar®, Sanofi Pasteur's Fluzone® and Menactra®, and GlaxoSmithKline's Infanrix® and Pediarix®.

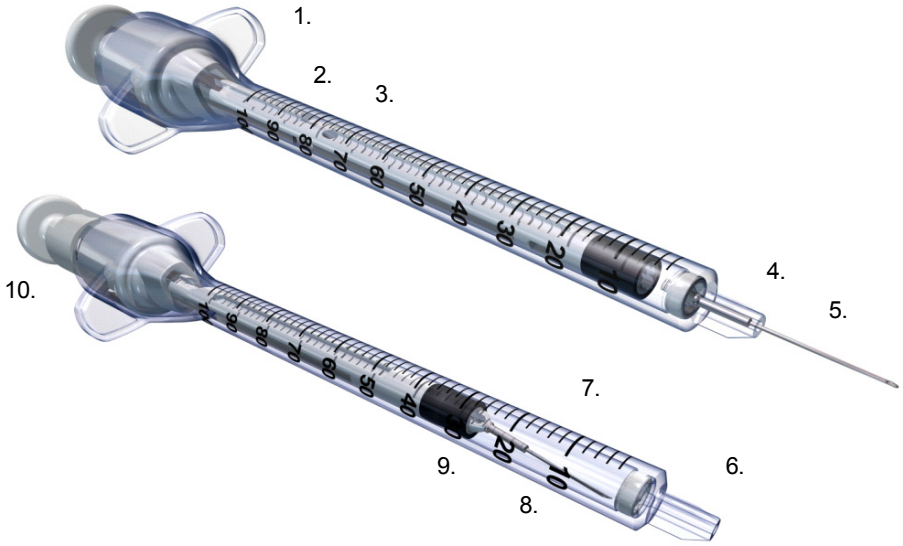
The Unitract™ Brand (Clinical Syringes)

Despite advancements in safety made to date, needlestick injuries still occur in U.S. healthcare facilities, many of which involve syringes with safety devices. A number of existing safety products require operators to undertake a secondary action to engage the protection mechanism. Others operate with a spring-fired (non-controlled) retraction mechanism, which may compel healthcare workers to retract the needle after it has been removed from the body. Thus, Unilife believes that the drug delivery market is still in need of improved clinical safety sharps, such as the Company's Unitract™ line, which is anticipated to offer several preferred use and safety advantages to the healthcare industry. Production of these syringes has commenced, with a targeted commercial launch during the first half of 2010.

Unitract™ 1mL Syringes

The Unitract™ 1mL Insulin, Tuberculin (TB), and Safe syringes incorporate a number of integrated safety features, including automatic, operator-controlled needle retraction and an auto-disable feature that prevents the risk of product tampering or reuse once the injection has been completed. Healthcare facilities, diabetes and self-injection, and global harm reduction markets may benefit from the Unitract™ range. Figure 14 illustrates the Unitract™ 1mL Syringes, depicting the key characteristics of the design.

Figure 14
Unilife Corp.
THE UNITRACT™ RANGE OF 1ML SYRINGES



1 Extra-wide flanges (finger grips) for easy handling
2 Suitable for single-handed use (left or right handed); Hands remain behind needle at all times
3 Designed for the administration of an injectable dose of up to 1mL (1cc or 100 units) in volume
4 Permanently attached (fixed) needle with standard bevel
5 Audible, tactile prompt signals activation of safety mechanism
6 Passive (automatic) needle retraction occurs inside the body to virtually eliminate the risk of needlestick injury
7 Operator-controlled rate of needle retraction directly from the body into the barrel
8 Tilting of needle to one side within the barrel to help prevent needle re-exposure
9 Automatic plunger lockout upon full retraction of the needle to prevent product tampering or reuse
10 Colored button to signify needle gauge as per ISO standards (e.g., gray button for 27-gauge needles)

Sources: Unilife Corp. and Crystal Research Associates, LLC.

Unitract™ 1mL Insulin Syringe

Millions of people worldwide regularly self-administer prescribed medication with a syringe outside of a healthcare facility. One of the largest markets for the self-injection of prescribed medications is the diabetes market. In the U.S., insulin syringes remain among the most common forms of administration for people with diabetes. People with Type 1 diabetes can require lifetime insulin injections on a daily basis, while people with Type 2 diabetes may also have insulin requirements. The Unitract™ 1mL Insulin Syringe is designed for use in healthcare facilities and by patients who self-administer prescription medication (e.g., insulin) in the home environment.

The mandatory use of safety syringes within healthcare facilities in most cases does not extend to the self-administration of prescribed medication by patients at home. However, U.S. government agencies and insurance providers are increasingly seeking to encourage the use of single-use syringes with needlestick prevention features. The majority of healthcare insurers in the U.S. now subsidize the cost of insulin syringes with a needlestick prevention feature under the same tier structure as standard products. Moreover, the Centers for Medicare & Medicaid Services (CMS) has introduced a requirement that all long-term care pharmacies and Medicare Part D sponsors (healthcare suppliers) provide insulin syringes with a sharps injury prevention feature.

The Unitract™ 1mL Insulin Syringe is designed for the administration of insulin and other prescription medications suitable for the injection of doses of up to 1mL (100 units) in volume. To comply with ISO standards, Unilife has added an orange cap. The Unitract™ Insulin Syringe is designed for general practitioners in the U.S. healthcare sector and by patients who self-administer prescribed medication. Like all of Unilife's products, this syringe incorporates automatic, controlled needle retraction from the patient directly into the barrel of the syringe. While protecting the operator, this feature also protects family members and trash collectors, among others, from needlestick injuries due to the unsafe disposal and storage of non-sterile insulin syringes. Unlike the Unitract™ Safe Syringe described below, the Insulin Syringe has a smooth non-gated plunger, as operators within designated target markets typically do not share syringes with others and are thus at a relatively low risk for the transmission of bloodborne diseases via shared syringes.

Unilife has also filed a 510(k) submission to the FDA seeking clearance for the Unitract™ Tuberculin (TB) Syringe, which is a variant of the Insulin Syringe that is primarily targeted for use within healthcare facilities.

Unitract™ 1mL Safe Syringe

The Safe Syringe is a variant of the Insulin Syringe, with the addition of a system of gates built into the plunger that automatically prevents the syringe from being reloaded once the injection has commenced. The Safe Syringe is 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. There are over 13.2 million IDUs globally, and this population now accounts for almost half of the new HIV infections in Asia and nearly one-third of the new HIV infections worldwide, except in Africa (Source: UNAIDS, the Joint United Nations Programme on HIV/AIDS). Likewise, the WHO estimates that up to 90% of people in developed countries with chronic hepatitis C are current or former IDUs or have a history of transfusion of unscreened blood or blood products. In the U.S., the CDC estimates that 20% of all AIDS cases are related to IDUs.

As many of the diseases transmitted through "dirty" needles are still incurable and have very high life-long treatment costs, such as HIV and hepatitis C, the prevention of needle sharing and the promotion of behavior advocating safe injection practices is becoming a major area of concern for governments worldwide. Ultimately, preventing the reuse of and encouraging the safe disposal of needles can deliver a significant return on investment in the form of reduced healthcare treatment costs. To this extent, a 2002 study by the Australian government—*Return on Investment in Needle and Syringe Programs*—validated the social and economic effectiveness of harm reduction initiatives at preventing disease transmission.

However, evidence suggests that merely providing standard syringes (those without an auto-disable or non-reuse feature) to IDUs is not sufficient to contain the transmission of bloodborne diseases within this population, as a significant portion of the IDU population continues to reuse and share these products due to convenience, habit, and social behavior. Thus, the supply of syringes such as those provided by Unilife—which cannot be used more than once and automatically engage a safety mechanism to eliminate the risk of needlestick injury—is critical.

In line with Unilife's market-driven approach to product development, the Company took its original Safe Syringe design directly to the end users—the IDUs—and solicited their input. The response from IDUs was that they would not use this original design because while injecting, a drug user's vein is prone to collapse. When this occurs, the drug user must remove the needle and try to acquire the vein again, which was not possible with Unilife's initial syringe design. Accordingly, the Company reengineered its syringes intended for global harm reduction markets to allow an operator to draw up on the plunger .05cc to ensure that the needle may reacquire a vein. Then, once the injection has been initiated, Unilife's safety syringes do not allow the operator to pull back on the plunger. By not being able to pull the plunger back, it ensures that the syringe cannot be loaded more than once, thereby eliminating sharing.

This redesign now accommodates the needs of the target population, which the Company believes is likely to assist market adoption of the product versus competing products, and still retains its integrated non-reuse feature—making the product favorable for government programs that seek to enhance harm reduction programs by virtually eradicating the risk of needle sharing. To the Company's knowledge, the Safe Syringe is the only product of its kind to incorporate a non-reuse feature independent of the needle retraction process.

As with all of its safety syringes, Unilife's Safe Syringe also includes the Company's automated needle retraction mechanism that locks and tilts the needle to one side within the barrel to prevent re-exposure or tampering. With this retractable syringe, even a barely conscious user can discard the syringe without any action required to make it safe.

Unilife believes that the Unitract™ range of 1mL Safe Syringes is well positioned to address the harm reduction market through its combination of operator-controlled passive needle retraction and a single-use, sharp, sterile needle that encourages safe vein care and reduces infection risks. With Unilife's syringes, operators can safely control the rate at which the needle is withdrawn from the body, creating minimal discomfort and reducing the risk of vein or tissue damage in intravenous injections versus other non-controlled retractable syringes. Moreover, while the Company recommends activating retraction of the Unitract™ 1mL syringes inside the body, should the operator elect to retract the needle in the open air, the ability to control the rate of needle withdrawal diminishes the risk of aerosol blood splatter.

Commercialization of the Unitract™ 1mL Range of Syringes

Unilife is manufacturing its Unitract™ 1mL range of syringes, targeted for use in healthcare facilities and by patients who self-administer prescription medication, at its FDA-registered manufacturing facility in Lewisberry, Pennsylvania. Initial production of the Unitract™ 1mL syringes began in China during 2008 to support regulatory approval and marketing activities. Production of the Unitract™ 1mL Insulin Syringe began in the U.S. in August 2009. In December 2009, Unilife completed its required product aging studies for the Unitract™ 1mL Syringes. Unilife anticipates having U.S. production capacity for these syringes of approximately 40 million units annually and intends to launch them across key international markets during 2010.

To this extent, the Company's upcoming milestones may include announcements of agreements with pharmaceutical and healthcare companies for the sale and distribution of the Unitract™ 1mL range. In October 2008, Unilife received 510(k) clearance from the FDA for its Chinese-manufactured Unitract™ 1mL Insulin Syringe, allowing the Company to market and sell this syringe within the U.S. Unilife secured FDA clearance of its U.S.-manufactured stock in April 2010. The Company is aiming for a commercial release of the Unitract™ 1mL Syringes during the first half of 2010, and has already begun identifying potential pharmaceutical and healthcare customers in the U.S., Europe, and Asia.

Unilife completed a Medical Device Directive (MDD) audit for CE Mark registration of Unitract™ in Europe in December 2009. Globally, the Company has secured regulatory approvals for its 1mL range within the U.S., Canada, Europe (the CE Mark), and Australia, and has appointed a number of distribution partners, many of which have committed to minimum annual orders.

In February 2010, Unilife donated its first shipment of Unitract™ 1mL safety syringes to Doctors Without Borders, a volunteer humanitarian medical organization, to support ongoing relief efforts in Haiti. The syringes were shipped to the Haitian cities of Jacmel and Les Cayes where medical teams on the ground were able to access and use the syringes.

In March 2010, Unilife signed an exclusive five-year agreement with Stason Pharmaceuticals, Inc., a U.S.-based pharmaceutical company, to market the Unitract™ 1mL syringes in Japan, China, and Taiwan. Stason's Taiwan-based strategic alliance affiliate, Standard Chem. and Pharm. Co., Ltd, acts as the primary distributor of the product in these designated territories. Under the agreement, Stason and Standard represent Unilife in securing product regulatory approval within these Asian countries.

The agreement includes a requirement for Stason to purchase a minimum of one million Unitract™ 1mL syringes per year during the contract term (subject to annual review). Stason has placed an immediate annual order with Unilife for the purchase of one million units of the Unitract™ 1mL syringe. Other countries within Southeast Asia may be added to the list of designated territories where Stason has exclusive rights if the parties reach agreement on minimum orders for those countries.

Unilife is continuing to negotiate with other pharmaceutical and healthcare companies worldwide for distribution rights for the Unitract™ 1mL syringes, and expects additional agreements to be signed in conjunction with the continued global launch of the Unitract™ 1mL syringes.

Automated Assembly System for Unitract™ Production

Unilife's in-house team fully designed, developed, built, and validated the automated assembly system used for Unitract™ production. Prior to commencing manufacturing at its Pennsylvania facility, Unilife was required to transfer its automated assembly system for the Unitract™ 1mL Syringes into a designated clean room. As part of this transition, the Company successfully completed a series of operational tests designed to validate its performance and product quality. Its automated assembly system is now rated at up to 90% of efficiency. A video of the production of the Unitract™ 1mL range is available for viewing at www.unilife.com. The Company considers its ability to design sophisticated, innovative medical devices, and the automated assembly systems used to manufacture them, to be a core business competency.

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 the development of 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 to help meet the injection safety needs of healthcare workers and their patients. The design and method of operation is intended to complement the Unifill™ Syringe to maximize levels of device functionality, user familiarity, and occupational safety.

Based on Unilife's market research, which has identified healthcare personnel's unwillingness to change their existing procedures as a major impediment to the adoption of new products, the Company has designed the Unitract™ Clinical Range prototype to accommodate for the costly medical waste disposal procedures of the healthcare sector. Automatic, controlled needle retraction in this syringe is facilitated by a spring built into a rod inside the plunger. Upon the completion of the retraction of the needle into the barrel, this rod may be removed by the operator in facilities where the reduction of waste disposal volume is a policy. As this rod has not been in the fluid path and thus is not contaminated waste, it can be disposed of in a normal bin while the remaining "medical waste" components can be discarded in the proper sharps receptacles—engineering that Unilife believes meets its target markets' demands.

Unilife's Manufacturing Activities

Unilife is centralizing its manufacturing activities in Pennsylvania to reduce future operating costs and improve economies of scale, among other benefits. In addition to its establishing a facility in Lewisberry, Pennsylvania, the Company began reviewing options to establish a major facility that can serve as a long-term global headquarters and facilitate the high-volume production of key products, particularly the Unifill™ Syringe. After an evaluation of financial and operational factors, Unilife found that proceeding with the development of its own custom-built facility in York, Pennsylvania, could be more cost-efficient than leasing and retrofitting an existing warehouse. Recent trends indicate that construction costs are as much as 25% to 30% below equivalent price levels from two years ago as a result of the current economic slowdown (Source: Keystone Redevelopment Group LLC, a Pennsylvania real estate company specializing in large-scale redevelopment).

Lewisberry, Pennsylvania

Unilife occupies an FDA-registered, 50,000 ft^2 medical device production facility in Lewisberry, Pennsylvania. This facility has two Class 8 clean rooms, which house a fully automated assembly system for manufacturing the Unitract™ 1mL syringes as well as space to assemble non-proprietary medical devices for B.Braun USA. Unilife's assembly system for Unitract™ was fully designed, developed, built, and qualified by the Company's in-house team. It has capacity for production of up to 40 million Unitract™ syringes each year. Remaining square footage at Lewisberry is presently used for offices, product design and prototyping, engineering activities, and the construction of automated assembly systems.

The Company's contract medical device activities have served to generate additional revenue for Unilife and strengthened its alliances with industry leaders in medical device and pharmaceutical markets. During the year ended June 30, 2009, Unilife reported revenues of $3.1 million due to contract manufacturing for B. Braun, which represented 15.6% of the Company's total revenue that year. However, Unilife has strategically decided to now focus substantially all of its commercial and operational efforts toward commercializing its own proprietary medical devices—specifically, the Unifill™ Syringe and the Unitract™ 1mL Syringes. Thus, contract manufacturing will not likely be a key activity going forward.

York, Pennsylvania

In December 2009, Unilife began development of its new global headquarters and commercial production facility on 38 acres of land at 250 Cross Farm Lane in York, Pennsylvania. An architectural rendering of this site is depicted in Figure 15.

Figure 15

Unilife Corp.

ARCHITECTURAL DESIGN OF UNILIFE'S FACILITY IN YORK, PENNSYLVANIA

Source: Unilife Corp.

This location is less than 10 miles from the Company's existing Lewisberry, Pennsylvania, facilities. The 165,000 ft^2 facility is designed to offer first-stage manufacturing capacity of up to 360 million syringes annually. At stage one, the facility is roughly equivalent in size to three football fields. It is expected to be ready for operations by late 2010 to support the completion of the industrialization program for the Unifill™ Syringe and the supply of the product to sanofi-aventis. Within the plant, 54,000 ft^2 are designated to become the Company's global offices, supporting administrative, marketing, new product development, quality laboratories, and other of Unilife's operational functions. In the future, a further 100,000 ft^2 of contiguous production space could be constructed, which may enable the installation of additional Unifill™ assembly lines for an anticipated total production capacity of up to one billion syringes annually. Unilife intends to begin progressively transferring, and ultimately consolidating, all of its U.S.-based staff and production systems from its current Lewisberry facilities into the York facility in early 2011. The York site (for which the ongoing construction is pictured in Figure 16) is located only a short distance from the Lewisberry site to maximize staff retention.

Figure 16
Unilife Corp.
CONSTRUCTION OF NEW FACILITY

Source: Unilife Corp.

The new facility was designed by L2 Architecture, a Philadelphia-based architectural and engineering design firm that specializes in the pharmaceutical and medical device sectors, with the goal of maximizing industrial productivity while adhering to U.S. **Good Manufacturing Practices (GMP)**. Keystone Redevelopment Group is managing the development of the plant, and HSC Builders and Constructions Managers (a Pennsylvania company specializing in custom-designed facilities for biotechnology, academic, healthcare, pharmaceutical, and technology companies) is performing the construction.

Building its New Facility is Likely to Cost Unilife Only up to $9 Million

Unilife has projected the total cost for its new facility to be $26 million, funded by a combination of debt and cash reserves. Up to $9 million will likely be funded out of the Company's existing cash, with the remaining amounts financed from a commercial bank or other U.S. lending institution as well as from the Commonwealth of Pennsylvania and other U.S. federal and state entities. Unilife anticipates that loan repayments could be as much as $400,000 to $500,000 less than the equivalent annual costs of leasing a facility. In October 2009, Unilife accepted a $5.2 million offer of assistance from Pennsylvania to support the construction of the Company's new facility and the subsequent creation of 241 new jobs within York County by 2013.

Unilife believes that its new headquarters and production capabilities can provide it with the flexibility to expand its business as it continues to move toward commercial production and the signing of supply agreements with current and future pharmaceutical customers. Unilife has fast-tracked the development of its new facility with the aim of supporting the scheduled completion of the Unifill™ Industrialization Program in late 2010. Table 11 (page 48) summarizes the Company's projected timetable for completion.

Table 11

Unilife Corp.

KEY DEVELOPMENT TIMELINES FOR THE NEW GLOBAL HEADQUARTERS AND PRODUCTION FACILITY

▪ Completion of clean rooms for equipment installation (Phase 1)	End October 2010
▪ Temporary occupancy permit for manufacturing/warehouse	End October 2010
▪ Scheduled delivery of the first commercial assembly line for Unifill™ syringes	Fourth Quarter 2010
▪ Unrestricted occupancy permit for manufacturing/warehouse (Phase 2)	End December 2010
▪ Unrestricted occupancy permit for office	End December 2010
▪ Progressive transfer and consolidation of the U.S. staff and production systems from the current Lewisberry, Pennsylvania, facilities into the York facility	Fourth Quarter 2010

Source: Unilife Corp.

Competition

Unilife may encounter competition from other medical device manufacturers as well as from large pharmaceutical and biotechnology companies that have device divisions, as these companies may develop enhanced or proprietary injectable technologies, such as injection pens suited for use with their own medications, or may offer customized development services that could compete with the Company's business model. Unilife may also be impacted by next-generation drug delivery technologies. While many injectable drug products are currently delivered either subcutaneously or intramuscularly via a needle, which the Company can address with its Unifill™ and Unifill™ Select products, some device and pharmaceutical companies are working on the development of alternatives to injections, such as needle-free technologies.

Further, there are believed to be at least 50 manufacturers of clinical plastic syringes (not prefilled) located across North America, Europe, and Asia-Pacific. Due to their simple design and low cost of manufacture, traditional plastic disposable syringes still retain distinct price advantages over newer, safer injection devices. Thus these products, while having relatively high safety and functionality disadvantages, still remain in the healthcare mainstream, particularly in developing economies.

The entities listed in Table 12 and overviewed thereafter on pages 50-51 are not intended to be an exhaustive summation of potential competitors, but are believed to be representative of the type of competition that Unilife may face as it strives to commercialize its products and technologies globally.

Table 12
Unilife Corp.
POTENTIAL COMPETITION

Company Name	Ticker (Exchange)	Last Trade (04/15/2010)	52-week Range	Avg. Vol. (3 month)	Market Cap.
Becton, Dickinson and Co.	BDX (NYSE)	$78.05	$60.40 - $80.56	1,220,590	$18.4B
Retractable Technologies, Inc.	RVP (NYSE Amex)	$1.41	$0.60 - $2.95	9,637	$33.59M
Safety Syringes, Inc.	*Closely held*	—	—	—	—
Covidien, Ltd.	COV (NYSE)	$51.82	$31.14 - $52.40	2,684,790	$25.92B
Terumo Corporation (Terumo Medical Corporation)*	4543 (TSE)	¥4,980.00	¥3,470 - ¥5,730	840,000	¥945.68B
Smiths Group plc** (Smiths Medical)	SMIN (LON)	£1,142.00	£649.00 - £1,175	1,060,080	£446B
Unilife Corp.***	UNIS (NASDAQ)	$6.30	$5.41 - $26.40	201,776	$342M
	UNS (ASX)	A$1.085	A$0.26 - A$1.78	1,045,030	A$310.1M

* Traded on the Tokyo Stock Exchange. At 04/15/2010, ¥1 = ~US$0.01.

** Traded on the London Stock Exchange. At 04/15/2010, £1 = ~US$1.54.

*** Unilife began trading as "UNIS" on NASDAQ on February 16, 2010.
For the Company's ASX listing, at 04/15/2010, A$1 = ~US$0.93.

Sources: the Tokyo Stock Exchange Group, Inc., London Stock Exchange plc, and Yahoo! Finance.

Becton, Dickinson and Company (BD)

BD is headquartered in New Jersey with offices in nearly 50 other countries worldwide. BD develops, manufactures, and sells medical supplies, devices, laboratory instruments, antibodies, reagents, and diagnostic products to healthcare institutions, life science researchers, clinical laboratories, the pharmaceutical industry, and other groups. In 1906, the BD Medical division built what was believed to be the first U.S. manufacturing facility for syringes and needles. Today, this division sells a variety of injectable products (among other medical devices), including needles, syringes, and intravenous catheters; self-injected syringes and pen needles; prefillable drug/device combination products; and disposal containers for used sharps as well as some needleless systems. BD's specific products that provide the greatest level of competition for Unilife are the BD Integra™ (a retractable syringe), the BD SafetyGlide™ (a needle guard), and the BD Preventis™ (an external sheath for prefilled syringes). The company also manufactures a range of other BD™ Pens to administer medicines such as insulin; a prefilled, disposable auto-disable injection system called BD Uniject SCF™ for intramuscular and subcutaneous injections (not a syringe); and is investigating the use of a new one-button activation disposable autoinjector for prefilled syringes called the BD Physioject™, among many other devices. Future developments may also entail microneedle devices that incorporate tiny needles roughly the diameter of a human hair. BD's target markets include hospitals, clinics, physicians' offices, consumers/retail pharmacies, public health agencies, pharmaceutical companies, and healthcare workers.

Retractable Technologies, Inc. (RTI)

RTI seeks to establish safe and reliable medical devices that reduce the worldwide spread of infectious bloodborne diseases. Based in Texas, RTI was first established in 1989 to address complaints by physicians that design engineers were insensitive and unresponsive to the daily dangers faced by frontline healthcare workers. Today, RTI produces a line of safety products under the VanishPoint® brand, which it believes virtually eliminates the risk of contaminated needlestick injuries. The primary feature of RTI's VanishPoint® devices is the company's patented friction ring mechanism, which enables automated retraction of the needle from the patient back into the device. In addition, these products are designed to be non-reusable and are intended to offer easy, single-handed activation. RTI's devices include retractable, auto-disable syringes; 1cc tuberculin, insulin, and allergy antigen VanishPoint® syringes; 3cc, 5cc, and 10cc VanishPoint® syringes; a VanishPoint® blood collection tube holder and small tube adapter; a VanishPoint® IV safety catheter; and Patient Safe™ syringes designed to reduce the risk of bloodstream infections resulting from catheter hub contamination.

Safety Syringes, Inc.

Safety Syringes was founded in 1990 and is headquartered in California. It develops anti-needlestick devices for the healthcare industry, such as prefilled pharmaceutical glass syringes and cartridges, as well as disposable plastic **hypodermic** syringes, among other products. One of Safety Syringes' primary product lines is the UltraSafe Passive® Delivery System for prefilled pharmaceutical glass syringes that are used for vaccines, **low-molecular-weight heparins (LMWHs)**, and many new biotechnology drugs, among other medicines. With this delivery system, a safety guard passively locks into place after the completion of the injection. The Company also offers a Tamper Evident UltraSafe Passive® Delivery System that seeks to prevent the counterfeiting of prefilled glass syringes, the UltraSafe Passive® Delivery System for Luer Lock and Luer Slip Syringes, an Auto Injector with the UltraSafe Passive® Delivery System, and UltraSafe® Needle Guards that attach to prefilled glass syringes. Safety Syringes' customers have included Amgen, Pfizer, and Merck, among others. In particular, Merck's human papillomavirus (HPV) vaccine, Gardasil®, is supplied in vials as well as in single-dose prefilled Luer Lock syringes pre-assembled with the UltraSafe Passive® Delivery System. Safety Syringes also began collaborating with Ypsomed Holding AG (YPSN-SWX) in April 2005 for the use of Ypsomed's reusable autoinjector with Safety Syringes' UltraSafe Passive® Delivery System.

Covidien, Ltd.

In 2007, Tyco Healthcare—a global manufacturer of medical devices and supplies, diagnostic imaging agents, and pharmaceuticals—separated from Tyco International Ltd. (TYC-NYSE) and changed its name to Covidien, Ltd. Covidien operates in three strategic business segments: (1) medical devices; (2) pharmaceuticals; and (3) medical supplies. Covidien's Kendall brand manufactures and distributes medical products used in various clinical settings, such as healthcare facilities and in patients' homes, and includes a line of sharp safety products. The company's line of Monoject™ safety syringes is compliant with OSHA's BPS for engineering controls, as each syringe includes a safety shield that locks into place in two steps to prevent accidental needlestick injuries during transport and disposal. Also under the Kendall brand, Covidien has developed Magellan™ Safety Needle and Syringe Combinations to protect healthcare workers from needlestick injuries. Magellan™ syringes incorporate a needle-based safety device that is intended to keep clinicians safe while providing clinical flexibility.

Terumo Medical Corporation (TMC)

Parented by the Terumo Corporation, TMC manufactures, exports, imports, and markets a variety of medical devices, supplies, and accessories. The company's North American headquarters are located in Somerset, New Jersey. The majority of TMC's products and devices are produced at its Elkton, Maryland, facility, which spans over 321,000 ft^2 and uses automated processes with a quality system that is certified to be in compliance with ISO 13485. TMC's devices are intended to offer solutions for healthcare providers that comply with the latest OSHA requirements for sharps devices with a built-in safety feature. Specifically, to reduce the number of accidental needlestick injuries, TMC has developed SurGuard2™ Syringes with Safety Needles, which incorporate a needle-locking mechanism. To ensure that this mechanism has been activated and the needle is locked into place, the operator is signaled by an audible click.

Smiths Medical

A division stemming from the UK-based Smiths Group plc, Smiths Medical is a global provider of medical devices for healthcare facilities as well as home and specialist environments. Smiths Medical has headquarters in London, England, and companies in Europe, North America, South Africa, Japan, and the Pacific region. Smiths Medical provides a wide range of safety devices for blood collection applications, such as venipuncture, winged needle draws, closed system procedures, syringe draws and needle-less transfer, lancet sampling, and arterial blood sampling. Under its Jelco™ division, the company has developed a line of sharps safety products that include the Needle-Pro® device. To reduce the risk of needlestick injuries, the company has added a patented, hinged sheath to the device in order to minimize the amount of time that the clinician is exposed to the needle. Smiths Medical has utilized the Needle-Pro® device as the basis of a range of needles that include applications for medication delivery, tuberculosis testing, insulin and allergy injections, immunizations, and **venous blood draws**.

Milestones

Over the past 12 months, Unilife has achieved key milestones that have served to better position the Company within the drug delivery and medical device markets, particularly at the corporate level. As such, the industrialization program for the Unifill™ Syringe is one year ahead of its original schedule and the Company believes that it can deliver on a number of objectives during 2010.

Recent Milestones

- April 2009: Completed the transition of Unilife's headquarters to the U.S.
- June 2009: Entered into an Industrialization Agreement with sanofi-aventis
- August 2009: Began U.S. production of the Unitract™ 1mL Syringes
- September 2009: Proposed a redomiciliation to the U.S. with trading on NASDAQ stock exchange
- October 2009: Received an $5.2 million package from the Pennsylvania government
- November 2009: Filed an Information Memorandum (Australian Securities and Investments Commission [ASIC]) and Form 10 (SEC) documents; Completed a $53.6 million capital raise; Appointed Mikron Group as an assembly line partner for Unifill™ production; Filed patents for a new pipeline prefilled syringe, the Unifill™ Select
- December 2009: Signed agreements for the construction of a new global headquarters and commercial production facility in York, Pennsylvania
- January 2010: Completed the final stage of its redomiciliation in the U.S.
- February 2010: Form 10 filed with the SEC declared effective; Commenced trading on NASDAQ stock exchange under the ticker "UNIS"; Donated its first shipment of Unitract™ 1mL safety syringes to Doctors Without Borders to support ongoing relief efforts in Haiti
- March 2010: Signed an Exclusivity List with sanofi-aventis for the Unifill™ syringe incorporating therapeutic areas including antithrombotics and vaccines; Entered into an exclusive five-year contract with Stason for the distribution of the Unitract™ 1mL syringe within Japan, Taiwan, and China, which included the placement of an order for one million units during the first year and an additional one million units during subsequent years of the contact
- April 2010: Received FDA clearance for U.S.-manufactured units of the Unitract™ 1mL Insulin Syringe and a subsequent change to four-shift, 24/7 operations at its Lewisberry facility

Potential Milestones

- Unilife expects to complete construction of its York, Pennsylvania, facility in late 2010.
- The Company aims to employ approximately 200 individuals by the end of 2010.
- The industrialization program with sanofi-aventis is on track to be completed one year ahead of schedule (during late 2010). Supply of the Unifill™ Syringe to sanofi-aventis could begin upon the completion of the industrialization program, with a high-volume automated assembly system expected to be established by the end of 2011.
- During 2010, the Company expects to begin to formalize additional relationships with a number of other pharmaceutical companies that wish to use the Unifill™ Syringe in areas not designated as exclusive to sanofi-aventis.
- Unilife intends to begin full commercial supply of its Unitract™ 1mL Syringes during the first half of 2010 and to secure further distribution agreements for this line of syringes in the U.S. and overseas.

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. Unilife has received milestone payments of €13 million from sanofi-aventis to date. The Company expects initial manufacturing capacity for Unifill™ to be 60 million units by late 2010, with annual production reaching 450 million units beyond 2014.
    - Unilife retains the right to supply Unifill™ to other third parties for use in therapeutic drug classes that are not exclusively designated to sanofi-aventis under the Exclusivity List signed in March 2010. Unilife anticipates entering into additional supply agreements for Unifill™ throughout 2010.
- Unilife has received regulatory clearances for its Unitract™ 1mL Insulin Syringe in the U.S., Canada, Europe, and Australia. Production of the Insulin Syringe began in August 2009 at the Company's FDA-registered and ISO 13485-certified Pennsylvania facility. Unilife intends to launch the Unitract™ 1mL Syringes across key international markets during 2010, and the first shipment of these syringes (in February 2010) was donated to Doctors Without Borders in support of Haitian relief efforts.
- Unilife has a wholly owned, U.S.-based medical device manufacturing subsidiary with expertise developing automated assembly systems. It brings key industrial and engineering requirements in-house. The subsidiary's expertise in the development of pilot production systems for Unifill™ had a key role in the signing of the Exclusive Licensing Agreement with sanofi-aventis.
- Unilife has attracted world-class medical device and pharmaceutical experts to its team, including the World Health Organization's former head of medical devices, who was responsible for developing global standards for single-use syringes, and the senior vice president of operations for Bayer AG.
- The Company has 26 issued patents in 14 countries; pending patent applications in the U.S., Australia, and under the Patent Cooperation Treaty (PCT); registered trademarks; and trade secrets.
- To date in 2010, Unilife redomiciled from Australia to the U.S. and commenced trading on NASDAQ—moves that support the Company's ongoing expansion activities. At December 31, 2009, Unilife had cash of over $41 million after raising ~$47.5 million in U.S. and Australian markets during November 2009 and securing a $5.2 million offer from the Pennsylvania government in October 2009.

Historical Financial Results

Tables 13, 14, and 15 provide a summary of Unilife's key historical financial data for the three and six months ended December 31, 2009—its Condensed Consolidated Statements of Operations, Balance Sheets, and Statements of Cash Flows.

Table 13
Unilife Corporation and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

	Three Months Ended December 31,		Six Months Ended December 31,	
	2009	2008	2009	2008
Revenues	$ 3,245	$ 5,822	$ 6,353	$ 8,127
Cost of sales	707	1,042	1,572	2,173
Gross profit	2,538	4,780	4,781	5,954
Operating expenses:				
Research and development	287	216	686	347
Selling, general, and administrative	7,517	5,241	11,259	7,663
Depreciation and amortization	776	155	1,031	299
Total operating expenses	8,580	5,612	12,976	8,309
Operating loss	(6,042)	(832)	(8,195)	(2,355)
Interest expense	14	106	61	231
Interest income	(252)	(165)	(257)	(285)
Other (income) expense, net	111	88	(20)	176
Net loss	$ (5,915)	$ (861)	$ (7,979)	$ (2,477)
Loss per share:				
Basic loss per share	$ (0.13)	$ (0.03)	$ (0.19)	$ (0.07)
Diluted loss per share	$ (0.13)	$ (0.03)	$ (0.19)	$ (0.07)

Source: Unilife Corp.

Table 14

Unilife Corporation and Subsidiaries

CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands, except share data)

(unaudited)

	December 31, 2009	June 30, 2009
Assets		
Current Assets:		
Cash and cash equivalents	$ 41,354	$ 3,627
Accounts receivable	2,376	7,333
Inventories	1,398	1,097
Prepaid expenses and other current assets	538	223
Total current assets	45,666	12,280
Property, plant, and equipment, net	15,936	9,137
Goodwill	11,235	10,235
Intangible assets, net	45	43
Other assets	196	517
Total assets	$ 73,078	$ 32,212
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,454	$ 1,103
Accrued expenses	908	6,097
Current portion of long-term debt	405	405
Deferred revenue	2,932	2,642
Total current liabilities	5,699	10,247
Long-term debt, less current portion	2,499	2,728
Deferred revenue	7,330	7,926
Total liabilities	15,528	20,901
Commitments and contingencies		
Stockholders' Equity:		
Preferred Stock, $0.01 par value, 50,000,000 shares authorized as of December 31, 2009; none issued or outstanding as of December 31, 2009 and June 30, 2009	—	—
Common Stock, $0.01 par value, 250,000,000 shares authorized as of December 31, 2009; 51,784,437 and 36,625,802 shares issued and outstanding as of December 31, 2009 and June 30, 2009, respectively	518	366
Additional paid-in-capital	113,430	57,987
Accumulated deficit	(57,881)	(49,902)
Accumulated other comprehensive income	1,483	2,860
Total stockholders' equity	57,550	11,311
Total liabilities and stockholders' equity	$ 73,078	$ 32,212

Source: Unilife Corp.

Table 15

Unilife Corporation and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands)

(unaudited)

	Six Months Ended December 31,	
	2009	2008
Cash flows from operating activities:		
Net loss	$ (7,979)	$ (2,477)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,300	352
Share-based compensation expense	771	2,298
Loss on sale of property, plant, and equipment	113	—
Changes in assets and liabilities		
Accounts receivable	5,470	(1,884)
Inventories	(301)	273
Prepaid expenses and other current assets	(294)	(258)
Other assets	319	(202)
Accounts payable	319	(60)
Accrued expenses	117	(735)
Deferred revenue	(1,429)	11,051
Net cash (used in) provided by operating activities	(1,594)	8,358
Cash flows from investing activities		
Purchases of property, plant, and equipment	(7,562)	(361)
Net cash used in investing activities	(7,562)	(361)
Cash flows from financing activities		
Proceeds from the issuance of long-term debt	—	88
Proceeds from the issuance of Common Stock, net of issuance costs	47,117	—
Proceeds from the exercise of Options to purchase Common Stock	1,817	38
Principal payments on long-term debt	(248)	(3,198)
Net cash provided by (used in) financing activities	48,686	(3,072)
Foreign currency exchange on cash	(1,803)	(292)
Net increase in cash and cash equivalents	37,727	4,633
Cash and cash equivalents at beginning of period	3,627	2,887
Cash and cash equivalents at end of period	$ 41,354	$ 7,520
Supplemental disclosure of cash flow information		
Supplemental disclosure of non-cash activities		
Conversion of Convertible Notes into Common Stock	—	$ 75
Issuance of Common Stock to former shareholders	$ 5,890	—

Source: Unilife Corp.

Risks

Some of the information in this Executive Informational Overview® (EIO®) 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, its Form 10 filed with the SEC, 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.

Investors should carefully consider the risks and information about Unilife's business described below. Investors should not interpret the order in which these considerations are presented as an indication of their relative importance. The risks and uncertainties described below are not the only risks that the Company faces. Additional risks and uncertainties not presently known to Unilife or that the Company currently believes to be immaterial may also adversely affect its business. If any of the following risks and uncertainties develops into actual events, the business, financial condition, and results of operations could be materially and adversely affected, and the trading price of the Company's shares could decline.

RISKS RELATING TO UNILIFE'S BUSINESS

Unilife's success depends in large part on its ability to finalize the design of and complete the industrialization program for its primary product, the Unifill™ Syringe. If the Company experiences problems or delays in completing these activities, its business, including its ability to generate significant revenues, will be materially and adversely affected.

The Company commenced the industrialization program for the Unifill™ Syringe in July 2008 and expects to finalize the design of and complete the industrialization program for the product, as well as the development of production systems to support its manufacture and commercial sale, by the end of calendar year 2010. Since the Unifill™ Syringe is Unilife's primary product, any failure or significant delay in completing these activities could materially harm Unilife's business and ability to generate any significant amount of revenues for the foreseeable future. The Company does not expect that its existing contract manufacturing business will generate significant revenues in the future. In addition, Unilife's contract with B. Braun expired on December 31, 2009, and while the Company and B. Braun continue to operate under the contract, there is no assurance that the Company will be able to renew this contract on favorable terms, if at all.

Unilife's business is substantially dependent on its relationship with its strategic partner, sanofi-aventis, which is funding the industrialization program for the Unifill™ Syringe, and Unilife's revenues from other sources are not significant.

To date, the Company has derived a substantial majority of revenues from its exclusive licensing and industrialization agreements with sanofi-aventis. For the year ended June 30, 2009, Unilife's revenues from these agreements were $16.1 million, which represented 81% of its revenues for the period. The Company expects that revenues from sanofi-aventis will continue to account for a substantial majority of revenues at least through the end of calendar 2010, which is when the Company expects to complete the industrialization program for the Unifill™ Syringe. In addition, the Company will need to negotiate successfully with sanofi-aventis to finalize a supply agreement for the Unifill™ Syringe. Even if the Company finalizes this agreement and commences commercial sales to sanofi-aventis, it expects that sanofi-aventis will be the most significant customer (at least until the exclusive period terminates) and that revenues from sanofi-aventis will continue to account for a substantial majority of Unilife's revenues and cash flows from operations. Any termination or material breach of the existing agreements between sanofi-aventis and the Company, any failure to successfully negotiate a supply agreement, or any failure to perform under any supply agreement that the Company does negotiate, would be likely to materially and adversely affect Unilife's business.

Unilife's R&D and other operating expenses are significant and the Company does not expect to be profitable unless and until it completes the industrialization program, negotiates a supply agreement with sanofi-aventis or other pharmaceutical companies, and begins commercial sale of the Unifill™ Syringe.

The Company has incurred and will continue to incur significant R&D expenses for the completion of the industrialization program for the Unifill™ Syringe, as well as for the development of other product variants of Unilife's technology, such as the Unitract™ Clinical Range of larger syringe sizes. The Company will also incur general and administrative expenses related to increasing manufacturing operations, expanding sales and marketing capabilities, seeking regulatory approvals, and complying with the requirements related to being a public company in both the U.S. and Australia. The Company will not be profitable unless it is successful in developing and commercializing the Unifill™ Syringe and other new products, obtaining regulatory approvals, and manufacturing, marketing and selling commercial products.

The Unifill™ Syringe has been designed to be compatible with the drug manufacturing systems currently utilized by sanofi-aventis, which may hinder Unilife's ability to sell the product to other pharmaceutical customers having manufacturing processes that may not be compatible with Unilife's current product designs.

The Unifill™ Syringe has been designed to be compatible with the drug filling and packaging systems of sanofi-aventis. 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-aventis. Furthermore, pharmaceutical companies may in some cases require the use of materials that are biocompatible with a particular drug compound and to which the Company does not have access. Such events may require design, material, or process changes to Unilife's product, or restrict Unilife's ability to enter into supply relationships with other pharmaceutical companies, and accordingly may have a material adverse effect on Unilife's results of operations and financial condition.

Unilife's ability to successfully market and sell its safety syringes outside of the pharmaceutical market may be impaired until the Company is able to offer a full range of safety syringes in sizes commonly used in acute care facilities.

In addition to the Unifill™ Syringe, Unilife's product portfolio includes the Unitract™ 1mL Syringe, a plastic syringe that the Company refers to as a clinical syringe. Acute care hospitals are the largest single healthcare market for clinical syringes. These facilities use a range of clinical syringes, including 1mL, 3mL, and 5mL sizes, for the subcutaneous and intramuscular administration of therapeutic drugs and vaccines. The Company has completed development and secured regulatory approvals only for the marketing and sale of Unilife's Unitract™ 1mL syringe. While the Company intends to market the Unitract™ 1mL syringe to other healthcare sectors in addition to acute care facilities, Unilife's ability to market and sell safety syringes successfully may be impaired until it is able to offer clinical syringes in a full range of sizes.

Unilife's success will depend on the full commercialization of its current products and the development and commercialization of other pipeline products. There can be no assurance that the Company will be successful in these efforts.

A significant element of Unilife's strategy focuses on developing products that deliver greater benefits to pharmaceutical companies, healthcare workers, and patients. The development of these products requires significant R&D, clinical evaluations, and regulatory approvals. The results of Unilife's product development efforts may be affected by a number of factors, including the Company's 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 Unilife's commercialization of a product. There can be no assurance that any products now in development, or that the Company may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval, or gain market acceptance.

The Company needs substantial additional funding and may be unable to raise capital when needed, which would force it to delay, reduce, or eliminate efforts in developing its new manufacturing facility and in product development or commercialization programs.

The Company is in the process of developing a new manufacturing facility in central Pennsylvania. The Company estimates the total cost to be approximately $26 million. The Company intends to internally fund $9 million of the cost and seek external financing for up to $17 million. Although Unilife currently believes that its current cash resources, together with anticipated cash flows, will be sufficient to fund operations (other than the development of the new manufacturing facility, which the Company expects to finance in part with proceeds of external financing) through at least the end of fiscal 2010, Unilife may also need to obtain additional funding in the future for product development programs and commercialization efforts. In particular, if the amount of funding that sanofi-aventis has agreed to provide to the Company under the Industrialization Agreement is insufficient to complete the industrialization program for the Unifill™ syringe, the Company may need to obtain additional funding unless sanofi-aventis were to agree to provide additional funding, which it has no obligation to provide. The Company cannot offer assurance that it will be able to raise capital when needed on favorable terms, or at all. If the Company raises additional funds from debt financing, it may be obligated to abide by restrictive covenants contained in the debt financing agreements, which may make it more difficult to operate Unilife's business. If the Company raises additional funds through the issuance of equity securities, its shares of Common Stock may suffer dilution. If the Company is unable to secure additional funding when needed, Unilife's ability to develop the new manufacturing facility and continue in product development and commercialization programs would be delayed, reduced, or eliminated.

The Company may encounter difficulties managing growth, which could materially harm business.

Unilife expects to expand operations and grow R&D, product development, regulatory, manufacturing, sales, marketing, and administrative operations. This expansion has placed, and is expected to continue to place, a significant strain on management, operational, and financial resources. To manage growth and to develop and commercialize products, the Company will be required to improve existing, and implement new, operational and financial systems, procedures, and controls and expand, train, and manage its growing employee base. In addition, the Company will need to manage relationships with various manufacturers, suppliers, customers, and other organizations. Unilife's ability to manage operations and growth will require the Company to improve operational, financial, and management controls, as well as internal reporting systems and controls. The Company may not be able to implement such improvements to management information, disclosure controls, and procedures and internal control systems in an efficient and timely manner and may discover deficiencies in existing systems and controls. Unilife's failure to accomplish any of these tasks could materially harm its business.

The Company depends on its executive officers and key personnel and the loss of these individuals could adversely affect its business.

Unilife's success depends upon the efforts and abilities of its executive officers and other key personnel, particularly Mr. Alan Shortall, chief executive officer (CEO), to provide strategic direction, manage Unilife's operations, and maintain a cohesive and stable environment. Although the Company has employment agreements with Mr. Shortall and other key personnel, as well as incentive compensation plans that provide various economic incentives for them to remain with the Company, these agreements and incentives may not be sufficient to retain them. Unilife's ability to operate successfully and manage potential future growth also depends significantly upon its ability to attract, retain, and motivate highly skilled and qualified research, technical, clinical, regulatory, sales, marketing, managerial, and financial personnel. The Company faces intense competition for such personnel and it may not be able to attract, retain, and motivate these individuals. The loss of Unilife's executive officers or other key personnel for any reason or Unilife's inability to hire, retain, and motivate additional qualified personnel in the future could prevent the Company from sustaining or growing its business. In addition, the Company has a limited history of operations under Unilife's current officers and directors. Unilife's officers have not worked together for an extensive length of time. If for any reason Unilife's management members cannot work efficiently as a team, Unilife's business will be adversely affected.

The Company will incur increased costs as a result of being a U.S. reporting company and has no experience as a U.S. reporting company.

Upon the effectiveness of its registration statement, the Company became subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Although Unilife Medical Solutions Ltd. (UMSL) has been listed on the ASX for several years and has been required to file financial information and make certain other filings with the ASX, Unilife's status as a U.S. reporting company under the Exchange Act will cause the Company to incur additional legal, accounting, and other expenses that it has not previously incurred, including costs related to compliance with the requirements of the Sarbanes-Oxley Act of 2002. The Company expects these rules and regulations to increase its legal and financial compliance costs and to make some activities more time consuming and costly. It cannot predict the additional costs that it may incur or the timing of such costs.

If Unilife's internal control over financial reporting or disclosure controls and procedures are not found to be effective by management or by an independent registered public accounting firm or if the Company makes disclosure of existing or potential significant deficiencies or material weaknesses in those controls, investors could lose confidence in its financial reports, the price of its shares of Common Stock may decline, and it may be subject to increased risks and liabilities.

By becoming a U.S. reporting company, the Company becomes subject to the Sarbanes-Oxley Act of 2002 and applicable rules and regulations thereunder. Section 404 of the Sarbanes-Oxley Act will require that the Company include a report of management on Unilife's internal control over financial reporting and a report of Unilife's independent registered public accounting firm on the effectiveness of Unilife's internal control over financial reporting in the Company's Annual Report on Form 10-K beginning with Unilife's Annual Report for the fiscal year ending June 30, 2011. The Company will also have to include quarterly reports and certifications of management regarding the effectiveness of disclosure controls and procedures. Unilife's management may conclude that its internal control over financial reporting is not effective. Moreover, even if Unilife's management concludes that internal control over financial reporting is effective, Unilife's independent registered public accounting firm, after conducting its own independent review, may issue a report that is qualified if it is not satisfied with Unilife's internal controls or the level at which Unilife's internal controls are documented, designed, operated, or reviewed, or if it interprets the relevant requirements differently from the way the Company interprets them. Unilife's management may also conclude that its disclosure controls and procedures are not effective.

If the Company fails to achieve and maintain an effective internal control environment and disclosure controls and procedures, it could suffer material misstatements in its financial statements and other information it reports and could fail to meet reporting obligations, which would likely cause investors to lose confidence in Unilife's reported financial and other information. This could lead to a decline in the trading price of Unilife's shares of Common Stock. Additionally, ineffective internal control over financial reporting could expose the Company to increased risk of fraud or misuse of corporate assets and subject it to potential delisting from NASDAQ, regulatory investigations, and civil or criminal sanctions.

The Company has limited sales, marketing, and distribution experience.

The Company has a small internal team to support the training of appointed distributors in the marketing and clinical use of Unitract™ 1mL syringes. Although the Company intends to expand this team as it commences sales of Unitract™ 1mL syringes, appoints additional distributors, and commercializes larger-sized clinical syringes, the Company will have to devote significant financial and management resources to this effort. In developing sales, marketing, and distribution functions, the Company could face a number of risks, including the following:

- it may not be able to attract and build a significant marketing or sales force;
- the cost of establishing, training, and providing regulatory oversight for a marketing or sales force may be substantial; and
- there are significant legal and regulatory risks in medical device marketing and sales, and any failure to comply with all legal and regulatory requirements for sales, marketing, and distribution could result in enforcement action by the FDA or other authorities that could jeopardize Unilife's ability to market its product(s) or could subject the Company to substantial liability.

The Company has outsourced the development of automated assembly systems for the Unifill™ Syringe to Mikron Assembly Technology, a third-party contractor. Unilife's ability to commercialize the Unifill™ Syringe will be dependent on the ability of this contractor to provide these systems according to specifications and in a timely manner.

The Company has outsourced the development of automated assembly systems for the Unifill™ Syringe to Mikron Assembly Technology, a third-party equipment manufacturer. The development of a pilot system with a target production capacity of approximately 60 million units per year began in December 2009 with completion and installation scheduled for the fourth quarter 2010. Additional assembly lines with higher annual manufacturing capacity are expected to commission and operate beyond 2010. The failure of this company to supply automated assembly systems that meet contracted specifications in a timely manner will significantly impair Unilife's business activities and the completion of the industrialization program.

If Unilife experiences delays in developing its new manufacturing facility, its ability to produce the Unifill™ Syringe in commercial quantities would be impaired, which would harm business. In addition, all of Unilife's current commercial and production activity occurs in one facility, which subjects the Company to risk if it were to experience a catastrophic event at this facility.

The Company has a 50,000 square foot, FDA-registered, medical device production facility in Lewisberry, Pennsylvania, for the production of the 1mL syringes and for the future production of the Unifill™ Syringe. However, the Company will need to expand manufacturing capabilities in order to produce the Unifill™ Syringe and other products in the quantities that may be necessary to meet anticipated market demand. The Company is in the process of developing additional manufacturing facilities in central Pennsylvania in conjunction with Keystone Redevelopment Group LLC, a Pennsylvania-based real estate company. The Company may not successfully complete the development of the new manufacturing facility in a timely manner, or at all. If the Company is unable to do so, it may not be able to produce products in sufficient quantities to meet the requirements for the launch of the products or to meet future demand, if at all.

In addition, because all of Unilife's operations are currently conducted out of its Lewisberry facility, a catastrophic event, such as fire, natural disaster, pandemic, war, terrorism, labor disruption, or governmental actions taken in response to such an event, could severely disrupt business activities and adversely affect Unilife's results of operations and financial condition.

Unilife's manufacturing facilities and its suppliers' manufacturing facilities must comply with applicable regulatory requirements. If these manufacturing facilities fail to achieve or maintain regulatory approval, Unilife's business and results of operations would be harmed.

Commercialization of Unilife's products requires access to, or the development of, manufacturing facilities that meet applicable regulatory standards to manufacture a sufficient supply of Unilife's products. In addition, the FDA must approve facilities that manufacture Unilife's products for U.S. commercial purposes, as well as the manufacturing processes and specifications for the product. Suppliers of components of, and products used to manufacture, Unilife's 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 the Company and its suppliers to potential regulatory inspections and stoppages. The Company and its suppliers may not satisfy these requirements. If the Company or its suppliers do not achieve or maintain required regulatory approval for manufacturing operations, Unilife's commercialization efforts could be delayed, which would harm business and results of operations.

The costs of raw materials have a significant impact on the level of expenses that the Company incurs. If the prices of raw materials and related factors (e.g., energy prices) increase, and the Company cannot pass those price increases on to its customers, Unilife's results of operations and financial condition would suffer.

The Company uses 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 the Company would generally attempt to pass along increased costs to customers in the form of sales price increases, the Company might not be able to do so for competitive or contract-related reasons or otherwise. If it could not set prices to reflect the costs of raw materials, Unilife's results of operations and financial condition would suffer.

Disruptions in the supply of key raw materials and difficulties in the supplier qualification process could adversely impact Unilife's operations.

Unilife employs a supply chain management strategy that seeks to source components and materials from a number of established third parties. Where possible, the Company seeks to establish dual supply contracts for particular components or services. However, there is a risk that Unilife's supply lines may be interrupted in the event of a supplier production problem, material recall, or financial difficulties. If one of Unilife's suppliers is unable to supply materials required for production of Unilife's products or Unilife's strategies for managing these risks are unsuccessful, the Company 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 Unilife's 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 Unilife's results of operations, financial condition, or cash flows.

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

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

The medical device industry is very competitive.

Competition in the medical device industry is intense. The Company faces this competition from a 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 the Company does. Unilife's ability to compete effectively depends upon its ability to distinguish its company and products from its competitors and competitors' products. Factors affecting Unilife's 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.

The Company may be adversely impacted by next-generation drug delivery technologies.

Much of Unilife's potential sales and potential profitability depends to a large extent on the sale of drug products delivered by subcutaneous or intramuscular injection. Other device 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. The development of new or improved products, processes, or technologies by other companies may render Unilife's products or proposed products obsolete or less competitive. If the products developed in the future by Unilife's customers or potential customers use another delivery system, Unilife's sales and potential profitability could suffer. Furthermore, the Company will be largely reliant upon the receipt of revenues from the sale of the Unifill™ and 1mL syringes and will not have the benefit of diversification.

The Company is subject to extensive regulation.

Unilife is subject to regulation by the FDA pursuant to the FDC Act, by comparable agencies in other countries, and by other regulatory agencies and governing bodies. Its products must receive clearance or approval from the FDA or counterpart non-U.S. regulatory agencies before they can be sold. The process for obtaining marketing approval or clearance may take significant time and require substantial resources. The process may also require changes to Unilife's products or result in limitations on the indicated uses of the products. As a result, Unilife's expectations with respect to marketing approval or clearance may prove to be inaccurate and the Company may not be able to obtain marketing approval or clearance in a timely manner or at all. For example, the Company has experienced two recent delays in its ability to commence commercial sales of U.S.-manufactured stock of Unitract™ 1mL syringes due to the delay in obtaining the FDA clearance. In addition, regulatory requirements outside of 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 manufacturing processes and product performance. Failure to comply with applicable Good Manufacturing Practices (GMP), adverse event reporting, clinical trial, and other requirements could delay or prevent the production, marketing, or sale of products and result in fines, delays, or suspensions of regulatory clearances, closure of manufacturing sites, seizures or recalls of products, and damage to Unilife's reputation.

Unilife is subject to government regulation worldwide. If these regulations are not complied with, existing and future operations may be curtailed and Unilife could be subject to liability.

The design, development, manufacturing, marketing, and labeling of Unilife's products are subject to regulation by authorities in the U.S., Europe, and other countries. 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. Unilife's business may be adversely affected by changes in the regulation of drug products and medical devices.

Unilife's 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 Unilife's customers' injectable drug products and manufacturing processes is that compliance with regulations makes it costly and time consuming to transition to the use of Unilife's devices for existing products or to secure approval for pipeline products targeted for use with Unilife's devices. If regulation of Unilife's customers' products incorporating Unilife's devices increases over time, it is likely that this would adversely affect the Company's sales and profitability.

Product defects could adversely affect the results of the Company's operations.

The design, manufacture, and marketing of medical devices involve certain inherent risks. Manufacturing or design defects, unanticipated use of Unilife's 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 Unilife's 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 Unilife's reputation that could reduce demand for the Company's products. Personal injuries relating to the use of the Company's products can also result in product liability claims being brought against Unilife. In some circumstances, such adverse events could also cause delays in new product approvals.

The Company may be sued for product liability, which could adversely affect its business.

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

The Company may not be able to effectively protect intellectual property rights, which could have an adverse effect on its business, financial condition, or results of operations.

Unilife's success depends in part on its ability to obtain and maintain protection in the U.S. and other countries of the intellectual property relating to or incorporated into its technology and products. Unilife's intellectual property portfolio includes, in addition to trademarks and trade secrets, 24 issued patents in 13 countries, a significant number of patent applications pending in the U.S., Australia, and the countries covered under the Patent Cooperation Treaty (PCT). Unilife's patents expire at various dates between

2018 and 2028. Unilife's pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide the Company with any competitive advantage. Even if issued, existing or future patents may be challenged, narrowed, invalidated, or circumvented, which could limit Unilife's ability to stop competitors from marketing similar products or limit the length of terms of patent protection the Company may have for its products. Changes in patent laws or their interpretation in the U.S. and other countries could also diminish the value of Unilife's intellectual property or narrow the scope of 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 rights to the same extent as the laws of the U.S. As such, Unilife's patent portfolio may not provide sufficient rights to exclude others from commercializing similar or identical products. In order to preserve and enforce patent and other rights, the Company may need to make claims or file lawsuits against third parties. This can entail significant costs and divert management's attention from developing and commercializing products.

Intellectual property litigation could be costly and disruptive to the Company.

The retractable syringe product lines in which the Company competes are relatively new inventions with numerous companies having patents. In recent years, there have been several patent infringement suits involving other industry participants. To date, Unilife has not been subject to any such patent infringement suits and holds Freedom to Operate (FTO) reports that it believes indicate that its technology and associated products are substantially different from other known patents. There is no assurance, however, that third parties will not assert any patent, copyright, trademark, and other intellectual property rights to technologies used in Unilife's business. Any claims, with or without merit, could be time consuming, result in costly litigation, divert the efforts of Unilife's technical and management personnel, or require the Company to pay substantial damages. If the Company is unsuccessful in defending against these types of claims, it may be required to do one or more of the following:

- delay or abandon 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; or
- redesign those products that use the relevant technology.

If the Company is unable to protect the confidentiality of its proprietary information and know-how, the value of its technology and products could be adversely affected.

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

Impairment of Unilife's goodwill, which represents a significant portion of its total assets, would adversely affect net income and the Company may never realize the full value of its goodwill.

A substantial portion of Unilife's assets is composed of goodwill, which the Company recorded as a result of acquisition activities. Goodwill is subject to, at a minimum, an annual impairment assessment of its carrying value. Goodwill impairment is deemed to possibly exist if the net book value of a reporting unit exceeds its estimated fair value. Any material impairment of Unilife's goodwill would likely have a material adverse impact on Unilife's results of operations and financial condition.

Fluctuations in foreign currency exchange rates could adversely affect Unilife's financial condition and results of operations.

Currently, the majority of Unilife's revenues are derived from payments under the Industrialization Agreement with sanofi-aventis, which provides that sanofi-aventis will pay the Company in euros, while the Company incurs most of Unilife's operating expenses in U.S. dollars or Australian dollars. Changes in

foreign currency exchange rates can affect the value of Unilife's assets and liabilities and the amount of Unilife's revenues and expenses. The Company does not currently try to mitigate exposure to currency exchange rate risks by using hedging transactions. The Company cannot predict future changes in foreign currency exchange rates and, as a result, may suffer losses as a result of future fluctuations.

RISK FACTORS RELATED TO SHARES OF UNILIFE'S COMMON STOCK

An active trading market for Unilife's shares of Common Stock in the U.S. may not develop and the trading price of Unilife's shares of Common Stock may fluctuate significantly.

Unilife's shares have not been previously listed on any U.S. securities exchange and there has been only a limited trading market in Unilife's shares in the U.S. If an active trading market does not develop in the U.S., the market price and liquidity of Unilife's shares may be adversely affected. Prior to the redomiciliation that was completed on January 27, 2010, the ordinary shares of UMSL were traded on the ASX. After the redomiciliation, Unilife Corp. replaced UMSL as the listed entity on the ASX and its shares of Common Stock are now traded on the ASX in the form of CHESS Depositary Interests (CDIs). It is possible that the development of an active trading market in the U.S. may be adversely impacted by the existence of a trading market for CDIs in Australia.

The price of UMSL's ordinary shares on ASX has been volatile and it is likely that the price of Unilife's shares and CDIs, on both NASDAQ and the ASX, may also 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 Unilife's operating performance or prospects. The trading price of Unilife's Common Stock could fluctuate significantly for many reasons, including the following:

- future announcements concerning Unilife's business and that of Unilife's competitors, in particular including the progress of the industrialization program for the Unifill™ Syringe;
- regulatory developments, enforcement actions bearing on advertising, marketing, or sales of Unilife's current or pipeline products;
- quarterly variations in operating results;
- introduction of new products or changes in product pricing policies by the Company or 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 Unilife's shares of Common Stock, the Company's share price could decline.

As of February 3, 2010, the Company had 53,783,769 shares of Common Stock issued and outstanding. All of those shares of Common Stock other than approximately 4,422,142 shares held by Unilife's affiliates will be freely tradable under the Securities Act. Commencing 90 days after the effectiveness of the Company's registration statement, shares held by Unilife's affiliates are eligible for resale pursuant to Rule 144. If Unilife's stockholders sell a large number of shares of Common Stock or the public market, should one develop, perceives that Unilife's stockholders might sell a large number of shares, the prices at which Unilife's Common Stock trades could decline significantly.

In addition, as of the date of this registration statement, 10,430,422 shares of Unilife's Common Stock are subject to outstanding Stock Options. The Company plans to file a registration statement on Form S-8 to cover the issuance of approximately 9,862,500 shares of its Common Stock that are issuable upon the exercise of outstanding Options or Options that may be issued in the future under Unilife's employee benefit plans. The Company may also file a registration statement on Form S-1 or another appropriate form to cover the resale of shares of Unilife's Common Stock that are issuable upon the exercise of options not eligible for inclusion in a registration statement on Form S-8. Even if no such registration statement is filed, the shares of Unilife's Common Stock issuable upon the exercise of Options may be sold in reliance upon Rule 144 or another exemption from registration. The exercise of those Options may have a dilutive effect on current stockholders and if those parties exercising their Options choose to sell their shares, it could have an adverse effect on the market price for Unilife's shares.

The Company does not intend to pay cash dividends in the foreseeable future.

For the foreseeable future, the Company does not intend to declare or pay any dividends on Unilife's Common Stock. The Company intends to retain its earnings, if any, to finance the development and expansion of its business and product lines. Any future decision to declare or pay dividends will be made by the Board of Directors and will depend upon a number of factors, including financial condition and results of operations. In addition, under Unilife's current bank financing agreements, the Company is not permitted to pay cash dividends without the prior written consent of the lender.

The Company may be subject to arbitrage risks.

Investors may seek to profit by exploiting the difference, if any, in the price of Unilife's shares of Common Stock on NASDAQ and on the ASX. Such arbitrage activities could cause Unilife's stock price in the market with the higher value to decrease to the price set by the market with the lower value.

Unilife's certificate of incorporation, bylaws, the Delaware General Corporation Law, and the terms of Unilife's Industrialization Agreement with sanofi-aventis may delay or deter a change of control transaction.

Certain provisions of Unilife's certificate of incorporation and bylaws may have the effect of deterring takeovers, such as those provisions authorizing the 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 66 - $^{2}/_{3}$ % majority stockholder approval in order for stockholders to amend Unilife's 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 Unilife's Board of Directors. Section 203 of the Delaware General Corporation Law, from which the Company did not elect to opt out, provides that if a holder acquires 15% or more of Unilife's stock without prior approval of Unilife's Board of Directors, that holder will be subject to certain restrictions on its ability to acquire the Company within three years. In addition, Unilife's industrialization agreement with sanofi-aventis provides to sanofi-aventis the right to match a change of control proposal and to terminate the Industrialization Agreement under certain circumstances of a change of control event. These provisions may delay or deter a change of control of the Company, and could limit the price that investors might be willing to pay in the future for shares of Unilife's Common Stock.

Recent Events

The accompanying pages summarize the Company's recent events, as described in Unilife's press releases. Unilife has also been featured in a variety of news publications, both general and industry specific. Most recently, the Company and its syringes were profiled within two drug delivery publications marketed to the pharmaceutical industry. Unilife's chief executive officer (CEO), Mr. Alan Shortall (biography provided on page 17), was featured in a four-page Executive Profile in the January 2010 issue of *Drug Delivery Technology*, a magazine providing information about the science, technology, and related business practices of drug delivery. In addition, an article on Unilife is included in a recent (early 2010) edition of ONdrugDelivery entitled *Prefilled Syringes: New Ideas for the New Decade*. ONdrugDelivery specializes in the science and business of drug delivery from a commercial perspective.

04/05/2010—Unilife Corp. announced that it received 510(k) market clearance from the U.S. Food and Drug Administration (FDA) for the Unitract™ 1mL Insulin Syringes assembled at its Lewisberry, Pennsylvania, manufacturing facility.

03/10/2010—The Company announced that it signed an exclusive five-year agreement with Stason Pharmaceuticals, Inc., a U.S.-based pharmaceutical company, to market the Unitract™ 1mL safety syringe in Japan, China, and Taiwan. Stason's Taiwan-based strategic alliance affiliate, Standard Chem. and Pharm. Co., Ltd, is acting as the primary distributor of the product within these designated territories.

03/09/2010—Unilife advised shareholders that the Australian Taxation Office (ATO) issued Class Ruling CR 2010/6 in connection with the redomiciliation of Unilife in the U.S. Under the Class Ruling, the ATO provided confirmation that Australian security holders of Unilife Medical Solutions Ltd. (UMSL) (as described in the Class Ruling) would likely be eligible for scrip for scrip capital gains tax roll-over relief with respect to the exchange of their shares and standalone options in UMSL for replacement securities in the Company as part of the redomiciliation. This ruling is consistent with the Company's request to the ATO and also the expectations as described in the Information Memorandum that was sent to all security holders for the Scheme Meetings. A copy of the Class Ruling is available on Unilife's website.

03/02/2010—The Company announced that it agreed to a list of therapeutic drug classes ("Exclusivity List") within which sanofi-aventis has the exclusive right to purchase the Unifill™ syringe.

02/22/2010—Unilife announced that it donated its first shipment of Unitract™ 1mL safety syringes to Doctors Without Borders to support ongoing relief efforts in Haiti.

02/22/2010—Unilife visited the NASDAQ MarketSite in New York City's Times Square where Mr. Shortall rang the NASDAQ Closing Bell.

02/16/2010—The Company announced that its Common Stock began trading on the NASDAQ Global Market under the ticker symbol "UNIS." The Company further advised that it had published on its website (www.unilife.com) a list of Frequently Asked Questions (FAQs) to support shareholders wishing to trade on either the ASX or NASDAQ. Unilife opened an Investor Hotline to assist with shareholder enquiries.

02/12/2010—Unilife announced that the U.S. Securities and Exchange Commission (SEC) declared its Form 10 registration statement effective, clearing the path for Unilife to list on NASDAQ.

01/28/2010—Unilife announced that implementation of the Schemes of Arrangement occurred on January 27, 2010, and accordingly Unilife completed the final stage of its redomiciliation in the U.S. Participants in the Schemes of Arrangement between Unilife and its shareholders and Option holders were allotted their new securities in Unilife Corp. on January 27, 2010.

01/14/2010—Unilife announced that the Federal Court of Australia ordered that the Schemes of Arrangement between the Company and its shareholders and Option holders be approved. With regard to trading in Unilife's securities on ASX, shareholders could elect to receive either one share of Unilife Corp. Common Stock for every six shares held in the Company as at the record date for the Schemes (these shares became tradable on NASDAQ) or one Unilife Corp. CHESS Depositary Interests (CDI) for every share held in the Company (subject to rounding). The CDIs are tradable on ASX.

01/11/2010—In accordance with ASX Listing Rule 3.13.2, Unilife confirmed that each of the resolutions put to shareholders and Option holders at the Court Ordered Scheme Meeting of Shareholders and Option holders (as applicable) and the Extraordinary General Meeting held on January 8, 2010, were passed.

12/23/2009—Unilife confirmed the dispatch, on December 21, 2009, of the Supplementary Information Memorandum to the Company's shareholders and Option holders in relation to the proposed transaction to redomicile Unilife in the U.S.

12/21/2009—Announced that Unilife commenced final preparations for the commercial release and sale of the Unitract™ 1mL Syringes following the successful completion of device aging studies for product manufactured at the Company's FDA-registered manufacturing facility in Pennsylvania.

12/16/2009—Announced the signing of agreements for the construction of the new global headquarters and commercial production facility in York, Pennsylvania. The 165,000 ft^2 medical device production facility is located at 250 Cross Farm Lane in York and is projected to be ready for operations by late 2010.

12/15/2009—Unilife advised shareholders of the release of a Finance News Network interview conducted recently with Mr. Shortall. The Finance News Network interview of Mr. Shortall is available on Unilife's website at www.unilife.com.

12/11/2009—Confirmed the dispatch of several documents to the Company's shareholders and Option holders in relation to the proposed transaction to redomicile the Unilife Group in the U.S.

12/05/2009—Announced that Unilife received approval from the Federal Court of Australia to convene meetings of the Company's shareholders and Option holders to vote on the proposed redomiciliation of Unilife in the U.S.

12/04/2009—Announced that a video of the recent Annual General Meeting (AGM) held in Sydney, Australia, on November 30, 2009, was placed on the Company's website. The Chairman's address and CEO presentation from the AGM were also available on Unilife's website.

11/25/2009—Announced the filing of patent applications in the U.S. for a new ready-to-fill syringe product to be marketed as the Unifill™ Select.

11/19/2009—Announced the appointment of Mikron Group as its contracted supply partner for the development and supply of automated assembly systems to support the commercial production of the Unifill™ Syringe. This included the successful assembly of the Unifill™ Syringe on Mikron's assembly systems as part of its proof-of-principle activities.

11/17/2009—Announced the allotment of certain securities pursuant to a recent capital raising. Unilife also announced that, as a result of the Company achieving the profit target of an excess of $12 million for the financial year ended June 30, 2009, it allotted 20,000,000 Ordinary Shares under the Deed of Settlement and Release entered into between the Company and certain of its founding shareholders as approved at the Company's 2008 AGM.

11/17/2009—Confirmed that the process for Unilife's NASDAQ listing commenced by way of filing a Form 10 registration statement for review by the SEC, a precursor to applying for the NASDAQ listing.

11/11/2009—Confirmed that the next stage of the process for the redomiciliation was completed by way of the lodgment of an Information Memorandum with respect to the proposed transaction with the Australian Securities and Investments Commission (ASIC) for review.

11/11/2009—With a view to strengthening the credentials of the Unilife Board prior to redomiciliation in the U.S. and to meet NASDAQ independence requirements, the Company announced that it appointed Mr. John M. Lund to its Board of Directors as a non-executive member. Mr. Lund, a certified public accountant (CPA), joined the Board of Directors as its fifth member. The Company believed that Mr. Lund brings valuable expertise to the Board in the areas of SEC reporting and compliance, mergers and acquisitions, and financial analysis that qualify him to serve as chairman of the Audit Committee following Unilife's listing on NASDAQ.

11/10/2009—Announced that Unilife's 2009 Share Purchase Plan (SPP), which closed October 30, 2009, was significantly oversubscribed with applications for approximately 33.7 million new, fully paid Ordinary Shares (SPP Shares) with a value of roughly A$28.7 million. As a result of the demand for shares under the SPP, the Board authorized an increase in the number of shares to be issued under the SPP from 11,764,705 shares for A$10 million to approximately 25.3 million shares for approximately A$21.5 million before costs, representing a pro-rata allotment to all shareholders of 75% of their application. In addition to the receipt of commitments for A$32.1 million from institutional investors in the U.S. and investors in Australia, the Board's decision to increase the amount to be accepted under the SPP to A$21.5 million resulted in the total sum committed amounting to A$53.6 million.

11/05/2009—Advised shareholders of a Finance News Network interview conducted with Mr. Shortall.

11/04/2009—Announced an amendment to the Merger Implementation Agreement signed with Unilife Corp. related to Unilife's decision to target a higher US$ listing price and to revise the consolidation ratio adopted under the Agreement as a result of a rise in Unilife's share price over the preceding 60 days.

10/30/2009—Announced that Unilife invited eligible shareholders in Australia and New Zealand to subscribe for up to A$15,000 worth of fully paid Ordinary Shares at A$0.85 per share under an SPP.

10/27/2009—Announced the filing of international trademarks for Unifill™, which became the market brand for Unilife's ready-to-fill safety syringes.

10/26/2009—Announced that the Company accepted an A$5.6 million (US$5.2 million) offer of assistance from the Commonwealth of Pennsylvania to support the creation of 241 new jobs within York County.

10/23/2009—Announced that Mr. Shortall made open market purchases of $500,000 in Company shares.

10/21/2009—Announced that Unilife was exhibiting at two pharmaceutical trade shows and conferences: (1) the Parenteral Drug Association (PDA) Universe of Prefilled Syringes and Injection Devices conference and exhibition from October 27 to 30, 2009, in Venice, Italy; and (2) PharmaPack 2010 on February 1 and 2, 2010, in Paris, France.

10/07/2009—Announced that the Company was successful in obtaining commitments for a capital raising of A$32.1 million.

09/01/2009—Announced that Unilife Medical Solutions Ltd. entered into a Merger Implementation Agreement with Unilife Corp. (a wholly owned subsidiary of Unilife Medical Solutions Ltd. incorporated in Delaware on July 2, 2009). The purpose of the Merger Implementation Agreement was to facilitate the redomiciliation of the Company to the U.S.

08/18/2009—Mr. Jim Bosnjak, OAM, non-executive chairman of Unilife's Board of Directors (biography on page 20), issued a letter to shareholders outlining recent developments and the Company's strategy for becoming a leader in the design, development, and supply of innovative safety medical devices for the pharmaceutical and healthcare markets.

08/12/2009—Unilife announced that it commenced U.S. production of the Unitract™ 1mL Insulin Syringe at its FDA-registered manufacturing facility in Lewisberry, Pennsylvania.

07/01/2009—Unilife announced that on June 30, 2009, it entered into an Industrialization Agreement with Sanofi Winthrop Industrie, a wholly owned subsidiary of sanofi-aventis, for the commercialization of the Unifill™ Syringe.

05/19/2009—Unilife advised shareholders that the Company was featured on Bloomberg television. The Company and its core safety syringe technology were profiled during a live studio interview where leading Wall Street healthcare analyst Jeffrey Kraws, cofounder of Crystal Research Associates, LLC, gave his market perspective on the international response to the global transmission of H1N1 influenza (swine flu). During the interview, Mr. Kraws demonstrated the Unitract™ 1mL Syringe to help outline the core proprietary features of the Unilife range of clinical and prefilled safety syringes. Bloomberg television is distributed globally on 10 network channels in seven languages, reaching over 200 million homes worldwide. The interview is available on Crystal Research Associates' website (www.crystalra.com).

Glossary

510(k) Clearance—Section 510(k) of the Food, Drug, and Cosmetic Act requires device manufacturers to notify the FDA at least 90 days in advance of an intent to market a medical device. The FDA may then issue a 510(k) marketing clearance, allowing the commercialization of the device, upon making a determination that the device to be introduced into commercial distribution is safe and effective.

Aerosol—A solid particle or liquid droplet suspended in air, such as blood splatter that can occur following an injection (as illustrated in Figure 9 [page 30]).

Antithrombotics—A type of anticoagulant drug therapy that prevents the formation of blood clots by inhibiting the action of the blood protein thrombin.

Auto-disable—Syringes that are automatically rendered unusable after having delivered a prescribed dose of vaccine.

Bloodborne Pathogens Standard (BPS)—A standard developed, promulgated, and enforced by the Occupational Safety and Health Administration (OSHA) directing employers to protect employees from occupational exposure to blood and other potentially infectious material.

CE Mark—The regulatory approval system for medical devices to be sold in the EU. It is used to indicate that a product conforms to the relevant European health, safety, and environmental quality standards.

Clinical Syringes—These syringes require healthcare workers or patients to draw up the dose of medication from a vial or ampoule immediately prior to the injection.

Deep Vein Thrombosis (DVT)—A blood clot (thrombus) in a deep vein of the thigh or leg. The clot can break off as an embolus and make its way to the lung, where it can cause respiratory distress and respiratory failure.

Drug Master File—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. For the Unifill™ syringe, the Drug Master File defines the manufacturing and safety characteristics while protecting proprietary information regarding its technical design.

Freedom to Operate (FTO)—The advice rendered by a patent attorney with respect to whether a technology could infringe a third party's patent. An FTO report typically involves a "product clearance" investigation to proactively identify and dispose of patents in the area of the entity's products, thereby proactively reducing the risk of subsequent patent problems.

Good Manufacturing Practices (GMP)—In the U.S., the Quality System Regulation (QSR) overseen by the FDA, which includes requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of medical devices intended for human use.

Group Purchasing Organizations—Organizations that secure competitive pricing for commodity items (e.g., 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.

Harm Reduction—The aim of harm reduction is to prevent or reduce the negative health consequences of high-risk behaviors associated with drug use. Essentially, harm reduction aims to prevent the transmission of bloodborne viruses, such as HIV, hepatitis B, and hepatitis C, that occur through the reuse and sharing of non-sterile injection equipment.

Hypodermic—A hollow needle used with a syringe that has been adapted for injection beneath the epidermis.

Intramuscular—Given by needle into the muscle. This is as opposed to a medication that is given by a needle into the skin (intradermal), just below the skin (subcutaneous), or into a vein (intravenous).

ISO 13485—Specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and regulatory requirements applicable to medical devices and related services.

Low-Molecular-Weight Heparins (LMWH)—An injectable form of heparin (a blood thinner) that is given underneath the skin. LMWH lasts longer, must be monitored differently, and generally has fewer side effects than standard heparin. It is often used as an alternative to heparin.

Luer—A glass syringe with a metal tip and locking device to secure the needle, used for hypodermic and intravenous purposes.

Multiple Sclerosis—A chronic autoimmune disease of the central nervous system in which gradual destruction of myelin occurs in patches throughout the brain or spinal cord or both, interfering with the nerve pathways and causing muscular weakness, loss of coordination, and speech and visual disturbances.

Needlestick Injuries—Penetrating wounds caused by mishandling a needle. Needlestick injuries are of the foremost concern to healthcare workers due to their potential to transmit infectious diseases or unwanted medication into a healthy individual.

Occupational Safety and Health Administration (OSHA)—The U.S. Congress established OSHA in 1971 to minimize and prevent work-related injuries, illnesses, and deaths through the issuance and enforcement of health and safety standards in the workplace. OSHA enforces its standards through monetary penalties for infractions of up to $70,000. The fines are issued based on the severity of the situation (how likely the violation is to result in serious harm to employees) and whether or not the incident is isolated. Since OSHA's origin, the rate of occupational deaths in the U.S. has declined by 62%, alongside a 42% reduction in work-related injuries.

Patent Cooperation Treaty (PCT)—A unified procedure for filing patent applications to protect inventions in over 140 countries. A single filing results in a single search accompanied by a written opinion, after which the examination and grant procedures are handled by the relevant national or regional authorities.

Percutaneous—Administered, removed, or absorbed by way of the skin, as an injection, needle biopsy, or transdermal drug.

Prefilled Syringes—Now a preferred drug delivery format for at least 50 injectable medicines and vaccines, prefilled syringes are filled with a measured dose of injectable medication by the pharmaceutical company. The completed drug delivery device is then packaged for shipment to end users, such as healthcare workers and patients who self-administer prescribed treatments at home.

Subcutaneous—Occurring or administered below the surface of the skin.

Venous Blood Draws—The process of obtaining a sample of blood from a vein.

Venous Tissue—Tissue relating to, or contained in, the veins.

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