EXECUTIVE INFORMATIONAL OVERVIEW

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Designer and Supplier of Next-Generation Safety Syringe Technology

Snapshot

January 6, 2009

Unilife Medical Solutions Limited ("Unilife" or "the Company") develops and supplies innovative safety medical devices to healthcare and pharmaceutical markets. Specifically, the Company is focused on targeting pharmaceutical markets for prefilled safety syringes; healthcare markets that mandate the use of sharps safety devices to prevent **needlestick injuries**†; and the U.S. medical device contract manufacturing market. Unilife has developed a patent-protected portfolio of safety syringes, with product lines including the Unilife Ready-to-Fill Syringe ([RTFS] hereafter referred to as the Unilife Prefilled Syringe), the Unitract™ 1mL Insulin and Safe Syringes, and the Unitract™ Clinical Range. The key distinctive feature in all of Unilife's safety syringes is that the operator may control the speed of automatic needle retraction within a **fully integrated** safety syringe. This novel combination of safety features, which Unilife does not believe is available with any other technology on the market today, can virtually eliminate the risk of acquiring bloodborne infections, such as the **human immunodeficiency virus (HIV)** or **hepatitis C**, via needlestick injuries or **aerosol** (blood splatter). In July 2008, sanofi-aventis SA (SNY-NYSE)—the world's fourth largest pharmaceutical group and largest purchaser of prefilled syringes—signed an Exclusive Agreement with Unilife, under which sanofi-aventis paid $13.9 million (€10 million) for the right to purchase the Unilife Prefilled Syringe for five years. Sanofi-aventis is also financing Unilife's three-year industrialization program for the Unilife Prefilled Syringe, which could have a total value of up to $23.6 million (€17 million). The Company believes that this alliance validates the strength of its proprietary technology and its competency in the development and operation of automated assembly systems. Upon the expected signing of two additional agreements with sanofi-aventis in the next 18 months, Unilife maintains a solid cash position and projects profitable operations moving forward.

Recent Financial Data

Ticker (Exchange)	UNI (ASX)*
Recent Price (01/06/2009)	A$0.25
52-week Range	A$0.18–A$0.49
Shares Outstanding	216.2 million
Market Capitalization	A$54 million
Average 3-month Volume	134,592
20 Largest Shareholders	~27%
Institutional Owners	~2%
EPS (Year ended 06/30/2008)	A$(0.044)
Employees	75

** Share data in Australian dollars (A$). At 01/06/2009, A$1.00 = ~US$0.71.*

Key Points

Note: Unless stated otherwise, all monetary amounts are in U.S. dollars.

- Integrating passive (automatic) and user-controlled needle retraction features into a complete medical device represents an important and distinctive competitive advantage for Unilife. To the Company's knowledge, the Unilife Prefilled Syringe is the first and only known technology that offers pharmaceutical companies an opportunity to market a prefilled syringe with fully integrated and passive safety features without changing standard drug filling and packaging procedures.
- Unilife has established a solid intellectual property portfolio for its technology, which includes a number of issued and pending patents in key international regions, such as the U.S. and Europe.
- In October 2008, Unilife received U.S. **510(k) clearance** of the Unitract™ 1mL Insulin Syringe, enabling the Company to continue with the commercialization of this product in target U.S. markets.
- Unilife's Board and management team has extensive medical device experience that ranges from the start-up stage to market leader status as well as the ability to drive the Company's international development and commercialization programs.
- Unilife has a U.S. Food and Drug Administration (FDA)-registered device production facility in Pennsylvania, an emerging commercial and operational presence in Europe, and a strategic alliance in China. As of September 30, 2008, Unilife's cash position was $10.6 million (A$13.4 million).

†**BOLD** WORDS ARE REFERENCED IN THE GLOSSARY ON PAGES 68-70.

Top Ten Investment Considerations

Unless stated otherwise, all monetary amounts are in U.S. dollars. At 01/02/2009, US$1.00 = ~A$1.43 and €0.72.

(1) Healthcare and pharmaceutical markets are transitioning to the mandatory use of safety syringes.

Up to 35 billion syringes are used globally each year, including an estimated six billion units in the U.S. alone. More than two billion prefilled syringes are also used annually as the preferred drug delivery device for at least 45 injectable drug products. Yet over 1.3 million people die each year from bloodborne pathogens, such as HIV and hepatitis C, that are transmitted via unsafe injection practices. An estimated 600,000 healthcare workers in the U.S. and one million in Europe receive a needlestick injury each year.

To protect healthcare workers from the risk of needlestick injury, the U.S. introduced legislation in 2000 requiring the mandatory use of safety syringes within healthcare facilities. This legislation, which is aggressively enforced, is now being adopted within other sophisticated international healthcare markets, such as Europe, Canada, and Australia, as well. Thus, pharmaceutical companies are moving toward the use of prefilled syringes with safety features that comply with these needlestick prevention laws.

(2) Target markets continue to await the arrival of products of choice.

Many currently available safety syringes continue to put healthcare workers and their patients at risk of harm. U.S.-based studies have found that safety syringes now cause more needlestick injuries each year than standard syringes. Approximately one in five U.S. healthcare facilities inspected by the **Occupational Safety and Health Administration (OSHA)** since 2002 has been issued a citation for non-compliance with federal needlestick prevention laws.

Both government and industry bodies have encouraged the use of safety syringes with integrated and passive (automatic) safety features; however, few such products are currently available. In contrast, most safety syringes require healthcare workers to manually activate the safety mechanism after the injection is complete. Many injuries are reported in these scenarios because the safety features are either activated incorrectly or not at all. Some other products incorporate a retractable needle mechanism, which may exacerbate harm if it is activated inside the patient or create the risk of infection via a needlestick injury or aerosol (blood splatter) if it is activated in the open air. Additionally, to Unilife's knowledge, there is no known technology for prefilled syringes that has a fully integrated automatic safety mechanism. Consequently, pharmaceutical companies must attach a clip-on safety product to a standard prefilled syringe, which can increase filling, packaging, and shipping costs by up to 70%.

(3) Unilife believes that its safety syringe portfolio is well-positioned to attain best-in-class status.

Unilife believes that it is an emerging global leader in the design, development, and supply of innovative safety medical devices. The Company has developed a portfolio of clinical and prefilled safety syringes, which possess three novel, patent-protected competitive features: (1) the needle retracts into the barrel automatically (passive activation) to virtually eliminate the risk of needlestick injury; (2) the operator is able to control the speed of needle withdrawal directly from the body to minimize patient discomfort and the risk of infection via aerosol transmission; and (3) all of the safety features are fully integrated into the barrel of the syringe to facilitate easy handling and convenient disposal. Unilife is not aware of any other safety syringe technology—in either clinical or prefilled form—that brings these three features together.

(4) The competitive strength of Unilife's technology can be validated by its exclusive partnerships.

Unilife believes that its signing of an Exclusive Agreement in July 2008 with sanofi-aventis—a top-five pharmaceutical company and the world's largest purchaser of prefilled syringes—validates the competitive strength of the Company's safety syringe portfolio. Under a (pre-sales) agreement valued at up to $37 million, sanofi-aventis has paid Unilife $13.9 million for the exclusive right to purchase the Unilife Prefilled Syringe for five years and is funding this product's industrialization. Unilife has also established exclusive relationships with other global industry leaders, including Gerresheimer Bünde GmbH, the world's second largest prefilled syringe manufacturer, and Shanghai Kindly Enterprise Development Group Co., Ltd ("KDL"), China's second largest medical device manufacturer.

(5) The Unilife Prefilled Syringe represents disruptive technology.

To the Company's knowledge, the Unilife Prefilled Syringe is the world's first known prefilled syringe with automatic safety features that are fully integrated into the device. As a result of a five-year business relationship with sanofi-aventis, the Unilife Prefilled Syringe has been engineered for high-volume production and is compatible with both target injectable drugs and their associated dose filling systems. By eliminating the need for pharmaceutical companies to purchase bulky clip-on safety products that must be attached separately onto a standard prefilled syringe, the Unilife Prefilled Syringe has the potential to reduce filling, packaging, and shipping costs by up to 70%. Further, Unilife's syringe is the same size as a standard prefilled syringe and shares the same steps of use. As such, it is suited for use both in healthcare facilities and by patients who self-administer prescribed medication. As such, the Company believes that its Unilife Prefilled Syringe is a benchmark for a new generation of prefilled safety syringes.

The Unilife Prefilled Syringe represents a significant marketing opportunity for pharmaceutical companies looking to differentiate products within therapeutic sectors that are increasingly threatened by new drugs or generic competition. By entering into an exclusive agreement with sanofi-aventis in this safety device arena for five years, Unilife has the opportunity to disrupt the status quo in this fast-growing market sector and attain market leadership status.

(6) The Industrialization Program has commenced and is being funded by sanofi-aventis.

Unilife and sanofi-aventis agreed to design specifications for the Unilife Prefilled Syringe in mid-2007. By early 2008, Unilife had commenced pilot production of the Unilife Prefilled Syringe at its Pennsylvania facilities to support the successful supply and evaluation of the product by sanofi-aventis. This pilot production process used an automated assembly system designed, developed, and operated by Unilife.

The Industrialization Program for the Unilife Prefilled Syringe began following the signing of an Exclusive Agreement on July 1, 2008. Under this program, Unilife is developing production systems that are intended to have an annual production capacity of 40 million units by 2011. Under an Industrialization Agreement expected to be signed in January 2009, sanofi-aventis is anticipated to pay Unilife up to $23.6 million in quarterly milestone payments to fund the development of these production systems and the related expansion of Unilife's operational capabilities, such as the recruitment of new personnel. Unilife has already received its first quarterly milestone payment of $2.1 million, with another payment due by February 2009.

Under the production plan for the Unilife Prefilled Syringe, the Company expects to initiate official supply of the product to sanofi-aventis in late 2010. Due to high anticipated demand, annual volumes are expected to quickly increase to approximately 400 million units per year by 2014 and up to one billion units per year beyond 2017. Unilife is at an advanced stage of planning with regard to the design of a modular high-volume assembly system capable of supporting the realization of this Industrialization Program. The Company is also negotiating with a number of major supply groups to support this production plan.

(7) Unilife has medical device expertise and FDA-registered U.S. manufacturing facilities.

Unilife currently employs 75 people across Australia, the U.S., Europe, and China, including the former head of medical devices for the World Health Organization (WHO) and a former vice president of engineering for Bayer AG (BAYRY-OTC). The majority of Unilife's staff is situated at its wholly owned FDA-registered production facility near Harrisburg, Pennsylvania. This facility is focused on the production of Unilife's safety syringes and other medical devices under contract for designated healthcare and pharmaceutical customers, such as an insulin pump. Following the signing of the Exclusive Agreement with sanofi-aventis in July 2008, Unilife embarked on an aggressive growth phase that is being largely financed under the Industrialization Program for the Unilife Prefilled Syringe. This phase entails Unilife further strengthening its operational capabilities, appointing additional skilled staff, and establishing a high-volume production facility in Europe.

(8) Unilife is ISO 13485 certified and has secured key global approvals, including from the FDA.

Unilife is **ISO 13485:2003** certified—the international quality standard for the design, development, and supply of medical devices. The Company has also obtained regulatory approval for its Unitract™ 1mL syringes in key international markets, including the U.S., Canada, Europe, and Australia.

(9) Unilife has a solid cash position and anticipates profitable operations moving forward.

Following the receipt of the exclusivity fee from sanofi-aventis in July 2008 and the payment of one quarterly milestone payment, Unilife's cash position was $10.6 million on September 30, 2008. Current commercial revenue sources outside the Industrialization Program for the Unilife Prefilled Syringe include initial commercial sales of the Unitract™ 1mL syringes to Unilife's strategic partner in China as well as medical device manufacturing contracts with healthcare equipment and pharmaceutical customers that outsource device production to Unilife.

Unilife projects profitable operations moving forward, with the anticipated payment of $20.8 million to $23.6 million (€15 million and €17 million) under the Industrialization Program for the Unilife Prefilled Syringe. While a purchase price for the product has yet to be negotiated, a Supply Agreement specifying high-volume orders is expected to be negotiated after the signing of the Industrialization Agreement. Sales of the Unilife Prefilled Syringe are forecast to commence in late 2010, and Unilife believes that annual revenues may reach more than $400 million beyond 2014. The Unilife Prefilled Syringe may also generate other significant revenue streams, such as the receipt of sub-licensing payments if sanofi-aventis should opt to also license the use of the product to other pharmaceutical companies.

(10) Unilife is transitioning to being a U.S.-based global industry leader for safety medical devices.

Unilife believes that it is in a favorable commercial and operational position to emerge as a global leader in the design, development, and supply of innovative safety medical devices. Having began production of its patent-protected range of safety syringes and signed an Exclusive Agreement with sanofi-aventis, Unilife has a solid cash position and a quickly growing transatlantic presence. To support current international expansion activities, Unilife intends to list on a respected international exchange, such as the National Association of Securities Dealers Automated Quotation (NASDAQ), to help enhance shareholder value from current business activities within Europe and the U.S. This listing process could be completed during 2009.

Table of Contents

Executive Overview

Unless stated otherwise, all monetary amounts are in U.S. dollars. At 01/02/2009, US$1.00 = ~A$1.43 and €0.72.

Unilife Medical Solutions Limited ("Unilife" or "the Company") is an Australian publicly listed (UNI-ASX) developer and supplier of innovative safety medical devices with U.S. Food and Drug Administration (FDA)-registered manufacturing facilities in Pennsylvania (U.S.). The Company's core business focus is the commercialization of a proprietary range of clinical and prefilled retractable syringes suitable for healthcare and pharmaceutical markets now transitioning to the mandatory use of such needlestick prevention products. 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. Unilife 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.

Needlestick injuries are a serious and recognized occupational hazard to healthcare workers. The first case of occupationally acquired human immunodeficiency virus (HIV) infection was reported roughly 25 years ago. This brought attention to the risk of exposure to HIV in the workplace, as well as the risk of transmitting other infectious bloodborne diseases, such as hepatitis C.

To protect healthcare workers from the risk of contracting a bloodborne disease from a needlestick injury, the U.S. Congress signed the Needlestick Safety and Prevention Act into law in 2000. This act mandated that the 1991 **Bloodborne Pathogens Standard (BPS)** be revised to require the use of engineering and work practice controls that eliminate or minimize employee exposure to bloodborne pathogens. U.S. healthcare facilities are now required to identify, review, and implement the use of safety engineered medical devices ("sharps safety products") where there is a risk of infection via potential transmission modes, such as needlestick injuries. Other international healthcare markets, including Europe, Canada, and Australia, are following the U.S. toward the mandatory use of sharps safety products as well.

In the past decade, a number of medical device companies have introduced clinical and prefilled syringes designed to protect healthcare workers and others at risk for unsafe injection practices. Since 2002, the number of citations issued annually by the Occupational Safety and Health Administration (OSHA) to U.S. healthcare facilities for non-compliance in the use of sharps safety products has doubled, with at least one in every five facilities inspected being cited. Despite this strong enforcement by OSHA, evidence suggests that currently available products are not adequately protecting those at risk of harm. For example, healthcare workers in Massachusetts are now being injured with safety syringes more often than standard syringes (Source: the Massachusetts Sharps Injury Surveillance System 2007). Likewise, a survey by the International Health Care Worker Safety Center found that of the 25% of healthcare workers who reported a needlestick injury, approximately 50% were injured with a sharps safety product.

For drugs that must be loaded into the syringe at the point of dose delivery, the most commonly preferred type of safety syringe has an integrated spring-activated needle retraction mechanism. Most retractable syringes require operators to exert additional pressure on the plunger at the completion of an injection 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, healthcare workers are often reported to first remove the needle from the body of the patient. However, while less painful for the patient, activating the safety mechanism in open air not only creates the risk of a needlestick injury, 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.

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. Due to their relative ease of use, prefilled syringes are now a preferred drug delivery device for at least 45 injectable medicines and vaccines. More than two billion units were expected to be used during 2008, with the market currently valued at nearly $1.5 billion and believed to be growing at a minimum of 12% per year (Source: ONdrugDelivery Ltd 2007). To comply with sharps safety legislation, prefilled syringes are also now commonly supplied with a needlestick prevention feature.

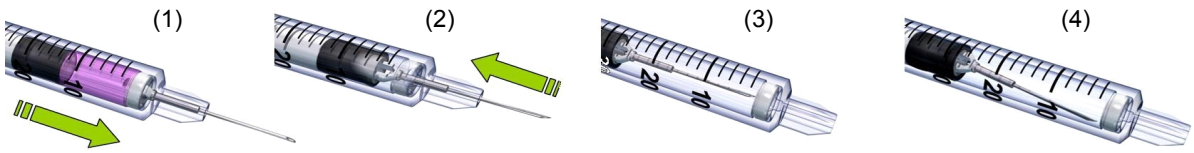
To Unilife's knowledge, there is no prefilled syringe with an integrated safety mechanism. As such, a number of pharmaceutical companies currently purchase safety devices, such as a needle guard or external sheath, for attachment onto standard prefilled syringes after dose filling but prior to shipment.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

Unilife's Safety Syringe Technology

Unilife's proprietary clinical and prefilled 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 the Unilife Prefilled Syringe, the Unitract™ 1mL Insulin and Safe Syringes, and the Unitract™ Clinical Range.

Each of the Company's products utilizes a core platform of innovative technological features, as illustrated in Figure 1, outlined briefly below, and described in greater detail on pages 42-52 in the Core Story of this Executive Informational Overview®.

Figure 1
Unilife Medical Solutions Limited
KEY ADVANTAGES OF UNILIFE'S SAFETY SYRINGES



Source: Unilife Medical Solutions Limited.

(1) *Integrated design*. All safety features are fully integrated into the core device design to facilitate compact handling, intuitive use, and convenient disposal.

(2) *Automatic (passive) retraction.* The retraction of the needle into the barrel occurs automatically, without any additional pressure necessary by the operator, to essentially eliminate the risk of needlestick injury.

(3) *Controlled retraction*. Operators can safely control the rate of needle withdrawal directly from the patient, minimizing discomfort and the potential for tissue damage, and thus eliminating the creation of aerosol.

(4) *Auto-disable*. Upon withdrawal of the needle into the barrel, it is automatically locked and tilted to one side to prevent re-exposure or reuse.

The Unilife Prefilled Syringe

The Unilife Prefilled Syringe is also referred to as the Ready-to-Fill Syringe (RTFS), as it is supplied in three separate parts to pharmaceutical companies "ready for filling" with a measured dose of an injectable drug. Once it has been filled, the RTFS becomes a "prefilled syringe." The Unilife Prefilled Syringe is virtually the same size as conventional (non-safety) prefilled syringes and is compatible with the dose-filling and packaging systems of pharmaceutical customers. It is also developed using component materials that are currently used with standard prefilled syringes in order to maximize biocompatibility with target injectable drug products. By eliminating the need to attach an ancillary safety product to the prefilled syringe, the Unilife Prefilled Syringe has the potential to reduce the packaging, transportation, and storage costs of pharmaceutical companies by up to 70%. Sanofi-aventis has paid Unilife $13.9 million (€10 million) for the exclusive right to purchase the product for five years, and is funding its industrialization. Sanofi-aventis' relationship with Unilife is overviewed on pages 8-9 and more fully detailed on pages 15-17. A full description of the Unilife Prefilled Syringe is provided on pages 44-46.

The Unitract™ 1mL Insulin and Safe Syringes

The Unitract™ 1mL range incorporates 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. 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 Safe Syringe is a variant of the Insulin Syringe, with the addition of a system of gates built into the plunger that automatically prevent the syringe from being reloaded once the injection has commenced. The Safe Syringe is designed to enhance the effectiveness of **harm reduction** 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. 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.

Unilife commenced production and commercial release of its Unitract™ 1mL Insulin and Safe Syringes out of China during 2008, and anticipates having annual U.S. production capacity of over 40 million units by mid-2009. Further, in October 2008, Unilife received 510(k) clearance from the FDA for its Unitract™ 1mL Insulin Syringe, allowing the Company to market and sell this syringe within the U.S. Ongoing product launch activities entail product evaluation trials within Unilife's target markets and the finalization of discussions with interested distributors. Globally, the Company has secured regulatory approvals for its 1mL range within Canada, Europe, and Australia and has appointed distribution partners, many of which have committed to minimum annual orders, in almost 40 countries, including Canada, Switzerland, Germany, Taiwan, and China.

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 development of the Unilife Prefilled Syringe. Yet, ultimately, the Unitract™ Clinical Range products are expected to be available in 3mL and 5mL sizes to meet the injection safety needs of healthcare workers and their patients. The design and method of operation is intended to complement the Unilife Prefilled Syringe to maximize levels of device functionality, user familiarity, and occupational safety.

Exclusive Agreement and Industrialization Program with sanofi-aventis for the Unilife Prefilled Syringe

In July 2008, Unilife signed an Exclusive Licensing Agreement with sanofi-aventis, the world's fourth largest pharmaceutical group, the largest pharmaceutical group in Europe, the global leader for vaccines, and the world's largest purchaser of prefilled syringes. Under the terms of the agreement, which followed a business development period of more than five years, sanofi-aventis paid Unilife $13.9 million (€10 million) for the exclusive right to purchase the Unilife Prefilled Syringe for a period of five years. In addition, Unilife expects to receive between $20.8 million and $23.6 million (€15 million and €17 million) in quarterly milestone payments in order to develop production systems to manufacture and supply an initial 40 million units per year (subject to the final negotiation in good faith and completion of the formal documentation of the industrialization requirements). This program commenced on July 1, 2008, and is expected to be completed by the end of 2011. During October 2008, Unilife received the first quarterly payment under the Industrialization Agreement of €1.5 million, which was equivalent to approximately $2 million (using the average exchange rate prevailing during October 2008).

Initial pilot production of the Unilife Prefilled Syringe to support its evaluation by sanofi-aventis commenced at Unilife's manufacturing facilities in Pennsylvania during early 2008. Initial sales of the Unilife Prefilled Syringe could begin in late 2010, with the initial high-volume assembly line expected to be online in 2011. Under a project plan developed by Unilife, annual production volumes for the Unilife Prefilled Syringe are intended to increase to approximately 400 million units by the end of 2014 and up to one billion units beyond 2017. To support the realization of this ramp up, both parties are in discussions to sign a Supply Agreement that is intended to specify long-term orders. Beyond 2014, Unilife has stated in its July 7, 2008, Chairman's Letter that it could receive annual revenues in excess of $400 million from the sale of the Unilife Prefilled Syringe.

Integrated BioSciences Inc. (IBS) Subsidiary

In 2007, Unilife acquired Integrated BioSciences Inc. (IBS), a medical device manufacturing business with FDA-registered facilities near Harrisburg, Pennsylvania. IBS designs and operates automated high-volume clean room assembly systems for the large-scale production of medical devices. The Company has built a core operational platform of expertise into the design and development of its innovative safety medical devices and the automated assembly systems used to manufacture these products. As an indication of its in-house expertise in this area, Unilife has successfully developed and tested a fully automated assembly system to support the high-volume production of its Unitract™ 1mL syringes at IBS' facilities in 2009. The Company also developed an automated assembly system that facilitated the successful pilot production and supply of the Unilife Prefilled Syringe at IBS in early 2008.

In addition to the production of its safety syringe products, Unilife's IBS subsidiary is a medical device contract manufacturer for a select number of multinational healthcare and pharmaceutical companies that outsource the production of proprietary medical devices. IBS has contracts in place, or is at an advanced stage of negotiations, for the production of a number of medical device products, including syringes used in specialty applications, an insulin pump device, a sterile prefilled orthopedic device, and a hemostatic gauze pad. These contract medical device activities generate additional revenue for Unilife and strengthen its alliances with industry leaders in fast-growing medical device and pharmaceutical markets.

IBS has dedicated design teams that can identify the most suitable production platform and assembly process for many types of medical devices. The high-precision automation systems developed by IBS have a low spatial footprint to minimize clean room space requirements and can be supplied in a modular turnkey format to support rapid growth in annual production capacities. IBS is also able to support companies in the commercialization of new devices with advanced prototyping services and the development of low-volume semi-automated systems that support regulatory applications and product trial activities. IBS' supply chain partners include U.S. leaders in key areas, such as the development of robotic systems and the production of high-quality components. Both Unilife and its subsidiary are ISO 13485:2003 certified and combined offer an experienced team of 50 manufacturing, quality, and engineering personnel.

Other Supply Chain Partners

Unilife signed an Exclusive Business Development Agreement with Gerresheimer Bünde GmbH, the world's second largest manufacturer of prefilled syringe systems, in November 2007. The Company also has a strategic partnership with China's Shanghai Kindly Enterprise Development Group Co., Ltd ("KDL") for the exclusive production and distribution of Unilife's safety syringes in China. Unilife further has a Development Agreement with West Pharmaceutical Services, Inc. (WST-NYSE), the world's largest producer of syringe components for global medical and pharmaceutical industry leaders, for the provision of specialist components, such as seals for Unitract™ products. The Company also manages a close relationship with Tessy Plastics Corp., a producer of medical device components. Tessy supplies the majority of plastic component requirements to Unilife's facility in Pennsylvania. These partnerships are more fully detailed on page 17.

Headquarters, Employees, and History

Founded in 2002, Unilife is currently headquartered in Sydney, Australia, with IBS located near Harrisburg, Pennsylvania. In addition to its activities in the U.S. and Australia, the Company also has staff situated in Paris and China. As of the date of this report, Unilife and its subsidiary together employed approximately 75 staff globally, with roughly 60 individuals located at the Pennsylvania facility.

In support of the industrialization of the Unilife Prefilled Syringe and the establishment of Unilife as a global leader in the development and supply of innovative safety medical devices, the Company is implementing a strategic expansion plan to make its Pennsylvania facility the main corporate and operational hub of Unilife. As part of this strategy, Unilife is in the midst of a recruitment campaign to strengthen its team with the addition of new personnel who have the commercial and operational expertise to help implement core business priorities, such as the Industrialization Program for the Unilife Prefilled Syringe. Recent appointments have included a U.S.-based chief financial officer (CFO) and a senior vice president of operations. In conjunction with this ongoing recruitment campaign, Unilife is significantly expanding its international operational capabilities in the high-volume production and supply of innovative safety medical devices. While much of this commercial and operational growth is funded under the Industrialization Program for the Unilife Prefilled Syringe, the Company expects to benefit from these expansion activities in a number of other areas of its business as well.

Unilife is also building a presence in Europe to support the industrialization of the Unilife Prefilled Syringe, and is in discussions with a number of European governments to secure an attractive incentive package to establish a high-volume manufacturing facility within an EU country.

Growth Strategy

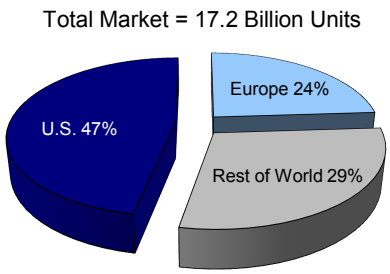
Since its public listing in 2002, Unilife has grown through continued advances of its intellectual property; the acquisition of its U.S. contract manufacturing subsidiary, IBS; and the development of exclusive partnerships with medical device and pharmaceutical leaders, such as sanofi-aventis. In addition to the development and supply of its own proprietary products, Unilife also contract manufactures medical devices for a number of healthcare equipment and pharmaceutical customers.

The prefilled syringe market continues to thrive as this technology improves patient compliance, facilitates the 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 cost and waste associated with the production and use of **vial**-packaged drugs. This has resulted in partnerships between device designers and drug developers—relationships that have become an essential element in the success of prefilled devices.

An Expanding Global Base

Unilife is focused on expanding corporate functions and operations in the U.S. and Europe, which represent the largest and fastest-growing global markets for innovative safety medical devices, as shown in Figure 2. The Company expects to significantly expand its industrial capabilities under the Industrialization Program for the Unilife Prefilled Syringe, which includes augmenting engineering and operational resources at IBS and establishing a European base. Unilife has also initiated recruitment activities to strengthen and expand its operational expertise via the appointment of skilled individuals to key positions relating to the industrialization of the Unilife Prefilled Syringe. A number of appointments have already been completed, including a U.S.-based CFO and a senior vice president of operations. Current and future operational items related to the Unilife Prefilled Syringe are to be funded through this Industrialization Program.

Figure 2
WORLDWIDE SYRINGE MARKET BY REGION (2005)



Source: Industry data and estimates from Greystone Associates 2007.

Highlights of the Company's U.S., European, and potential Chinese expansions are included below.

- *United States.* A number of key corporate and operational functions at Unilife are being transferred from Australia to IBS' facilities in Pennsylvania. This is intended to help strengthen the overall cost efficiency of Unilife and to ensure that the industrialization of the Unilife Prefilled Syringe and other key projects remain on-track. Unilife has commenced a program to double the size of its presence in Pennsylvania to support the development of assembly systems for the Unilife Prefilled Syringe, the Unitract™ 1mL syringes, and other key contract manufacturing projects. The industrial expansion of the IBS facilities are intended to include the development and operation of the first high-volume automated assembly line for the Unilife Prefilled Syringe and other critical equipment, including the installation of washing facilities and expansion of clean room facilities. Unilife is working closely with the government of Pennsylvania as part of its U.S. expansion plans.

- *Europe.* To help meet anticipated long-term global demand for the Unilife Prefilled Syringe, Unilife is reviewing potential locations in Europe so that it may secure financial incentives suitable for the establishment of a new facility that would be capable of producing a minimum of 400 million units per year. Site selection is to be determined by a number of factors, including incentives, access to key markets, and the skill base of the labor force. The Company expects to make this decision during 2009. To facilitate its relationship with sanofi-aventis and European-based supply partners, Unilife has also opened an office in Paris.

- *China.* To support the high-volume industrialization of its range of safety syringes, Unilife is reviewing opportunities to expand its operational alliances in China.

Current Funding and Revenue Streams

Unilife currently has a solid cash position, following the receipt of a $13.9 million (€10 million) exclusivity fee from sanofi-aventis in July 2008, in return for the exclusive right to purchase the Unilife Prefilled Syringe for five years. In addition, the Company is currently receiving funding and revenue streams via the activities listed below.

- *Industrialization Program.* Under the Industrialization Program for the Unilife Prefilled Syringe, Unilife expects to receive between $20.8 million and $23.6 million (€15 million and €17 million) from sanofi-aventis via regular quarterly milestone payments, subject to the expected signing in good faith of an Industrialization Agreement in early 2009.

- *Initial Sale of Unitract™ 1mL Syringes.* Initial commercial release of the Unitract™ 1mL range of safety syringes commenced in recent months to support product rollout activities and to coincide with regulatory approvals in the U.S. (FDA), Europe (**CE Mark**), Canada, and Australia. Distribution partners have been appointed in some European countries, Canada, China, Taiwan, and other emerging markets. Additional sales opportunities are being negotiated across a number of markets.

- *Contract Medical Device Manufacturing.* Unilife derives a reliable revenue stream from the contract medical device manufacturing activities undertaken by IBS.

Additional Future Funding and Revenue Streams

Unilife expects to derive additional funding and revenue streams from a number of sources in future years, primarily related to the Unilife Prefilled Syringe, as listed below.

- *Sublicensing.* Should sanofi-aventis seek to sublicense the product to a third party, Unilife would likely receive license payments commensurate with the scale of these agreements.

- *Sales of the Unilife Prefilled Syringe.* Beyond 2014, Unilife projects that it could generate revenues in excess of $400 million through the sale of the Unilife Prefilled Syringe at a premium price per unit with solid operating margins and minimal go-to-market costs.

- *Launch of the Unitract™ Clinical Range.* Unilife is currently finalizing design specifications for a range of 3mL and 5mL syringes suitable for use in acute care facilities that are intended to complement the safety features and functionality of the Unilife Prefilled Syringe. Qualified production of the Unitract™ Clinical Range is expected to begin beyond 2010.

- *Contract Medical Device Manufacturing*. Significant growth is expected within this market during 2009 and 2010, with the commencement of scheduled contracts with global healthcare and pharmaceutical leaders that include the production of an insulin pump device. These manufacturing projects are detailed on page 53.

Corporate Expansion

Other additional areas for growth may include those listed below.

- *Listing on a Respected International Exchange.* Unilife expects to undertake a listing on a respected international exchange, such as the National Association of Securities Dealers Automated Quotation (NASDAQ) or the American Stock Exchange (AMEX), to help enhance shareholder value from business activities within Europe and the U.S. This listing process is intended to be completed during 2009.

- *Potential Mergers and Acquisitions.* Once Unilife has completed its transition to the U.S., recruited key initial employees, and further strengthened its financial position, the Company expects to review opportunities to acquire additional companies with complementary products or proven technologies that can benefit from Unilife's experience, management, and facilities.

Intellectual Property

Unilife has established a solid intellectual property portfolio to protect the Company's product and technology developments. As summarized in Table 1 (page 14), Unilife's intellectual property includes a number of issued and pending patents in Australia, the U.S., Europe, and many other countries worldwide. In addition to those specifically listed in Table 1, the Company holds **provisional patent applications** in both the U.S. and Australia, several registered trademarks, and possesses **Freedom to Operate (FTO)** reports.

FTO reports entail advice from a patent attorney regarding the likelihood of a technology infringing a third party's patent. For instance, 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 Unilife Prefilled Syringe did not infringe on identified U.S. and European patents and patent applications. The Company's intellectual property attorneys are Fisher Adams Kelly in Australia and Nixon Peabody LLP in the U.S. In addition, Unilife has created an Intellectual Property Management Committee to manage and strengthen its intellectual property portfolio.

Unilife classifies its patents and patent applications as they relate to four product categories: (1) Insulin and Safe Syringes; (2) Clinical Syringes; (3) Vaccination Syringes; and (4) RTFS. Many of the features claimed in the Insulin and Safe Syringes patents also apply to other Unitract™ products, such as the mechanism allowing for automatic and controlled needle retraction within an integrated medical device.

Patent Cooperation Treaty (PCT)

Many of the Company's international patent applications are pending under a vehicle known as the **Patent Cooperation Treaty (PCT)**, which enables an entity to seek patent protection simultaneously in 139 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, as referenced in Table 1. Additionally, the Company has filed (and has been granted) international patent applications in some non-PCT countries as well, such as Taiwan and Thailand.

Registered Trademarks

Unilife's trademarks include the Unitract™ name, which is a registered trademark in the U.S. and is also filed 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 several countries while only filing an application in that entity's own national or regional trademark office. This system facilitates trademark registration in many global jurisdictions, including France, Germany, Japan, China, Russia, Switzerland, and the UK.

Additionally, Unitract™ is a registered trademark in Australia, Mexico, and New Zealand, and trademark applications for the brand have been filed in Canada, India, Indonesia, South Africa, and Brazil as well. Unitract™ Safe Syringe is also a registered trademark in Australia.

Table 1
Unilife Medical Solutions Limited
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
	Vaccination Syringe		
01/28/2005	One use syringe with ratchet on plunger and pawl on body Granted in Taiwan Pending in Australia, Canada, China, Europe, the U.S., Malaysia, and Thailand	PCT/AU2005/000106	WO2005/072797
07/18/2005	Syringe needle sheath Pending in Australia, China, Europe, India, Indonesia, South Africa, and the U.S.	PCT/AU2005/001054	WO2006/007642
	Ready-to-Fill Syringe (RTFS)		
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 Medical Solutions Limited, 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>.

Key Business Relationships

Unilife has leveraged the competitive strength of its patented technology and operational expertise to produce and supply innovative safety medical devices as well as to secure exclusive industry partnerships with global healthcare and pharmaceutical leaders. Each of the relationships is highlighted in Figure 3 and is described in the accompanying section.

Figure 3
Unilife Medical Solutions Limited
KEY BUSINESS RELATIONSHIPS

Source: Unilife Medical Solutions Limited.

Sanofi-aventis

Unilife and sanofi-aventis have entered into an exclusive five-year licensing agreement for the Unilife Prefilled Syringe. Sanofi-aventis, an employer of roughly 100,000 individuals, is a world leader within the pharmaceutical industry. It is ranked number one in Europe and number four worldwide according to 2007 sales, with full year 2007 reported revenues of €28 billion. Sanofi-aventis is the single largest purchaser of prefilled syringes in the world, with primary business activities in the development and marketing of injectable drugs across five core therapeutic areas: anti-coagulants (**deep vein thrombosis [DVT]**), central nervous system (**multiple sclerosis [MS]**), metabolic disorders (diabetes), vaccines, and oncology (cancer). Sanofi-aventis uses prefilled syringes as its drug delivery device of choice for each of the aforementioned respective markets, with the exception of diabetes, where insulin is administered with a pen device, and cancer, where vials are currently used.

Some of the largest selling injectable drugs and vaccines marketed by sanofi-aventis available in a prefilled syringe format include those listed below.

- *Lovenox®/Clexane®.* As the most widely studied and used **low-molecular-weight heparin (LMWH)** in the world, this drug has treated an estimated 200 million patients in more than 115 countries and is approved for more clinical indications than any other LMWH. Lovenox® has a 72% share of the overall heparin market and 80% of the LMWH market. As well, it is the largest selling prefilled therapy in the U.S. and reported 2007 global sales of $3.8 billion.

- *Copaxone®.* Marketed by sanofi-aventis in collaboration with Teva Pharmaceutical Industries Ltd. (TEVA-NASDAQ), Copaxone® is an immunomodulator that is indicated for the reduction of frequency in attacks of MS. The treatment is used by more than 100,000 patients in more than 40 countries. In 2007, sanofi-aventis reported revenues of $1.5 billion for the drug.

- *Influenza Vaccines.* Sanofi Pasteur Inc., the vaccines division of sanofi-aventis, is a world leader in the production and marketing of influenza vaccines. Sanofi Pasteur produces approximately half of the influenza vaccines distributed worldwide. In the U.S. alone, this division produced more than 40% of the influenza vaccines distributed for the 2007-2008 influenza season. Annual production volumes increased to 180 million doses in 2007 with reported influenza vaccine sales of more than $1 billion.

Background of Relationship

Sanofi-aventis approached Unilife roughly five years ago after sanofi-aventis had conducted a global search of all safety syringe technologies beyond those in the prefilled arena. Sanofi-aventis asked if Unilife could develop a prefilled safety syringe in a glass barrel that would fit into sanofi-aventis' current 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 was able to demonstrate 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 an Exclusive Business Development Agreement, called a Memorandum of Understanding (MOU), with product design specifications for the Unilife Prefilled Syringe 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.

Details of Relationship

In July 2008, Unilife and sanofi-aventis signed an Exclusive Licensing Agreement for the Unilife Prefilled Syringe. Under the terms of the agreement, sanofi-aventis paid Unilife a $13.9 million (€10 million) exclusivity fee for the exclusive right to buy the Unilife Prefilled Syringe for a period of five years. In addition, Unilife is to receive between $20.8 million and $23.6 million (€15 million and €17 million) in order to develop production systems to manufacture and supply an initial 40 million units per year (subject to the final negotiation in good faith and completion of the formal documentation of the industrialization requirements). The Industrialization Program began on July 1, 2008, with Unilife receiving the first quarterly payment of €1.5 million (roughly $2 million) in October 2008. The Industrialization Agreement document is in process and is expected to be signed in early 2009.

The Industrialization Program includes the finalization of the design, a requirement that sanofi-aventis apply for regulatory approval of the device, 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. Earlier in 2008, Unilife initiated automatic pilot production of the Unilife Prefilled Syringe on an automated assembly line that it developed at IBS. This indicates that the Company possesses the knowledge of how the syringe's components fit together and are to be handled at high commercial volumes. By late 2009 or early 2010, Unilife expects to receive commercial orders from sanofi-aventis for high-volume manufacturing. The automated robotic assembly system developed by Unilife to initiate pilot production of the Unilife Prefilled Syringe in early 2008 is intended to also support the sale of sufficient product quantities to sanofi-aventis in 2010 for market registration activities. Additionally, the first high-volume assembly system for the Unilife Prefilled Syringe that Unilife expects to establish and operate at its U.S. facility will likely serve to demonstrate the manufacturing site's volume and production process.

Unilife anticipates selecting a manufacturing site in Europe where the Company can develop a facility with clean rooms, replicating the modular design of the first high-volume U.S. assembly line to be established at IBS in Pennsylvania. The replication of this modular, automated system may facilitate a fast, cost-effective ramp-up of targeted annual volumes. 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 regulatory, marketing, or distribution costs, but only administration costs.

In addition to obtaining the license to use the Unilife Prefilled Syringe with its own injectable drug and vaccine products, sanofi-aventis may also seek to license the product for use by its commercial partners or other pharmaceutical companies. Should sanofi-aventis sublicense the Unilife Prefilled Syringe to a third party, the Company would likely receive additional license payments that are commensurate with the scale of these agreements. Unilife expects to remain the sole supplier of the Unilife Prefilled Syringe to any sublicensing partner under the terms of this agreement.

When the five-year period expires, sanofi-aventis would be required to renegotiate with Unilife should it wish to retain its right to the exclusive use of the Unilife Prefilled Syringe. As a brand image for sanofi-aventis' delivery system, Unilife believes that the Unilife Prefilled Syringe can become synonymous with sanofi-aventis' injectable drugs. This is important given the highly competitive drug market where generics are eroding brand market share. Unilife's product has significant potential to provide a major differentiator in the marketplace with a clearly identifiable brand image that may enable the extension of patent protection for certain brand products.

Initial production and sales of the Unilife Prefilled Syringe to sanofi-aventis is scheduled to commence in late 2010. By 2014, Unilife expects to be in a position to manufacture approximately 400 million units of the Unilife Prefilled Syringe per year. Based upon the successful realization of its project plan for the Unilife Prefilled Syringe, Unilife expects revenues to exceed $400 million a year beyond 2014.

Gerresheimer Bünde GmbH

In November 2007, Unilife signed a Business Development Agreement with German-based Gerresheimer Bünde, a wholly owned subsidiary of Gerresheimer AG (GXI-FRA), the world's second largest manufacturer of prefilled syringe systems. Gerresheimer Bünde is a leading supplier of prefilled glass barrel syringes to many of the world's major pharmaceutical companies, including sanofi-aventis. The company operates 41 manufacturing plants in the U.S., Europe, and Asia; employs 10,000 people; and reported 2007 sales of roughly $1.6 billion.

The agreement with Gerresheimer Bünde sets out the principles on which the parties are developing a joint venture or supply agreement to support the production of a minimum of 400 million units of the Unilife Prefilled Syringe per year. The agreement restricts both parties from working with any other company in this sector. The main Gerresheimer Bünde manufacturing facility in Germany produced the custom-made glass barrels that were used to manufacture the initial production batch of Unilife Prefilled Syringes and were supplied to sanofi-aventis in 2008 for product evaluation activities.

Supply Chain Partners

Shanghai Kindly Enterprise Development Group Co., Ltd ("KDL")

KDL is the second largest medical device manufacturer in China, employing approximately 3,000 individuals, and reporting revenues in 2006 of $100 million. In 2006, KDL manufactured five billion needles and 600 million syringes, with the majority exported to countries outside of China. Unilife is the exclusive partner for KDL in the safety syringe market. For Unilife, KDL is already producing approximately 100,000 to 150,000 units of the Unitract™ 1mL syringes per month using semi-automated assembly systems developed by IBS. Beyond exporting products to North America, Europe, and South America, KDL also has an integrated distribution network that supplies the majority of hospitals and other healthcare facilities in China. KDL has secured exclusive rights to distribute the Unitract™ 1mL syringes in China and other export markets, including much of South America, Asia, the Middle East, and Africa. Commercial sales of the 1mL syringes to KDL commenced in mid-2008.

West Pharmaceutical Services, Inc.

West is the world's largest producer of syringe components for global medical and pharmaceutical industry leaders. Headquartered in Pennsylvania, West operates over 20 global production sites, supplying sophisticated syringe components (e.g., seals) for some of the world's largest pharmaceutical, biotechnology, and medical device companies. Unilife has a Development Agreement with West for the provision of specialist components, such as seals, for its products.

Tessy Plastics, Corp.

Unilife has a close relationship with Tessy Plastics, a New York-based producer of high quality medical device components. Tessy supplies the majority of plastic component requirements to Unilife's facility in Pennsylvania, including components to support production of B.Braun USA and Unilife production lines, noting that IBS manufactures approximately 50 different parts for B.Braun, as further detailed on page 53. Tessy has over 200 molding machines with FDA-approved and **Good Manufacturing Practices (GMP)**-qualified facilities.

Company Leadership

Unilife has assembled a solid and experienced Board of Directors and management team with an extensive medical device history that ranges from the start-up stage to market leader status. The Company believes that the capabilities of its leadership team can be used to successfully drive its international development and commercialization programs. Unilife and its subsidiaries together employ 75 staff across Australia, China, and the U.S. The engineering and operational capabilities of Unilife are now being significantly expanded in Europe and the U.S. under the Industrialization Program for the Unilife Prefilled Syringe. Unilife has also commenced recruitment activities to appoint a number of qualified individuals for management and manufacturing positions.

Board of Directors

Unilife's Board of Directors oversees the conduct of and supervises the Company's key management team. Table 2 provides a summary of Board members, followed by detailed biographies.

Table 2
Unilife Medical Solutions Limited
BOARD OF DIRECTORS

Jim Bosnjak, OAM	Non-executive Chairman
Alan Shortall	Chief Executive Officer (CEO)
William Galle	Non-executive Director
Jeff Carter, M.App.Fin.	Non-executive Director

Source: Unilife Medical Solutions Limited.

Jim Bosnjak, OAM, Non-executive Chairman

Mr. Bosnjak is a prominent Australian businessman with solid government experience and broad investments across Australia, Asia, and Europe. He was appointed chairman of Unilife in April 2006 and has served as a member of Unilife's Board of Directors since February 2003. Mr. Bosnjak has been involved in numerous commercial enterprises related to transport, manufacturing, funds management, advertising, hospitality, and tourism. Mr. Bosnjak is a co-owner of the Le Meridien 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. Mr. Bosnjak is also chairman and cofounder of Ultimate Outdoor Ltd, a media company delivering outdoor and indoor media advertising across Australia. Among other roles, he was formerly the director and chairman of one of Australia's largest closely held bus companies, Westbus Pty Ltd, and has held positions on Commonwealth and New South Wales (NSW) advisory bodies, including the Greater Western Sydney Economic Development Board and the GROW Employment Council. His prominent industry positions included serving as chairman of the Tourism Council of Australia and Bus 2000, which coordinated bus services for the Sydney 2000 Olympic Games. Mr. Bosnjak has been awarded an honorary doctorate from the University of Western Sydney for services toward employment growth and economic development, the Medal of the Order of Australia for his services to road transport and the community, and an Order of Merit from the NSW Olympic Council.

Alan Shortall, Chief Executive Officer (CEO)

Mr. Shortall is an experienced entrepreneur who has guided the growth and international development of Unilife since its inception. He has served as CEO and a member of the Company's Board of Directors since September 2002 and has been involved in the commercialization of Unilife's safety syringe technology for more than eight years. Mr. Shortall was also primarily responsible for the establishment of Unilife on the ASX. He 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

medical device industry. Mr. Shortall has recently relocated from Sydney, Australia, to Pennsylvania to support the continued global expansion of Unilife.

William Galle, Non-executive Director

Mr. Galle is a U.S.-based consultant with over 30 years of experience in the development and implementation of business growth and alternative investment strategies. He consults for international companies that seek to undertake growth activities, such as listing on a major U.S. exchange, raising capital from key U.S. institutions, and enhancing internal operating efficiencies. He is president of Diversified Portfolio Strategies LLC, a Washington D.C.-based firm that provides alternative investment advisory services for institutions and substantial investors. He is also managing director of American Marketing Complex, a New York City-based group that has implemented balance sheet enhancement strategies and developed strategic business plans for more than 400 public and private companies since 1978. Mr. Galle is a graduate of Columbia University, Rutgers University, and the New York Institute of Finance, and has served as a member of Unilife's Board of Directors since June 2008.

Jeff Carter, M.App.Fin., Non-executive Director

Mr. Carter is a chartered accountant (CA) with more than 25 years of experience in financial and senior management roles in both Australia and the U.S. He has served as a member of Unilife's Board of Directors since April 2006 and was also appointed company secretary in March 2007. His experience includes a background in the healthcare industry, where he has previously held chief financial officer (CFO) and chief operating officer (COO) positions. Prior to joining Unilife, Mr. Carter worked with Ambri Ltd. (now Diversa Ltd.) as CFO and company secretary; Agenix Ltd. (AGX-ASX) as CFO and COO; Coca-Cola Amatil Ltd. (CCL-ASX) as strategic planning manager; Santos Ltd. (STOSY-NASDAQ) as manager of corporate development international; CIBC Australia Ltd. as manager of investment banking; and Touche Ross (now Deloitte Touche Tohmatsu) as a senior manager. Mr. Carter holds a Master's degree in applied finance (M.App.Fin.). In December 2008, Mr. Carter resigned as CFO in Australia to facilitate the appointment of a U.S.-based CFO (now Mr. Daniel K. Calvert, biography on page 21). Mr. Carter continues to act as a consultant to Unilife, supporting the Company in corporate secretarial functions, corporate restructuring activities, and ASX reporting requirements.

Management

Table 3 (page 20) summarizes the additional key members of Unilife's leadership team as well as the Company's corporate advisors, accompanied by detailed biographies.

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

Dr. Verollet is the former head of the World Health Organization's (WHO) 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) and national government agencies. He was responsible for the creation and adoption of new International Organization for Standardization (ISO) standards for auto-disable syringes, and helped create an alliance with the World Bank for worldwide access to safe injection technologies. Dr. Verollet has also 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. In the 1980s, he was responsible for regional sales in France for the former pharmaceutical companies Glaxo Laboratories (now GlaxoSmithKline plc [GSK-NYSE]) and Rhône-Poulenc. Dr. Verollet maintains a high regard for the adoption of safe injection technologies worldwide. His decision in 2003 to join the Company as vice president of scientific and international affairs was made in order to realize the same injection safety policies that he developed during his career at the WHO.

Table 3 Unilife Medical Solutions Limited MANAGEMENT	
Gerald Verollet, Ph.D.	Vice President of Scientific and International Affairs
Bernhard Opitz, M.Sc.	Senior Vice President of Operations
Daniel K. Calvert, CMA, MBA	Chief Financial Officer
Eugene Shortall	RTFS Project Director
Ed Paukovits, MBA	President of IBS
Mark Iampietro	Vice President of Quality and Regulatory Affairs
Michelle Gow, MBA	Director of Quality and Regulatory Affairs
Stephen Allan	Vice President of Communications
Lisa MacKenzie	Clinical Director
Graham Purches, Ph.D.	Director of RTFS Operations
Dan Adlon	Vice President of Strategic Business Development
Keith Bocchicchio	Vice President of Automation and Engineering
Craig Thorley	Manager of Research and Development
Joe Kaal	Manager of Research and Development
Corporate Advisors	
Edward Fine	Senior Corporate Advisor
Inteq Ltd.	Corporate Advisor

Source: Unilife Medical Solutions Limited.

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

Mr. Opitz was appointed to the position of senior vice president of operations at Unilife in November 2008. He holds an M.Sc. in mechanical/process engineering, is fluent in English and German, and speaks conversational Italian and French. During his 28-year career, he has become internationally recognized for driving product innovation and productivity improvement initiatives, streamlining branded product launches, and establishing high-performance, rapid-response engineering organizations in Europe and the U.S. Mr. Opitz has also managed the building of manufacturing plants in Europe and the U.S. and has held senior operational positions at some of the world's largest and fastest growing medical device, diagnostic, and biotechnology companies.

In 1980, he began a 20-year career at Bayer AG as a project engineer and later held positions as manager of plant engineering, manager of engineering, production manager, and vice president of operations, culminating as 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 has also held senior management positions for other major public and private companies, including Wells' Dairy, Inc., Ikonisys, Inc., and Nanosphere, Inc. (NSPH-NASDAQ). In addition to the construction and operation of semi-automatic and fully automatic production lines and sterile filling facilities, Mr. Opitz also has a strong background in the use of high-speed robotic equipment. At Unilife, his unique blend of skills, team building, expertise, and experience are used to coordinate the production and commercial supply of the Unilife Prefilled Syringe and other key products on a global basis. He is also responsible for the recruitment of a number of key operational positions to support rapid growth in production and sales, with a key priority of sustaining operational liquidity and improving bottom line earnings as Unilife expands into the U.S. and Europe to support the Industrialization Program for the Unilife Prefilled Syringe.

Daniel K. Calvert, CMA, MBA, Chief Financial Officer

Mr. Calvert was appointed to the position of CFO of Unilife in December 2008. He has over 25 years of financial, strategic, and operational management experience in diversified national and international companies. He is experienced in the U.S. Securities and Exchange Commission's (SEC) reporting requirements for publicly listed companies, Sarbanes-Oxley compliance, merger and acquisition activities, investor relations, and tax planning. Mr. Calvert is a certified management accountant (CMA) and holds an MBA in finance from Michigan State University and a Master's in taxation from the University of Baltimore, where he graduated in finance and accounting. Mr. Calvert was previously executive vice president and chief accounting officer of Standard Management Corp. (SMAN-OTC.PK), a national institutional pharmacy and home healthcare company. At Standard Management, Mr. Calvert served as the principal financial officer helping to raise capital and conduct due diligence to acquire a new business. His previous roles have included being CFO of MBT International Inc., an international consumer product distribution and third-party logistics company, B.Allen Group of San Francisco, and Hayes Marketing Inc.

Eugene Shortall, RTFS Project Director

Mr. Shortall is a highly experienced manager of major projects in Europe and the Middle East. Joining Unilife in 2008 and based in Paris, France, he is responsible for the development and implementation of an Industrialization Program for the Unilife Prefilled Syringe, as well as the establishment of relationships with key project partners, suppliers, and customers. Prior to joining Unilife, Mr. Shortall was engaged to manage the development of construction projects in the UK, Europe, and the Middle East. 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.

Ed Paukovits, MBA, President of IBS

Mr. Paukovits has 25 years of experience in contract manufacturing activities, marketing, business planning, intellectual property, and creating innovative synergies with academic and industry partners. His background includes serving as a liaison on technology initiatives in manufacturing, medical devices, and optics. He is a co-founder of IBS, establishing the business as a contract manufacturer of specialist medical device products in 2003. In 1999, he founded Assistive Technology Products, a medical device company based in Harrisburg. From 1989 to 1999, he served as CEO of Synergistech, Inc., a company involved in advanced manufacturing technologies. Also during the 1990s, Mr. Paukovits was director and treasurer of the Technology Council of Central Pennsylvania, where he was honored as a Person of the Year in 1993. Prior to his work with Synergistech, Mr. Paukovits held various roles with AMP, Inc., including manager of the Aerospace Group, business manager of the Automation Systems Group, and development engineering manager. He holds an MBA in finance from Shippensburg University as well as 16 issued and multiple pending U.S. patents for medical devices, electronics, and manufacturing and is a licensed professional mechanical engineer in Pennsylvania. Mr. Paukovits was elected to the Board of the Hershey Center for Applied Research, a life science and high technology park, in 2008.

Mark Iampietro, Vice President of Quality and Regulatory Affairs

Mr. Iampietro was appointed to the position of vice president of quality and regulatory affairs in October 2008. With more than 30 years of quality experience across global pharmaceutical, biologics, and medical device markets, Mr. Iampietro focuses on the development and maintenance of international quality and regulatory systems to support the industrialization and supply of key products, such as the Unilife Prefilled Syringe. 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. Mr. Iampietro came to Unilife from Spherics Inc., a closely held, Boston-based pharmaceutical manufacturer where he managed all phases of quality, regulatory, and clinical programs for four years. Prior to this, Mr. Iampietro 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. He is a visiting scientist at Brown University in Providence, Rhode Island, a senior member of The American Society for Quality (ASQ), holds ASQ certifications as both a quality and reliability engineer, has had articles published in *Quality Magazine*, has a B.S. in life sciences with a minor in engineering, and holds a U.S. patent.

Michelle Gow, MBA, Director of Quality and Regulatory Affairs

Ms. Gow has 25 years of experience in regulatory affairs and is responsible for coordinating Unilife's quality management system as well as activities between Unilife and IBS. Prior to joining the Company in January 2004, Ms. Gow served as the manager of quality and regulatory affairs for Unomedical Pty Ltd. (previously traded as Maersk Medical Pty Ltd.) in Sydney, Australia. In this capacity, she managed GMP, quality, product design and development, incident reporting, product recalls, product listing and registration, and regulatory functions within the Australian manufacturing division. Ms. Gow also worked to implement systems for CE product marking for the EU market and developed a framework for electronic quality assurance reporting systems, including procedures and product complaint databases. Formerly, she was a consultant for Dori Alimentos LTDA (a confectionary in Brazil) and held various manufacturing coordinator and quality assurance roles in Malaysia for Nestlé Pty Ltd (part of Nestlé SA [NSRGY-OTC]). She has also served as quality assurance coordinator for Deepfreezing and Preserving Pty Ltd., technical officer (R&D) for Sea Harvest Pty Ltd, and both technical research and quality assurance officer for Reckitt & Colman Pty Ltd (now Reckitt Benckiser Group plc [RB-LON]). Her professional affiliations include the Association of Regulatory and Clinical Scientists, the Medical Industry Association of Australia, and the Australian Contamination Control Society. Ms. Gow holds an MBA from the Sydney Graduate School of Management, part of the University of Western Sydney (UWS).

Stephen Allan, Vice President of Communications

Mr. Allan has more than 15 years of media, government, and public relations experience. Since joining Unilife prior to its Australian listing in 2002, he has been responsible for all communications, public relations, and public affairs activities undertaken by the Company on a global level. In particular, he is responsible for the development and implementation of communication programs for Unilife and external stakeholder groups, including shareholders, media, business partners, elected government officials, and government agencies. Previously, Mr. Allan owned and operated an Australian media and government relations firm that provided consultancy services to a range of state and national industry groups, government agencies, and private companies. Special projects undertaken during this consultancy period included the management of media relations for bus transport services during the Sydney 2000 Olympic Games, a government lobbying campaign for one of Australia's largest privately funded motorway projects, and the management of public relations activities for private bus and tourism industry groups. After attaining a Bachelor of Communications from Charles Sturt University, Mr. Allan spent five years as a journalist for a number of Sydney-based newspaper groups.

Lisa MacKenzie, Clinical Director

Ms. MacKenzie is a skilled clinician with nearly 20 years of experience in the medical field. Since joining Unilife in 2006, she has been responsible for lifecycle product management and project management for Unilife's range of products. Ms. MacKenzie also manages internal user clinical trials and evaluations, coordinates independent clinical trials on an international basis, and is responsible for product training of distributor sales staff and nursing staff. In the period between 1998 and her appointment at Unilife, Ms. MacKenzie was employed in various capacities with ResMed Ltd., a developer, manufacturer, and marketer of products for the screening, treatment, and long-term management of sleep-disordered breathing and other respiratory disorders. At ResMed, Ms. MacKenzie was responsible for soliciting and analyzing input from relevant global sources to prepare marketing plans and documents; managing and sustaining the product lifecycle of specific product portfolios to ensure continual supply; developing, implementing, and delivering clinical and product training programs for ResMed's sales and clinical staff; and strategically launching new products on a global basis. She has a Dip.Sc. in nursing, became a registered nurse (RN) in 1990 in Queensland, Australia, and is a qualified **polysomnographer**.

Graham Purches, Ph.D., Director of RTFS Operations

Dr. Purches joined Unilife in September 2008 to coordinate the industrialization of the Unilife Prefilled Syringe. His key roles include serving as a technical liaison with primary customers, identifying and communicating with appointed suppliers, researching and procuring relevant manufacturing equipment, and developing production capabilities for the Unilife Prefilled Syringe. Dr. Purches came to Unilife following an eight-year period with ResMed, where he held several positions, including quality engineer

involved in developing the quality system, project manager responsible for many projects from design to manufacturing and leading to market launch, and supplier alliance manager responsible for the selection of primary and alternative suppliers on a global basis and the liaison with these suppliers to enhance quality levels and improve overall cost efficiencies. Dr. Purches has been trained in **Six Sigma** (Black Belt in 2007), and has also been trained in the FDA's GMP. He received a Ph.D. in organometallic chemistry from Sydney University in 1998, undertook postdoctoral studies in Florence, Italy, in 1996, and secured a B.Sc. (honors) in chemistry from Sydney University in 1991.

Dan Adlon, Vice President of Strategic Business Development

Mr. Adlon has more than 25 years of medical device and automation expertise. He is experienced in new product development, sales, engineering, manufacturing, strategic planning, and program management. In terms of business development, Mr. Adlon's leadership has been instrumental at securing multimillion dollar partnership agreements for the contract manufacture of medical devices for various customers, securing a $10 million contract for building multiple machines for a telecommunications customer, securing a contract to build a $1.7 million assembly machine for an advanced restraint module connector, and expanding customer bases. His program and departmental management successes include managing a $1.2 million connector assembly automation project to completion, coordinating the work of engineers across multiple departments to complete various other medical product and manufacturing system program designs, managing an eight-person engineering department, creating engineering standards, and implementing ISO quality standards. Prior to joining IBS, Mr. Adlon has served as business development manager and manager of machine design at Synergistech and held various positions at AMP, Inc., including project machine designer.

Keith Bocchicchio, Vice President of Automation and Engineering

Mr. Bocchicchio has over 25 years of experience in the design and qualification of automated assembly lines for medical device, electrical, and aviation industries. He has designed hundreds of automation systems using diverse technologies, created new in-process inspection controls resulting in numerous patents, and conceived and developed advanced interconnection products for military and aerospace applications, such as the Stealth Fighter and Stealth Bomber. Mr. Bocchicchio has also planned, directed, and executed the conversion of an electronics manufacturing and automation company into a medical products contract manufacturing operation, which included guiding the development of a quality management system in conformance with **FDA 21 CFR 820** guidelines and certified for **ISO 9001:2000** and ISO 13485:2003 and directing all activities involved in facility planning and setup, capital equipment development and acquisition, process documentation and validation, customer product and process transfer, and manufacturing, operation, and procurement. In addition, he has experience implementing a strategic plan for a custom automation equipment manufacturer that reorganized company structure in order to reduce overhead and improve the shareholder equity position. Mr. Bocchicchio is a member of the American Society of Mechanical Engineers, the Automated Imaging Association, and the Society of Mechanical Engineers, and is a former director of the Penn State Alumni Association.

Craig Thorley, Manager of Research and Development

Mr. Thorley is one of the original co-inventors of Unilife's core suite of safety syringe technologies and has an extensive background as a mechanical engineer. Following the receipt of multiple needlestick exposures to his mother, a highly qualified nurse at a local hospital in the Hunter Valley of NSW, Australia, Mr. Thorley worked with colleague Mr. Joe Kaal (biography on page 24) over several years to complete designs for the core safety syringe technology and to develop initial working prototypes. In 2004, Unilife established a Research and Development Office and Facility to support the activities of Mr. Thorley and Mr. Kaal. In 2004, Mr. Thorley collected the Prize of the State of Geneva Award on behalf of Mr. Kaal and Unilife at the 32nd International Exhibition of Inventions and New Technologies in Geneva, Switzerland. Since the Australian listing of Unilife in 2002, Mr. Thorley has continued to have a key role in the enhancement, expansion, and commercialization of the Unilife portfolio of safety syringes. This has included input into the filing of Unilife's patents regarding its safety syringe technology and associated products and the development of initial design concepts for the Unilife Prefilled Syringe and the Unitract™ Clinical Range. Mr. Thorley has also utilized his engineering expertise to support the design and development of manufacturing systems for the production of safety syringe products.

Joe Kaal, Manager of Research and Development

Mr. Kaal is the joint original co-inventor of Unilife's core suite of safety syringe technologies and has an extensive engineering background. He and Mr. Thorley worked in full cooperation over several years to complete designs for the core safety syringe technology and to develop initial working prototypes. Mr. Kaal shared the Prize of the State of Geneva Award accepted by Mr. Thorley in 2004. Mr. Kaal also shares a number of the key research and development responsibilities listed on page 23 under Mr. Thorley's biography.

Corporate Advisors

Edward Fine, Senior Corporate Advisor

Mr. Fine is a U.S.-based specialist for corporate and marketing alliances with 40 years of experience in U.S. financial, pharmaceutical, manufacturing, and information technology markets. He is president of Carpe DM Inc., a New York-based public relations, investor relations, and business development firm established in 2000 specializing in strategic alliances, partnerships, manufacturing, and royalty agreements. A self-described entrepreneur, Mr. Fine has served in chairman, director, CEO, CFO, COO, certified public accountant (CPA), and other executive management positions with a wide range of companies, including Pfizer Inc. (PFE-NYSE), Dyna-Lease Corp., Intercapital Planning Corp., Reliance Group, Newtron Pharmaceuticals, Inc., and Biopharmaceuticals Inc. Together with his son, Mr. Fine has established EIF Capital as an offshoot of Carpe DM, focused on financial investment consulting. He has also founded a number of businesses, including a financial services company and a plastics manufacturer.

Inteq Ltd., Corporate Advisor

Inteq (www.inteq.com.au) is an Australian corporate advisory subsidiary of the Blue Oar Group (BLUE-AIM), a UK-listed financial services group with over 100 employees and 75 retained nominated advisor (NOMAD) clients. Inteq was established in 1988 and has offices in Sydney, Melbourne, and Perth, Australia. The company seeks to provide its clients with the resources of the entire Blue Oar Group, including facilitating mergers and acquisitions, raising capital in Australia and Europe, providing NOMAD services, and offering access to research, institutional sales brokerage, and private client services. Inteq's track record of completing transactions for clients around the world includes advising and arranging nearly $2 billion of capital. Inteq holds an Australian Financial Services License and its parent, Blue Oar Securities Plc, is licensed by the UK Financial Services Authority, allowing the company to offer a full range of services from advising to underwriting issues of securities.

Core Story

Unless stated otherwise, all monetary amounts are in U.S. dollars. At 01/02/2009, US$1.00 = ~A$1.43 and €0.72.

INDUSTRY OVERVIEW

Syringes are sterile devices used to inject solutions into or withdraw secretions from the body. A syringe is a calibrated glass or plastic cylinder with a plunger at one end and an opening at the other end that attaches to a needle. The needle is a hollow metal tube with a pointed tip. Syringes are often used to administer medicines, such as is necessary when a person cannot take a medication by mouth or when the drug would otherwise be destroyed by digestive secretions. Figure 4 provides an illustration of a typical syringe.

Figure 4
TYPICAL SYRINGE

Source: Queensland Health 2008.

The Occupational Safety and Health Administration (OSHA)

Under the **Occupational Safety and Health Act** of 1970, the U.S. Congress established the Occupational Safety and Health Administration (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. More specifically, the recorded incidence of injuries and illnesses in the workplace among private industry employers has decreased by roughly 0.2 cases per 100 employees each year since 2003 (Source: the Bureau of Labor Statistics' *Workplace Injury and Illness Summary* 2007).

The Bloodborne Pathogens Standard (BPS)

To address concerns specifically related to the occupational transmission of bloodborne pathogens, OSHA implemented the BPS in 1992. The standard was primarily implemented to protect employees at hospitals, funeral homes, nursing homes, clinics, and research laboratories, as well as law enforcement and emergency responder personnel (Source: Oklahoma State University). However, any employee whose occupation may cause exposure to bodily fluids, such as human blood, or other potentially infectious materials is also protected under OSHA's standard. 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).

The Needlestick Safety and Prevention Act

Following the implementation of the BPS, exposure to bloodborne pathogens from accidental sharps injuries in healthcare and other occupational 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 to update and improve the BPS.

The revised BPS was placed into the **Federal Register** in January 2001. Following a short initial period in which OSHA educated healthcare facilities on the adoption of appropriate measures to ensure compliance with the BPS, the agency began to actively enforce these new standards. In 2003, the BPS 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 also comply with the BPS.

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 used to withdraw bodily fluids, access a vein or artery, or administer medications or other fluids that includes a built-in safety feature or mechanism to effectively minimize the risk of an exposure incident. In addition to the standards that were already in place, the new legislation incorporated four additional requirements to reduce the occupational transmission of bloodborne pathogens:

(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.

The law does not actually provide a formal list of approved or endorsed products, thus placing 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.

However, in its “Hospital eTool,” OSHA does make 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 the following safety device selection criteria, as developed by the U.S. Food and Drug Administration (FDA):

(1) 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;

(2) Be an integral part of the device and not an accessory;

(3) Be in effect before disassembly (passive) and remain in effect after disposal to protect users and trash handlers as well as for environmental safety; and

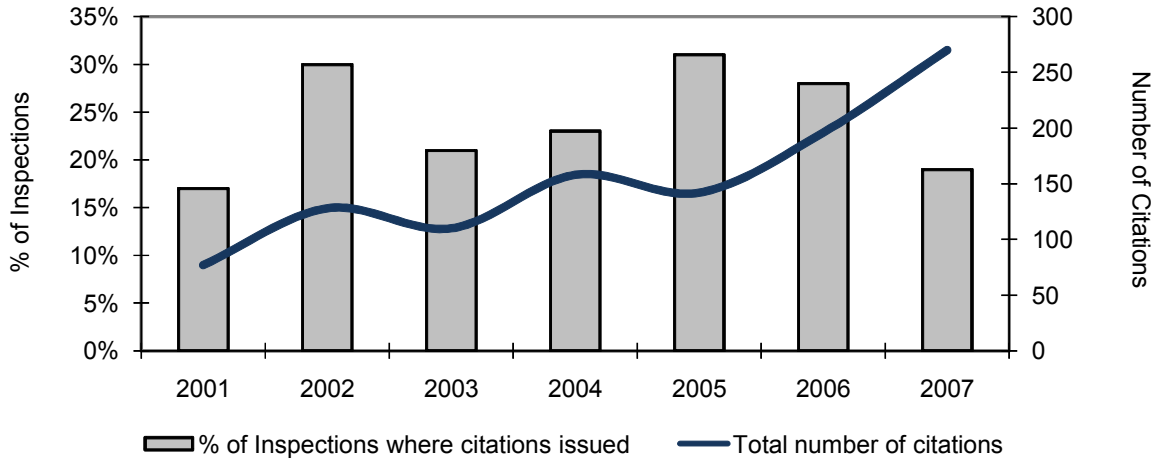
(4) Be as simple as possible, requiring little or no training to use effectively.

Citations Related to Noncompliance

It is noteworthy that OSHA has taken action against a number of U.S. healthcare facilities for noncompliance with the BPS. During just the first six months of 2007, the International Sharps Injury Prevention Society (ISIPS) reported that OSHA issued 429 citations to U.S. healthcare facilities, with 321 involving BPS violations. In particular, 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 non-compliance in the use of safety devices went from 77 (in 2001) to 270 (in 2007), as illustrated in Figure 5 (page 27). 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 significant fines when these devices are not implemented facility-wide.

Figure 5

FEDERAL OSHA CITATIONS RELATED TO MISUSE OF SHARPS SAFETY DEVICES (2001 - 2007)



Source: the Occupational Safety and Health Administration (OSHA).

Followed by an increase in demand for safety syringes seen in the U.S., developed countries throughout the world are also seeking alternatives to reduce the incidence of needlestick injuries. For example, organized healthcare worker unions in several European countries—including France, England, Germany, and Italy—are seeking to make safety a higher priority in hospitals and government agencies through the implementation and use of safer medical devices.

The European leader in this regard is Germany, which in 2007 introduced legislation (TRBA 250) that made safety syringes mandatory without exception in all healthcare facilities. Noncompliance carries the risk of significant monetary fines or up to three years imprisonment in the event of an injury or claim. In particular, German employers must provide working instruments with integrated safety features that can be activated with one hand immediately after use and that prevent any opportunity for reuse. In addition, 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.

Recent Example of an OSHA Violation

The California Division of Occupational Safety and Health (Cal/OSHA) was recently alerted to the sale in California and nationwide of prefilled syringes with fixed needles containing Fluvirin®, manufactured by Novartis AG (NVS-NYSE), which is one of the 2008 seasonal influenza vaccines. The needles did not have engineered sharps injury protection and were not able to be removed and replaced with safety needle products that have 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. Novartis states that it has 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 can make direct contact with them to provide information to their customers; and obtained “add-on” safety devices that can 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.

Syringe Market Highlights

In the U.S. alone, approximately six billion syringes are thought to be used each year. Moreover, it is estimated that as many as 35 billion syringes are used worldwide annually (Source: the International Association of Safe Injection Technology [IASIT] 2004), believed to represent a $4 billion to $5 billion market. Yet, many of these syringes are used more than once. The World Health Organization (WHO) estimates that over 1.3 million people die each year from unsafe injection practices. Three key risk areas regarding the unsafe use of syringes are summarized below and detailed on the accompanying pages.

(1) *Reuse and Sharing of Non-sterile Syringes.* While intended as single-use injection devices, many disposable syringes are instead being reused by injecting drug users (IDUs) and in developing countries where there are limited resources to purchase new sterile needles. The reuse and sharing of standard syringes is a prime accelerant in human immunodeficiency virus (HIV) and hepatitis C epidemics worldwide. For instance, this practice within healthcare facilities in developing countries combined with other injecting groups, such as IDUs, accounts for roughly one-third of new global HIV infections outside sub-Saharan Africa.

(2) *Unsafe Disposal of Non-sterile Syringes.* The disposal of non-sterile standard syringes by IDUs and patients who self-administer prescribed medication can place garbage disposal personnel and other members of the community at risk of needlestick injury.

(3) *Needlestick Injuries to Healthcare Workers.* The conventional syringe design leaves patients, practitioners, and the general population prone to accidental needlestick injuries. The WHO estimates that three million healthcare workers (10%) are exposed to bloodborne pathogens annually due to needlestick injuries. Additionally, approximately 600,000 healthcare workers in the U.S. and one million more in Europe are expected to incur a needlestick injury each year. 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.

Beginning in the 1990s, pharmaceutical and medical device companies began incorporating safety mechanisms onto syringes. This trend has accelerated in the past decade in sophisticated healthcare markets, such as the U.S., Canada, and Europe, in response to the passage of legislation mandating the use of safety syringes. Some countries have introduced needlestick prevention legislation that is in many ways more stringent than in the U.S. For example, as described on page 27, safety syringe products used in German healthcare facilities are required to include a safety mechanism as a component of the device (integrated) that engages immediately after use (automatic activation). Despite this progress, conventional syringes are still used frequently in a number of international markets and still possess significant drawbacks, namely those overviewed above.

While the total market for syringe-based injection devices is expected to expand in excess of 7% through 2010, sales of traditional syringes are expected to contract as more practitioners and healthcare facilities adopt alternatives, such as improved safety syringes to address the sharps cross-contamination issue.

The Unsafe Reuse of Injectable Devices

In countries such as the U.S., immunization processes are well established and advanced, and safe injection systems are generally available. However, 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” unsterilized needles.

The WHO estimates that these unsafe injections account for 33% of new hepatitis B and 42% of new hepatitis C cases in developing and transitional countries. The supply of a cost-efficient injection device that does not require skilled administration and does not permit reuse would be able to help improve the safety of injections in developing countries, thereby also helping to reduce disease transmission. According to Ron Stoker, executive director of ISIPS, in *Anatomy of a Needlestick Injury* (2004), what is needed is an autodestruct syringe that protects healthcare workers and others from sharps injuries.

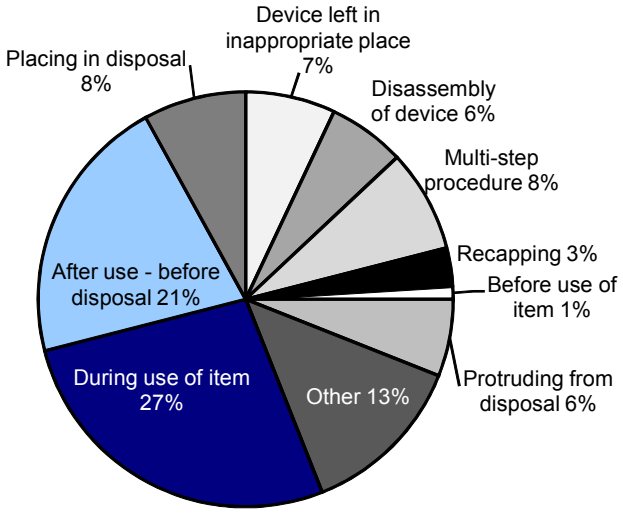
Risks of Needlestick Injuries

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. Inherently, even the smallest needle prick that contacts bodily fluid carries the risk of transmitting dangerous infectious diseases.

The majority of these sharps injuries occur when individuals are working primarily on 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). A summary of when needlestick injuries typically occur is provided in Figure 6.

Figure 6

WHEN NEEDLESTICK INJURIES OCCUR



Source: Greystone Associates' Retractable Safety Syringes 2007.

Approximately one million healthcare workers are injured by sharp instruments in the U.S. each year, which accounts for about one out of every seven healthcare employees (Source: ISIPS). In the U.S. annually, there are approximately 385,000 sharps-related injuries to hospital-based healthcare personnel in particular, which represents an average of 1,000 punctures per day (Source: the Centers for Disease Control and Prevention [CDC] 2004). These numbers do not include needlestick injuries to patients or to workers at non-hospital institutions, such as home healthcare, long-term care, and private practice. In addition, the CDC estimates that as much as 50% of healthcare personnel do not report their occupational **percutaneous** wounds, specifically physicians who are much less likely to report a needlestick injury than other healthcare professionals. Additional estimates place the number of needle injuries in the U.S. each year at approximately 600,000, with as many as 2,000 of these resulting in the transmission of bloodborne viruses.

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, as illustrated in Figure 7 (page 30). A study of 19 of Australia's Queensland Health hospitals from February 2002 to December 2005 found that of the more than 5,300 occupational exposures to blood and bodily fluids, approximately 68% were due to percutaneous (through the skin) sharps injuries. Roughly 55% of these sharp injuries were caused by hollow-bore (**hypodermic**) needles.

Figure 7

INFECTIONS TRANSMITTED VIA SHARPS INJURIES DURING PATIENT CARE (PC) AND/OR LABORATORY/AUTOPSY (L/A)

Infection	PC	L/A	Infection	PC	L/A
Blastomycosis		○	Herpes	●	
Cryptococossis		○	Leptospirosis		○
Diphtheria		○	Malaria	●	
Ebola		○	M. tuberculosis	●	○
Gonorrhea		○	Rocky Mountain spotted fever		○
Hepatitis B	●	○	Scrub typhus		○
Hepatitis C	●	○	Strep pyogenes		○
HIV	●	○	Syphilis		○
			Toxoplasmosis		○

Source: the U.S. Centers for Disease Control and Prevention (CDC) 2004.

The direct costs associated with treatment of 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.

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 actually has an injection phobia that makes injectable treatments difficult or even 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. A selection of physicians was also interviewed, with 79% of healthcare providers acknowledging that their patients skip insulin 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. Most complications arise from extended periods of elevated, uncontrolled blood glucose levels, and each year, roughly four million adults die of these side effects (Source: International Diabetes Federation [IDF]). 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

Healthcare markets throughout the world are transitioning to the mandatory use of safety syringes in an effort to help protect healthcare workers from needlestick injury. The U.S. was the first country to adopt and actively enforce legislation requiring healthcare facilities to use safety syringes, with the passage of the Needlestick Safety and Prevention Act in 2000 (described on pages 25-26). Canadian, EU, and Australian healthcare markets are now following the U.S. in the mandatory protection of healthcare workers from needlestick injury. Several factors, as listed below and on page 31, are driving this trend to safety syringes.

- *Risk of Harm*. Although nurses sustain the highest rate of needlestick injuries, all healthcare workers from physicians to cleaning staff and other individuals are at risk for harm. Disposable syringes cause more needlestick injuries than any other type of device.

- *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 (as is illustrated in Figure 5 [page 27]) and heavy fines for noncompliance.

- *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: CDC).

- *Staff Retention*. Fear of contracting a bloodborne disease from a needlestick injury is one of the greatest workplace concerns for healthcare workers.

- *Litigation*. Employees who incur a needlestick injury may choose to take legal action against employers who have not provided a safe working environment.

In countries such as 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 of fines or litigation. Unilife believes that this regulatory pressure is likely to bode well for its technology, which is described on pages 42-52.

Current Standards of Safety Syringes

At present, there are several types of safety syringes in use, ranging from automatically disabled to manually disabled and from those with clip-on safety devices to retractable needles. 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 $0.40 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). 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 $0.70 per unit, which comprises roughly $0.33 for the prefilled syringe and $0.25 for the clip-on device, among other additional assembly and packaging costs. The most common styles of safety syringes currently used are summarized below and on pages 32-33, followed by a detailed description of the market dynamics for prefilled syringes on pages 34-41.

Auto-disable (Non-reuse) Syringes

According to data from the WHO, there are approximately 1.3 million deaths per year from unsafe needle practices reusing dirty syringes. Thus, the WHO has implemented standards requiring auto-disable syringes in order to address the reuse of syringes. At present, auto-disable syringes are most commonly used in developing countries and in the immunization programs of non-governmental organizations (NGOs), such as the United Nations Children's Fund (UNICEF).

A number of manufacturers have designed different methods to account for an auto-disable function. One particular syringe creates an auto-disable function through a vacuum after the first use that consequently cannot be used a second time. Another manufacturer has addressed this issue by creating a spiral at the center of the syringe, so that once the syringe has been used, the plunger is disabled and the syringe cannot be reloaded. The problem with both of these technologies, however, is that individuals can still receive needlestick injuries.

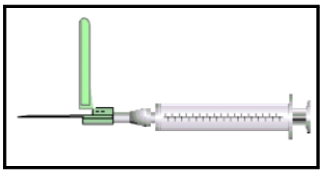
Safety Syringes with a Needlestick Protection Device

There are a number of different types of syringe products currently available that are designed to reduce the risk of needlestick injury. These products generally differ in the way in which the safety mechanisms are activated and the extent to which the safety features are integrated into the device. The main types of needlestick protection devices are illustrated in Figure 8 (page 32), followed by greater details of retractable syringes—specifically, the current generation of syringes using spring-based, non-controlled retraction.

Figure 8

FEATURES AND POTENTIAL LIMITATIONS OF OTHER TYPES OF SAFETY MECHANISMS

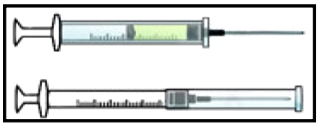
Needle Guard



- A guard slides over the needle to cover it after use
- The guard 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
- Procedure interference, syringe reuse, and tampering are all possible

Needle Sheath

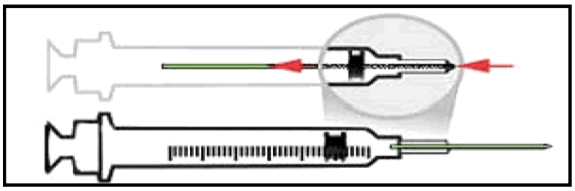
Before Use



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 if multiple injections are needed
- Has the potential to create aerosols (blood splatters) if retracted outside the body

Sources: the CDC, Crystal Research Associates, LLC, and Unilife Medical Solutions Limited.

Spring-based Non-controlled Retracting Needle Syringes

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. They are not currently available in a prefilled syringe format. 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) more sophisticated products, referred to as “spring-based non-controlled retracting needle syringes,” which 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 has to apply additional pressure (in some cases up to 5 kilograms [10 pounds]) 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 system of needle retraction is not considered ideal by many healthcare authorities, and is often not performed by healthcare workers 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 the ECRI Institute (www.ecri.org), have reported that healthcare workers often first remove the device from the patient before activating the safety mechanism in the open air. 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).

One retractable syringe to have received a "preferred for use" rating by ECRI in its 2003 guide, *Sharps Safety and Needlestick Prevention Second Edition*, is the Integra™ product manufactured by Becton, Dickinson and Company (BD) (BDX-NYSE). According to Greystone Associates, BD held a 77% share of the worldwide market for retractable syringes in 2006, with Retractable Technologies, Inc.'s (RVP-AMEX) VanishPoint® having approximately 10% of the market. These retractable devices, which work similarly, require the operator to apply additional pressure to the plunger in order to break the syringe's seal.

Rather than performing the recommended action for retraction, device evaluation guides such as those published by ECRI state that the practitioner often first removes the exposed needle from the patient after delivering the injection but before activating the safety mechanism. This creates a situation where the practitioners or their colleagues are at immediate risk for needlestick injury and exposure from the blood, tissue, or residue that remains on the needle. It is also possible that the activation of the safety mechanism may not take place at all following removal of the needle from the patient, particularly in emergencies. In such a situation, the patient is often attended to as a priority and the non-sterile syringe with the exposed needle may turn up in other places, for instance among the bed linens, creating the risk of needlestick injury to personnel downstream, such as cleaning staff.

Both the ECRI and CDC have identified a number of clinical challenges relating to the use of spring-activated retractable syringes, as summarized below.

- *Non-activation of Safety Mechanism in Situ.* Retraction of the needle inside the body (pre-removal activation) is recommended to eliminate the risk of infection via needlestick injury or aerosol. However, as acknowledged by the ECRI, the primary safety advantage of pre-removal activation (which is what led to the institute's "preferred" ratings) can still be bypassed if the operator chooses not to activate the safety mechanism until after removing the needle from the patient. Moreover, ECRI's research suggests that many practitioners have a strong tendency to do just this.

- *Generation of Aerosol (Blood Splatter) from Needle Retraction in Open Air.* ECRI further affirms that post-removal activation of the safety mechanism can lead to blood or medication splatter with these devices, which is also confirmed by the CDC. To this extent, the Australian government has had to cancel a trial of retractable syringes for use by IDUs once it was identified that the products under trial caused visible splatter.

- *Potential Discomfort for Patients.* An operator may be required to apply considerable downward plunger force to activate the safety mechanism, which can cause patient discomfort or harm and is considered to be a prime reason for healthcare workers opting to not perform pre-removal activation.

Due to the aforementioned limitations of the current generation of retractable syringes, there is a resistance from certain healthcare workers to embrace these types of technologies. In addition, at up to triple the price of a traditional syringe (or more), the current generation of retractable syringes also requires healthcare workers to change their procedures (which these individuals would prefer not to do), and actually may 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 resistance to the currently available retractable syringes.

PREFILLED SYRINGES

Traditionally, injectable drugs have been supplied in vials that are administered either via an intravenous infusion or a standard syringe. Yet, over the past two decades, there has been a trend toward the use of prefilled syringes to deliver injectable medications and vaccines. As such, prefilled syringes are now commonly used for a number of injectable products, particularly in U.S. and European markets. To this extent, pharmaceutical companies are increasingly recognizing the benefits of employing prefilled syringes, as these delivery devices offer a number of advantages over traditional vial packaging. For instance, using a prefilled syringe eliminates several of the steps that are required with using vials, thereby facilitating greater ease of use. Prefilled syringes can also accommodate volumes of drug that range from 0.25mL to 5.0mL, making them appropriate for products administered **subcutaneously** or **intramuscularly**. Table 4 outlines some advantages of prefilled syringes.

Table 4
KEY ADVANTAGES OF PREFILLED SYRINGES

Market Driver	Possible Benefits of Prefilled Syringes	Who Benefits	
		Pharma	End User
Reduced Drug Wastage	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 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		✓
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		✓

Source: Unilife Medical Solutions Limited.

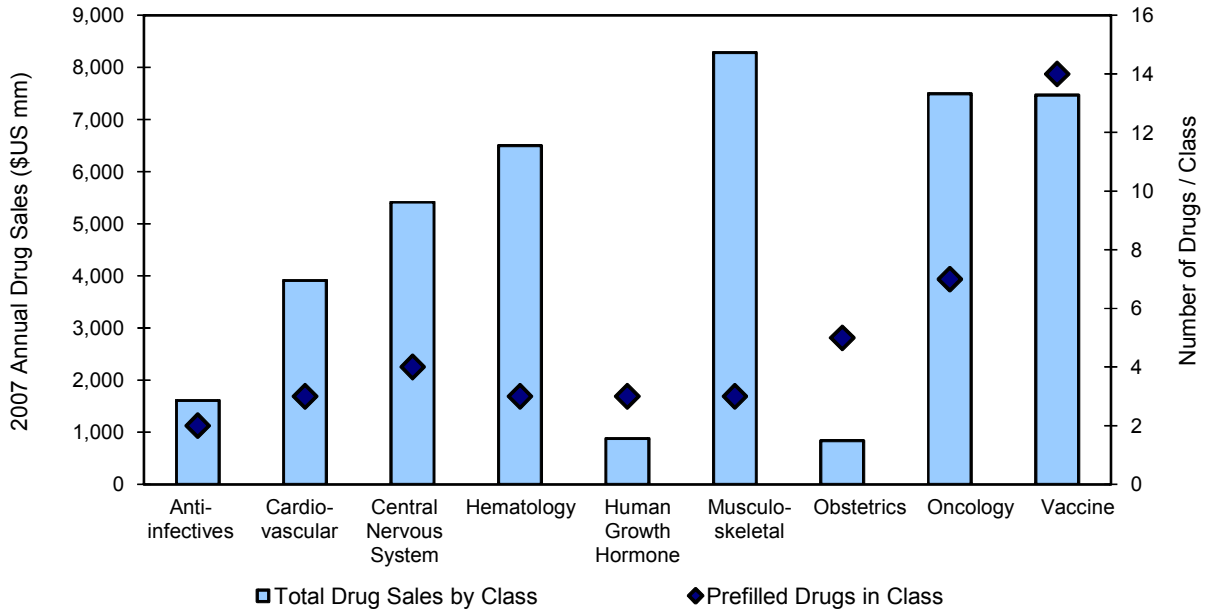
Therapeutic Usage of Prefilled Syringes

There are at least 45 injectable drugs currently marketed by pharmaceutical companies in a prefilled syringe format. While the majority of these drugs are commonly administered with a prefilled syringe, many are also available in other prefilled delivery device formats, such as auto-injectors, pens, or vials. However, Unilife believes that prefilled syringes represent the preferred drug delivery device of choice for pharmaceutical companies where the drug does not require reconstitution and can be easily administered in standard dose volumes by either healthcare workers or by patients at home. Based on Unilife's compilation of annual sales data, these 45 identified drugs collectively generated more than $40 billion in annual sales in 2007, with 15 products attaining blockbuster status (annual sales in excess of $1 billion). Combined, the 15 blockbusters generate nearly 90% of the total revenue of all drugs marketed in a prefilled syringe format, according to Unilife's calculations.

Prefilled syringes are currently used across nine core therapeutic sectors, as illustrated in Figure 9 (page 35). The therapeutic areas where prefilled syringes are most commonly used are the cardiovascular, central nervous system, hematology, musculoskeletal, oncology, and vaccination markets. Nevertheless, all of these therapeutic sectors are characterized as being highly competitive, with multiple products aggressively marketed against each other by the major pharmaceutical companies. Following Figure 9, pages 35-37 summarize each of the core therapeutic markets employing prefilled syringes.

Figure 9

ANNUAL SALES AND NUMBER OF DRUGS IN THE CORE THERAPEUTIC AREAS FOR PREFILLED SYRINGES



Source: Unilife Medical Solutions Limited.

Note: All annual product sales and patient data referenced below and on pages 36-37 was obtained from Unilife's internal compilation of this information.

Anti-infective Market

Injectable drugs identified within the anti-infective sector are targeted at the treatment of chronic viral infections, such as hepatitis B, hepatitis C, and HIV. These medications include PegIntron™ and Intron®A by Schering Corp., Synagis® by MedImmune, Inc. (part of AstraZeneca plc [AZN-NYSE]), and Pegasys® and Roferon®-A by Hoffmann-La Roche Inc. ("Roche"). Combined, these five injectable products have total annual sales of more than $3 billion. With many of these drugs requiring regular injections (e.g., weekly), prefilled syringes suitable for self-administration by patients are increasingly preferred. At least two anti-infective products are now supplied in a prefilled syringe, including Pegasys®, which is one of the top drugs in its class with annual sales of more than $1.5 billion.

Cardiovascular (Antithrombotic) Market

In the cardiovascular (**antithrombotic**) market, low-molecular-weight heparin (LMWH) is used to prevent and treat blood clots and illnesses, such as deep vein thrombosis (DVT), a condition that may lead to a **pulmonary embolism**. In addition to the treatment of DVT in both inpatient and outpatient settings, LMWH drugs are also commonly administered and prescribed to patients following standard hospital procedures, such as abdominal, hip replacement, and knee replacement surgeries. Due to the frequency of use of LMWH in both healthcare facilities and by patients at home, a number of injectable drugs marketed within this class are supplied in a prefilled syringe format—accounting for approximately 40% of all prefilled syringes available globally (Source: *Pharmaceutical and Medical Packaging News* May 2003).

The leading LMWH worldwide, Lovenox®, is available from sanofi-aventis as a prefilled syringe designed to help ensure proper administration, patient safety, and convenience. Key patents for Lovenox® expire in 2012, with the threat of generic competition representing an emerging challenge to the product. The cardiovascular market for prefilled syringes also includes Arixtra® from GlaxoSmithKline, which is indicated for the **prophylaxis** of DVT, and Fragmin® (trademark of Pfizer Health AB and licensed to Eisai Inc.), a LMWH used to prevent DVT in patients who are immobile and hospitalized due to severe illness, have had hip replacement surgery, or have had abdominal surgery and are at risk for DVT. All three of these injectable products are suitable for self-administration by patients and are supplied with a needlestick prevention feature to comply with legislation in markets such as the U.S.

Central Nervous System Market

The most common area of indication for this class is the treatment of patients with multiple sclerosis (MS), an autoimmune condition in which the immune system attacks the central nervous system. Three market leaders for central nervous system drugs are supplied in a prefilled syringe format suitable for patients' at-home self-administration. Biogen Idec Inc.'s (BIIB-NASDAQ) Avonex® (requiring a weekly intramuscular injection) is one of the leaders in this space, with 135,000 patients and annual global sales of $1.8 billion. Narrowly behind Avonex® in terms of annual sales and prescription patients are Copaxone® from Teva and sanofi-aventis (requiring a weekly subcutaneous injection) and Rebif® from EMD Serono, Inc. and Pfizer (requiring subcutaneous injection three times per week). Copaxone® and Rebif® each have annual sales of more than $1.5 billion and are used by more than 100,000 patients worldwide. Another central nervous system product supplied in a prefilled syringe format is Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Risperdal® CONSTA®, indicated for the treatment of schizophrenia.

Hematology Market

A number of injectable drugs are also indicated for the treatment of anemia associated with chronic renal failure (chronic kidney disease) or chemotherapy. The largest selling injectable drug available in a prefilled syringe format for this therapeutic class is Aranesp® from Amgen, Inc. (AMGN-NASDAQ), with annual sales of $3.7 billion in 2007. It is also available in an auto-injector system; however, this alternative delivery method is only suitable for patients who are permitted to inject a full dose. Roche has recently launched its new anemia drug, Mircera®, in an exclusive prefilled syringe format that may require only half the injections per month as Aranesp®. Ortho Biotech Products, L.P.'s Procrit® is another key hematology product provided in a prefilled syringe format. Procrit® had 2007 annual sales of $2.7 billion, which represented a decline of roughly 9% from previous years due to patent expiry and FDA concerns over clinical trials of hematology products in patients with both cancer and anemia. Both Aranesp® and Procrit® are available with a needlestick prevention feature.

Human Growth Hormone (hGH)

A limited number of injectable drugs to treat hGH deficiencies in either adults or children are available in a prefilled syringe format. Genotropin® (Pfizer), Valtropin® (Biopartners GmbH), and Somatuline® Depot (Tercica, Inc.) are among those products where a prefilled syringe delivery option is available.

Musculoskeletal Market

Unilife believes that the injectable drug market for the treatment of rheumatoid arthritis is highly competitive with solid growth. Humira® from Abbott Laboratories (ABT-NYSE) and Enbrel® from Wyeth (WYE-NYSE) and Amgen are commonly prescribed to treat rheumatoid arthritis and are among some of the highest grossing injectable medications. In 2007, Abbott reported annual Humira® sales of more than $3 billion, and Wyeth reported total global sales for Enbrel® of $5 billion (including sales generated by Amgen). These two blockbusters also compete in other indications, such as psoriasis and Crohn's disease. Both are available in standard prefilled syringe and pen formats, and have patents set to expire from 2014 to 2015. The main difference between the two products is that Humira® can be injected once every two weeks while Enbrel® must only be administered once a week. This therapeutic sector also includes Roche's Boniva® Injection, which is given once every three months using a prefilled syringe with a needlestick protection device to treat osteoporosis. Boniva®, which is also available as a tablet, reported annual sales of approximately $800 million in 2007.

Obstetrics Market

This niche drug class is focused on the treatment and care of women during conception, pregnancy, and childbirth. The largest sector of the market is hormone-replacement therapy to enhance fertility. The highest selling injectable drug product in this market (available in a prefilled syringe format) is Schering-Plough Corp.'s (SGP-NYSE) Orgalutron®, which generated $400 million in 2007. Other medications in this sector available in a prefilled syringe format include EMD Serono's Ovidrel® and Cetrotide® and Pfizer's birth control treatment Depo-Provera®.

Oncology Market

While the majority of oncology products to treat cancer are suitable for injection via an intravenous infusion or require reconstitution, some are readily available in a prefilled syringe format. Amgen's Neulasta® and Neupogen®, which are used when **myelosuppressive chemotherapy** is administered with the intent to treat cancer, are available in a prefilled syringe format and have an attached needlestick prevention feature. Combined, Neulasta® and Neupogen® had annual sales of more than $4.2 billion in 2007. Roche's NeoRecormon®, used to treat lymphoid cancers and anemia, is supplied in prefilled, vial, and pen formats and had sales of $1.9 billion in 2007. Other prefilled oncology medications include AstraZeneca's Faslodex® and Abbott's Lupron Depot®.

Vaccines Market

Vaccinations represent one of the largest and fastest-growing therapeutic sectors for prefilled syringes. Traditionally, vaccines have been supplied in either single- or multi-dose vials or ampoules, or in a powdered form requiring reconstitution. One key factor driving the transition from vials to prefilled syringes in this sector is the removal of the preservative **thimerosal** from vaccine formulations. With the removal of the preservative, moving from a 10- or 15-dose vial to a single-dose prefilled syringe may provide a more efficient alternative.

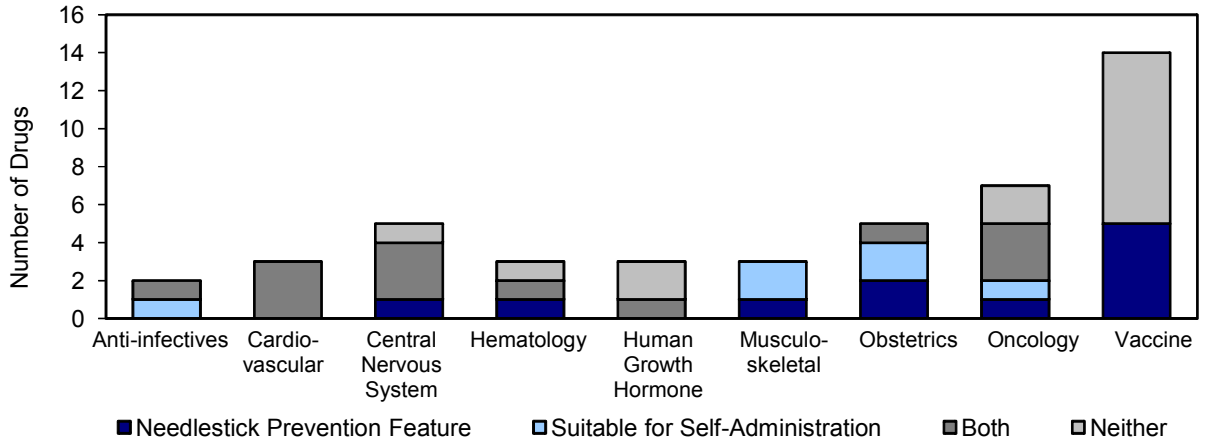
There are at least 14 vaccines available in a prefilled syringe format used to prevent a variety of diseases, such as hepatitis, diphtheria, tetanus, polio, measles, mumps, rubella, meningitis, influenza, and pneumococcal disease. Unilife believes that these products combined generated more than $7 billion in sales in 2007. Virtually all are supplied in a 0.5mL dose and administered via an intramuscular injection. 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 in 2007 included Wyeth's Prevnar®, Sanofi Pasteur's Fluzone® and Menactra®, and GlaxoSmithKline's Infanrix® and Pediarix®.

Flexible Administration Requirements of Prefilled Syringes

Prefilled syringes are being increasingly used by patients at home and by healthcare workers in facilities where devices with needlestick prevention features are required. More than two-thirds of the aforementioned prefilled syringe products are specifically designed for regular self-administration by patients or are equipped with a needlestick prevention feature that complies with global sharps safety laws. As shown in Figure 10, needlestick prevention features are available in all nine target therapeutic sectors and prefilled syringes suitable for self-administration by patients are used in all sectors except vaccines. Further, there are 13 identified injectable products across seven sectors that have the flexibility to be administered both by healthcare workers at risk of needlestick injury and by patients at home.

Figure 10

PREFILLED SYRINGES SUITABLE FOR SELF-ADMINISTRATION



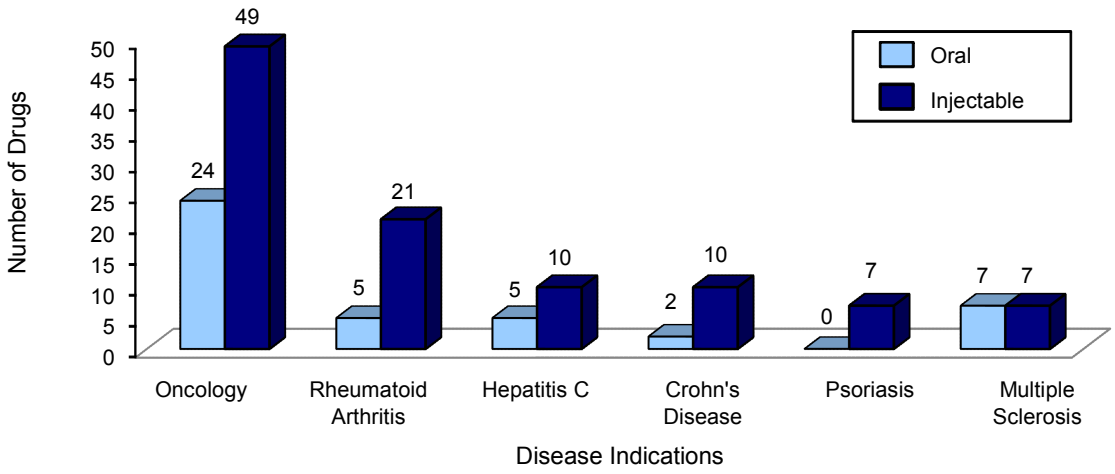
Source: Unilife Medical Solutions Limited.

Specialty Pipeline Drugs Targeted for Use With Prefilled Syringes

In addition to those therapeutic areas listed on pages 35-37 that are already using prefilled syringes, there are a great number of specialty drugs now in development that are feasible candidates for delivery in a prefilled syringe format. As illustrated in Figure 11, many specialty medications presently in development are being optimized for administration as an injection rather than orally. 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. With oral administration, many proteins suffer an effect called **first-pass metabolism**, which occurs after the medication is swallowed. Once ingested, the drug is absorbed by the digestive system and metabolized by the liver before it reaches 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. As a result, oral administration could require larger doses of medication in order for the required amount to reach the affected area.

Figure 11

SPECIALTY DRUGS IN DEVELOPMENT - ROUTES OF ADMINISTRATION



Source: Adapted by Greystone Associates from published information (Retractable Safety Syringes January 2007).

In addition, the gastrointestinal tract's acid environment, digestive enzymes, and permeable membranes may hinder the delivery of protein drugs, sequestering, deactivating, or altering these products in the stomach or another organ. However, intravenous or subcutaneous injections can bypass many of these issues, thereby improving absorption, systemic dose accuracy, and time until onset of action. Specifically, more than two-thirds of all therapeutic proteins for chronic diseases are currently supplied in an autoinjector or injection pen format (Source: Greystone Associates May 2008), and many biologic products are likely to continue to be injected. Unilife anticipates that the trend toward a greater use of injections in general will likely also fuel market demand for efficient, convenient, safe, and cost-effective injection systems using prefilled syringes, as further detailed on the accompanying pages.

There are a number of 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, as overviewed below and on page 39.

- *Albuferon® (Novartis and Human Genome Sciences, Inc. [HGSI-NASDAQ]).* Targeted for the treatment of chronic hepatitis C, Albuferon® is anticipated to be administered with a prefilled syringe via subcutaneous injection. The candidate would likely require injections once every two weeks, which is half that of Pegasys®. Albuferon® is in Phase III trials, with global marketing applications scheduled to be filed in late 2009, pending the receipt of favorable Phase III data in March 2009.

- *Orencia® (Bristol-Myers Squibb Co. [BMY-NYSE]).* Orencia® is currently approved to treat rheumatoid arthritis via intravenous infusion. Additional trials are also ongoing to examine the possibility of delivering Orencia® via a weekly subcutaneous injection with a prefilled syringe.

- *Apixaban (Pfizer and Bristol-Myers).* Apixaban is an anticoagulant targeted to prevent and treat a broad range of venous and arterial thrombotic conditions, such as DVT. An extensive Phase III clinical program of apixaban is underway, which includes comparing apixaban and Lovenox® in twice daily subcutaneous injections. In August 2008, Pfizer and Bristol-Myers reported that apixaban did not meet a primary Phase III endpoint, as it did not demonstrate non-inferiority to Lovenox®.

- *Atacicept (Merck Serono S.A.).* Phase II studies of atacicept are underway for rheumatoid arthritis and MS, with the candidate targeted for subcutaneous injection in a prefilled syringe format.

- *Denosumab (Amgen).* Phase II and Phase III trials of denosumab prefilled syringes are underway to evaluate its use in osteoporosis, treatment-induced bone loss, bone metastases, rheumatoid arthritis, and myeloma.

- *AVE5026 (sanofi-aventis).* Several Phase III trials of AVE5026 are presently recruiting patients to evaluate the candidate's ability to replace Lovenox® in preventing DVT for patients undergoing a variety of surgeries. Administration is via subcutaneous injection.

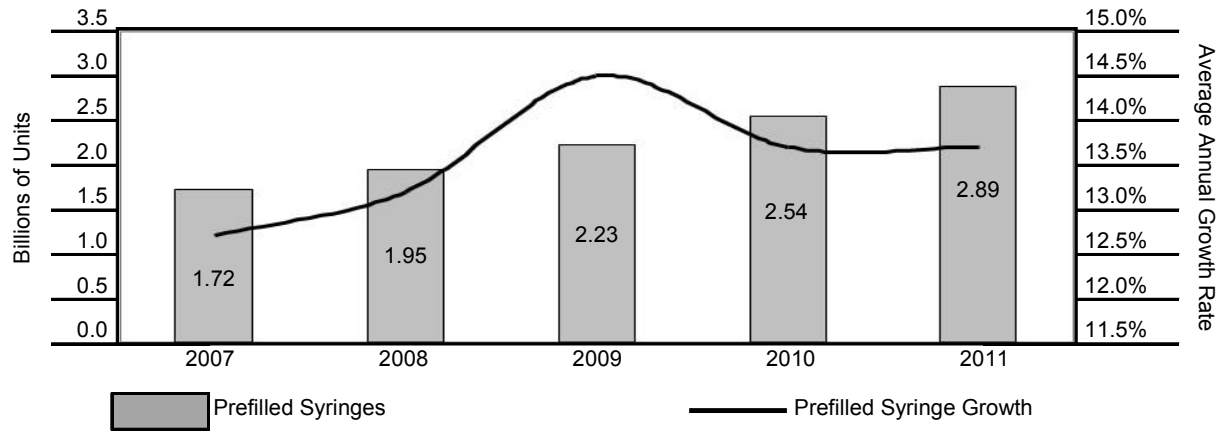
- *Idraparinux (sanofi-aventis).* Idraparinux is in Phase III to prevent and treat DVT. It may require only one weekly subcutaneous injection to prevent strokes and blood clotting in patients.

Market Demand for Prefilled Syringes

Due to the increasing popularity of prefilled syringes, Greystone Associates estimates that global consumption of these products could increase from nearly two billion units per year in 2008 to almost three billion units in 2011 (Source: *Prefilled Syringes* 2008). Annual growth rates are expected to exceed 12%, as evidenced in Figure 12.

Figure 12

PREFILLED SYRINGES FORECAST WORLDWIDE GROWTH



Source: Greystone Associates' estimates, February 2008.

Production of Prefilled Syringes

Due to biocompatibility issues, barrels of prefilled syringes are generally made of glass. Glass is a more stable material than plastic, which can leak or become porous, allowing oxygen to affect the medication. Since the drug must have a shelf life in the syringe of over two years in order to receive regulatory approval, biocompatibility issues have significantly slowed the development of prefilled syringes.

There are only approximately five providers of prefilled syringes in the world, and demand is believed to be much greater than the current supply. By far the two largest manufacturers of prefilled syringes are BD and Gerresheimer Bünde, which together account for well over half of total global supply. In 2006, BD projected that its targeted annual production capacity would increase to upward of 2.5 billion units. As such, Unilife believes that this market could expand well beyond 12% each year, at between 15% and 30% per annum. To this extent, ONdrugDelivery's *Prefilled Syringes: Device Suppliers Meeting*

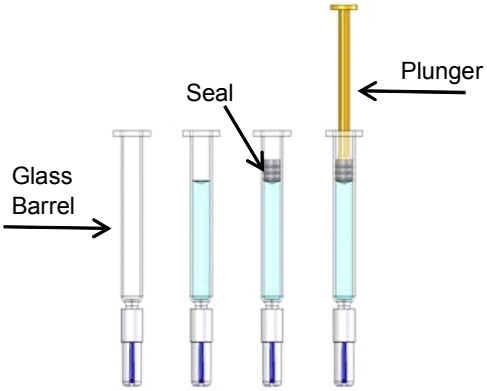
Pharmaceutical Standards (2007) references growth rates of almost 22% in this sector over the past several years. Page 31 under Current Standards of Safety Syringes overviews current price ranges for a variety of syringes, including prefilled.

Dose Filling and Packaging of Prefilled Syringes

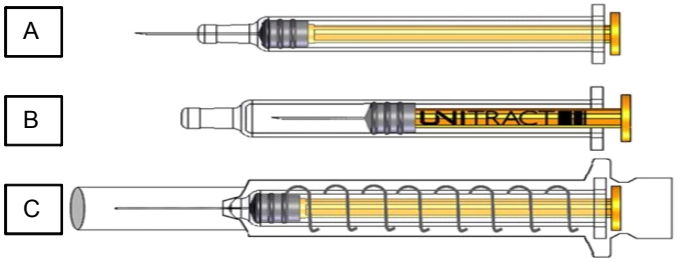
Prefilled syringes are provided to pharmaceutical companies "ready to fill" in three separate pieces—a glass barrel, a seal, and a plunger—as illustrated in the left side of Figure 13. Tubs of 100 or more glass barrels are automatically loaded onto a sterile filling line, before being filled with a measured 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.

Figure 13
PREFILLED SYRINGES

Filling and Packaging



Approximate To-Scale Diagrams of Prefilled Syringes



(A) A standard prefilled syringe
(B) The Unilife Prefilled Syringe
(C) An external sheath attached to a prefilled syringe

Sources: Unilife Medical Solutions Limited and Crystal Research Associates, LLC.

Types of Prefilled Safety Syringes

According to Unilife, there are currently no known prefilled syringes with an integrated safety feature because the positioning of the seal to maintain drug biocompatibility and sterility would act as an impediment to the activation of traditional retractable needle technologies. As pharmaceutical companies must provide a safety feature for use with prefilled syringes in order to comply with legislation in markets such as the U.S., these entities currently opt to offer a clip-on safety device that attaches onto the entire syringe and thus does not present biocompatibility challenges. There are two main types of safety products commonly attached onto standard prefilled syringes.

- *External Sheaths.* These products are clipped onto a standard prefilled syringe after it is filled and assembled but prior to final packaging. Pharmaceutical companies must devote considerable time and resources to assemble these clip-on devices at filling facilities. As shown in the right side of Figure 13, 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 on the shields to 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.

Currently, a standard prefilled syringe costs a pharmaceutical company roughly $0.33 and the clip-on device is estimated to be an additional $0.25. Combined with additional assembly and packaging costs, Unilife has estimated the final cost of a prefilled syringe (excluding the drug) at the point of shipment to be approximately $0.70 per unit.

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 accepted that clip-on devices were the only viable solution, and as such, to the Company's knowledge, no new technology has come onto the market in the past five years.

TARGET MARKETS AWAIT PREMIUM PRODUCTS

There are four sectors of the global syringe market that Unilife has identified as transitioning toward the use of safety syringes. These are as follows: (1) diabetes and self-administration applications; (2) harm reduction (the supply of sterile syringes to IDUs [more fully detailed on pages 47-49]); (3) healthcare markets; and (4) pharmaceutical markets. Altogether, Unilife estimates that these markets represent half of total global injections and 80% of revenues. 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.

The 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. Other 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. This may create an additional risk of infection from a bloodborne disease via aerosol. Figure 8 (page 32) summarizes some of the current safety mechanisms also available.

Unilife's research indicates that there is still an unmet need for safety syringes with the following design components incorporated, noting that one device is not yet on the market that integrates all of these features.

- *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. Furthermore, Unilife does not believe that there is a retractable syringe of any kind that allows operators to have full control of the speed of needle withdrawal directly from the body.

- *Integrated Safety*. The integration of a device's safety features into the core design can 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.

- *Tamper-proof*. Re-exposure of the needle is prevented following use.

Unilife believes that its technology is capable of meeting each of these needs in a fully integrated device.

UNILIFE'S TECHNOLOGY

Unilife is focused on developing and supplying innovative safety medical devices, specifically within the pharmaceutical market for prefilled safety syringes; healthcare markets such as the U.S., which mandate sharps safety device usage to prevent needlestick injury; and the U.S. medical device contract manufacturing market. The Company has grown continually by advancing its intellectual property; acquiring a U.S. contract manufacturing subsidiary, Integrated BioSciences Inc. (IBS); and signing exclusive agreements with medical device and pharmaceutical leaders. The Company is focused on developing and supplying its own products as well as manufacturing devices under contract for other healthcare and pharmaceutical entities.

Unilife has developed a novel, patent-protected portfolio of clinical and prefilled safety syringes designed for use in healthcare and pharmaceutical markets that are transitioning to the mandatory use of sharps safety products to protect those at risk of needlestick injury and other unsafe injection practices. Unilife's safety syringes are novel in the safety syringe market as the products employ an automatic needle retraction system that is fully integrated into the device itself, enabling operators to control the rate of needle withdrawal from the body. This differs from current retractable products on the market, which require additional pressure to be applied to the plunger of the syringe in order to break the seal, at which point the needle retracts into the syringe very quickly. Production of Unilife's 1mL and prefilled products began in early 2008, with Unilife now preparing for high-volume production at its IBS facility.

In July 2008, Unilife signed an Exclusive Licensing Agreement with sanofi-aventis, the world's fourth largest pharmaceutical entity and leading global purchaser of prefilled syringes. Under this agreement (detailed on pages 15-17), Unilife received a $13.9 million (€10 million) exclusivity fee from sanofi-aventis for the exclusive right to purchase the Unilife Prefilled Syringe from Unilife for five years. The companies also agreed to negotiate in good faith to finalize an Industrialization Agreement expected to be signed in early 2009. Under this Industrialization Agreement, Unilife is to receive between $20.8 million and $23.6 million (€15 million and €17 million) in order to develop production systems to manufacture and supply an initial 40 million units per year. During October 2008, Unilife received the first quarterly payment under the Industrialization Agreement of €1.5 million, which was equivalent to approximately $2 million (using the average exchange rate prevailing during October 2008).

Initial sales of the Unilife Prefilled Syringe are scheduled to commence in late 2010. Annual production volumes are scheduled to increase to approximately 400 million units by the end of 2014 and up to one billion units beyond 2017. To support the realization of this plan, Unilife and sanofi-aventis are in discussions to sign a Supply Agreement that is to specify long-term unit orders. Beyond 2014, Unilife expects to receive annual revenues in excess of $400 million from the sale of the Unilife Prefilled Syringe.

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

Unilife has identified four global markets for its syringes:

(1) the prefilled market;

(2) the self-administration of prescribed medication (insulin) market;

(3) the injecting drug user (IDU) market; and

(4) the clinical market.

Competitors are Technology Driven, Unilife is Market Driven

There is a requirement in the marketplace to provide safety syringes. To date, nearly all of Unilife's 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 is *market driven*. To develop its products, Unilife went directly to the market to discover the market's needs. One of the key things the Company learned as a result of its research is that medical practitioners are averse to changing their procedures. They also do not like to invoke pain or fear in their patients, even to the extent that many would actually rather put themselves at risk.

As Unilife looked to provide functional and safety features in its syringe, it realized that each of the market sectors that it was pursuing had different requirements. As such, Unilife has developed different technologies for each target sector. In contrast, competitors often have only one technology that is marketed into all sectors even if it does not specifically perfectly conform to the safety and functionality requirements of any single market. Unilife equates such technology as akin to trying to fit a square peg into a round hole. In contrast, Unilife has developed a round peg for a round hole—technology for each market sector that fits its specific needs.

Three Key Features of Unilife's Syringes

All of Unilife's syringes contain fully integrated safety features—automatic retraction and user-controlled retraction—which are believed to provide the highest level of protection in a syringe.

- *Automatic Retraction*. Currently marketed retractable syringes can require up to 5 kilograms (10 pounds) of pressure while the needle is in the patient to trigger the safety mechanism. However, Unilife's market research indicated that medical practitioners may sometimes avoid inflicting pain on their patients to the extent that they may put themselves at risk. As such, rather than completing the retraction of the device by leveraging the device toward the patient, healthcare workers may remove the device prematurely to trigger the retraction externally. This action, while meant to prevent pain to the patient, unnecessarily increases the risk of needlestick injury and aerosol exposure to the healthcare professional. To promote procedural compliance, Unilife has incorporated a truly automatic retraction mechanism—one that does not require significant added pressure while in the patient. The Company's retraction mechanism is 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 an injection is completed while the needle is still inside the body with no additional action required by the administrator. Thus, the risk of a needlestick injury may be virtually eliminated as the administrator never sees the needle in the open air following dose delivery.

- *User-controlled Retraction*. The current generation of retractable syringes is equipped with an automatic retraction rate that is rapid and cannot be adjusted. These characteristics of the present technology are known 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. However, Unilife's devices are specifically designed with a user-controlled retraction to avoid the aforementioned risks and encourage retraction of the needle directly from the body rather than the open air. Once a Unilife syringe has been used to deliver an injection, the operator is signaled by an audible click to indicate that the full dose of medicine has been administered to the patient. Beyond this point, the rate of retraction of the needle is completely controlled by the operator of the syringe. As such, 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 the safety for the operator by preventing blood splatter. This technique also maximizes the patient's level of comfort relative to other spring-fired non-controlled retractable syringes, as slower retraction minimizes damage to the venous tissue.

- *Integrated Safety.* All safety features contained in Unilife's safety syringe products, including automatic, user-controlled retraction, are fully integrated (built-in) within the core 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. As such, Unilife maintains that its syringes can be marketed as a true safety medical device, rather than as a safety product.

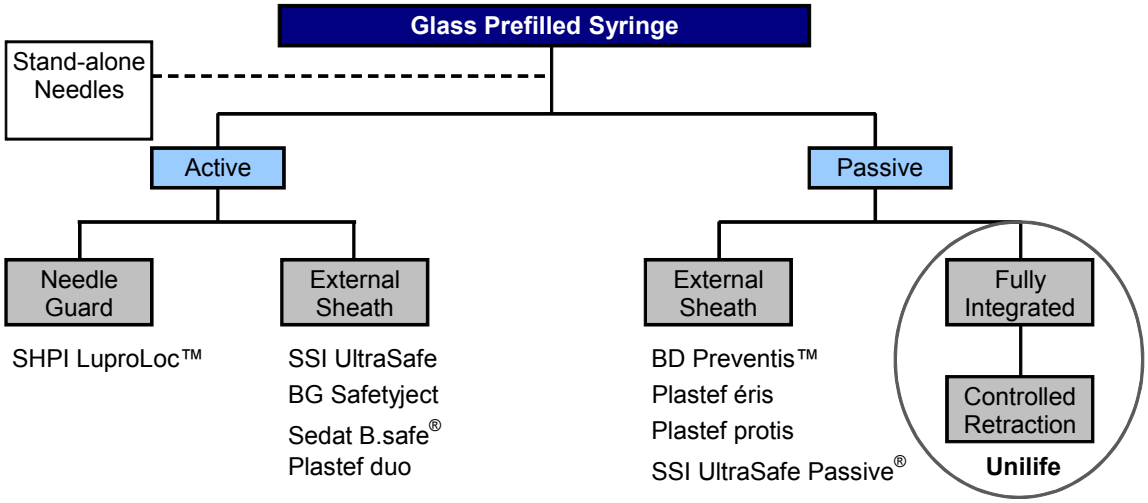
Portfolio of Safety Syringes

Unilife has developed an extensive patent-protected portfolio of clinical and prefilled safety syringes that has been custom designed to meet the injection safety and functionality requirements of target healthcare and pharmaceutical markets. The integration of automatic and user-controlled needle retraction features into a complete medical device represents a major and highly distinctive competitive advantage. Unilife is not aware of any other technology where automatic, user-controlled needle retraction is fully integrated within the barrel of the syringe.

Unilife Ready-to-Fill Syringe (RTFS), also called the Unilife Prefilled Syringe

While Unilife is aware of 22 injectable medicines currently supplied in a prefilled syringe format with a safety product designed to address needlestick prevention, the Company does not know of any prefilled syringe other than its Unilife Prefilled Syringe that possesses an automatic needle retraction feature fully integrated into the device. A summary of competing prefilled safety products (including the Preventis™ and SafetyGlide™ from BD and the UltraSafe® products from Safety Syringes, Inc.) is provided in the Competition section on pages 54-56. Figure 14 provides an illustration of the current pharmaceutical market for prefilled safety syringes. This highlights the sector of the market in which Unilife participates relative to other manufacturers of ancillary safety products suitable for attachment onto standard glass-barrel prefilled syringes.

Figure 14
Unilife Medical Solutions Limited
PHARMACEUTICAL MARKET FOR PREFILLED SYRINGES



Source: Unilife Medical Solutions Limited.

Key Features of the Unilife Prefilled Syringe

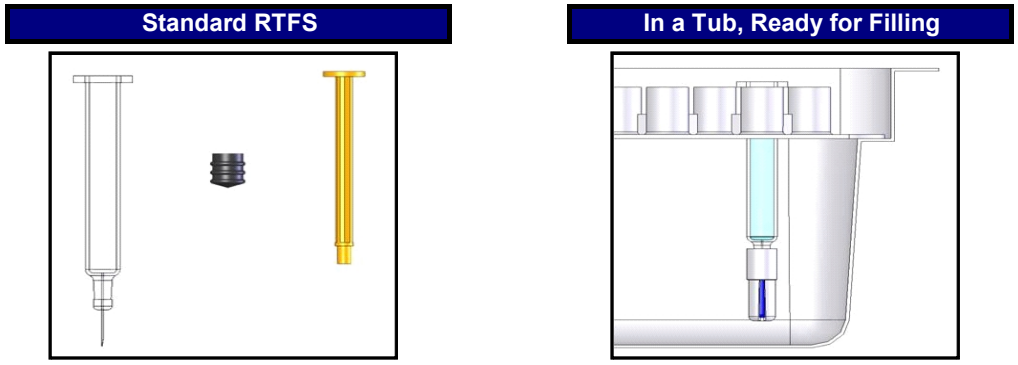
The following summary highlights the key features of Unilife's prefilled syringe technology.

- *Premium Protection.* The highly distinctive automatic (passive) needle retraction system virtually eliminates the risk of needlestick injury. Furthermore, the ability for operators to safely control the rate of needle withdrawal directly from the body may help reduce patient discomfort and the risk of infection via other potential transmission modes, such as blood splatter.

- *Integrated Safety Features.* Unlike conventional prefilled safety products, all safety features in the Unilife Prefilled Syringe are fully integrated into the core device design, making the product compact and simple to use and offering convenient, cost-effective disposal. 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 costs through the use of the Unilife Prefilled Syringe.

- *Retrofitting onto Existing Filling Lines*. To deliver full compatibility with existing drug filling systems, the Unilife Prefilled Syringe is a similar size to standard non-safety prefilled syringes and is supplied in the three standard sub-assembly pieces, as shown in Figure 15. The design compatibility minimizes the time and cost required by pharmaceutical companies to retrofit the product onto current filling lines. This was key to Unilife's agreement with sanofi-aventis. It also generates production and transport savings to companies that would have had to attach bulky clip-on safety products.

Figure 15
Unilife Medical Solutions Limited
RETROFITTING ONTO EXISTING FILLING LINES



Source: Unilife Medical Solutions Limited.

- *The 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 glass barrel for the Unilife Prefilled Syringe to require forming at only one end. This gives Unilife the potential to enter into supply contracts with up to 30 suppliers of glass vials and ampoules.

- *Expanding Drug Marketability.* The safety benefits and ease-of-use of the Unilife Prefilled Syringe can allow pharmaceutical companies to better promote the self-injection of current and pipeline drugs by patients at home. Self-administration of drugs by the patient is significantly lower than the equivalent cost of receiving treatment by a trained clinician within a healthcare facility.

- *Increased Competitiveness.* Unilife's product provides pharmaceutical companies with a significant market differentiator to promote the use of injectable products in competitive arenas—predominantly when a drug is approaching patent expiry or is under pressure from generic competition. The Company also expects that a number of new pipeline drugs can benefit from a launch with the Unilife Prefilled 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 to disrupt the status quo in the global market for prefilled syringes.

Industrialization of the Unilife Prefilled Syringe

The Industrialization Program for the Unilife Prefilled Syringe is being coordinated by Unilife under its ISO 13485-certified quality management systems. The project has a design history of three years with both the device and its initial production processes now proven. To support the successful supply and evaluation of the product by sanofi-aventis, initial pilot production of the Unilife Prefilled Syringe has commenced at the FDA-registered U.S. facilities of IBS. This pilot system, which has a capacity of one million units per year, is expected to be employed to begin initial supply and sales during 2010.

Unilife has also initiated designing a high-volume assembly line for the Unilife Prefilled Syringe, which is expected to be built and operated at the IBS facility. Upon the completion of the Industrialization Program in early 2011, Unilife believes that it can be in a position to deliver to sanofi-aventis 40 million units per year. The initial automated assembly system for the Unilife Prefilled Syringe will likely feature a modular

design format and incorporate the use of proven off-the-shelf production equipment to support its cost-effective replication. Through the replication of this modular assembly system, Unilife intends to have annual production capacities of approximately 400 million units per year by 2014, with expansion planned for the production of up to one billion units beyond 2017.

As Unilife expects to expand its industrial capabilities significantly under its Industrialization Program, the Company has commenced recruitment activities to appoint a number of individuals into new positions. Importantly, Unilife is not responsible for obtaining regulatory approvals for the completed drug delivery device; these are under the control of sanofi-aventis. Unilife and sanofi-aventis are working in good faith toward the signing of a supply agreement to specify commercial orders for the Unilife Prefilled Syringe.

To support the development of an efficient and continuous supply chain, Unilife is in negotiations with a number of European-based government agencies regarding the potential establishment of a high-volume manufacturing facility. Discussions with a number of potential component suppliers are also underway. These potential suppliers include Gerresheimer Bünde, the world's second largest prefilled syringe manufacturer, which signed an exclusive agreement with Unilife in November 2007. Gerresheimer Bünde supplied a batch of custom-designed glass barrels, which were successfully used by Unilife in the pilot production of the Unilife Prefilled Syringe.

Commercialization of Unilife's Other Safety Technologies

Currently available safety syringes continue to expose healthcare workers to the risk of needlestick injury, as the safety mechanism can be either bypassed or activated incorrectly. As a result, between one-third to one-half of all needlestick injuries in U.S. healthcare facilities involve syringes with safety mechanisms. A number of safety syringe products require healthcare workers to undertake a secondary action to engage the protection mechanism. Others operate with a spring-fired (non-controllable) retraction mechanism, which may compel healthcare workers to retract the needle after it has been removed from the body. While retracting a non-controlled, spring-fired needle after its removal from the patient minimizes patient discomfort, this approach also increases the risk of infection from a bloodborne disease via blood splatter. Thus, the Unitract™ Clinical Range of safety syringes may offer several preferred use and safety advantages to the healthcare market. Further, self-administration and global harm reduction markets may benefit from the Unitract™ range of 1mL syringes, as detailed on the accompanying pages.

Self-administration of Prescribed Medication (Including Insulin) by Patients

Millions of people worldwide regularly self-administer prescribed medication with a syringe outside of a healthcare facility. The most common market for the self-administration of prescribed drugs with a syringe is the diabetes market. In particular, people with Type 1 diabetes can require lifetime injection of insulin on a daily basis.

In the U.S., according to the Coalition for Safe Community Needle Disposal, approximately nine million people administer over three billion injections outside of traditional healthcare facilities each year. Nearly two-thirds of these "at-home" injectors are people with diabetes and patients who self-administer prescription medication for allergies, infertility, arthritis, migraines, HIV, and hepatitis C, among other ailments. This trend toward at-home self-care is driven by the rising cost constraints of healthcare facilities and the development of injectable drugs that can be self-administered by most patients on a routine basis. Furthermore, there are two key factors driving the self-administration market toward the use of safety syringes, as overviewed below.

- *Syringe Reuse.* Often, people with insulin-dependent diabetes reuse a standard syringe between two and six times prior to disposal. While the reuse of syringes is unlikely to result in others becoming infected with a bloodborne disease, many healthcare and diabetes organizations discourage the reuse of standard insulin syringes, as potential health risks associated with syringe reuse can include the blunting or breaking off of the needle, tissue **microtrauma**, and **lipodystrophy**.

- *Unsafe Disposal.* In addition, government and community groups have expressed concern about the occurrence of needlestick injuries to members of the general public and employees, such as waste disposal workers, following the unsafe disposal of non-sterile syringes.

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 also 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.

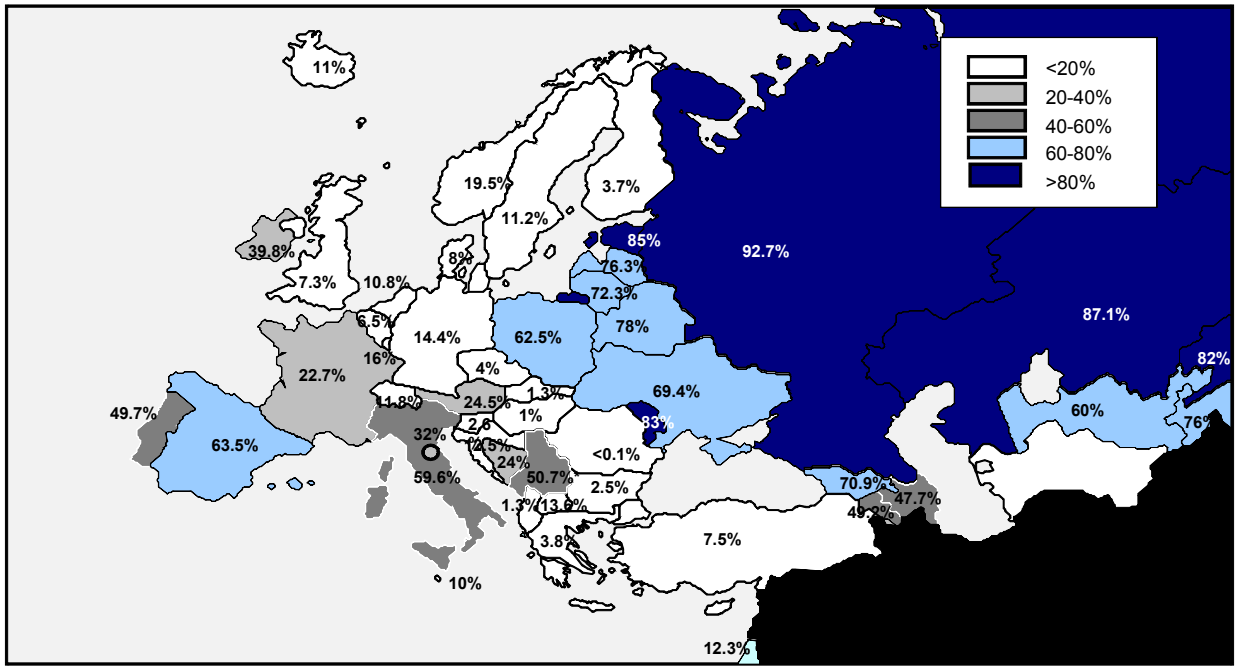
Global Harm Reduction: Minimizing Unsafe Injection Practices by Injecting Drug Users (IDUs)

Global harm reduction programs may also represent a considerable commercial opportunity for Unilife and are one of the primary target markets of the Company's range of Unitract™ 1mL Safe Syringes. These programs, implemented by government agencies in over 60 countries, seek to minimize the social and economic costs of unsafe injection practices among IDUs. The continued sharing of standard syringes by IDUs as well as their unsafe disposal of used needles (which leaves others vulnerable to needlesticks) are key factors accelerating the transmission of HIV, hepatitis C, and other bloodborne diseases.

Worldwide, the number of IDUs is estimated at over 13.2 million, approximately 50% of whom live in Asia (Source: the Open Society Institute's [OSI] *Harm Reduction Developments 2008*). Within this community of drug users, multiple needle reuses and unsafe syringe disposal is rampant. As a result, IDUs now account 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). Furthermore, as evidenced in Figure 16, IDU behavior in Europe accounts for at least 40% of all HIV cases in Spain, Italy, Eastern Europe, and Russia—indicating that disease epidemics driven by IDUs' unsafe injection practices is not just a concern in developing countries, but in countries with established healthcare systems as well.

Figure 16

PROPORTION OF IDUs AMONG REPORTED HIV CASES* IN SELECTED COUNTRIES

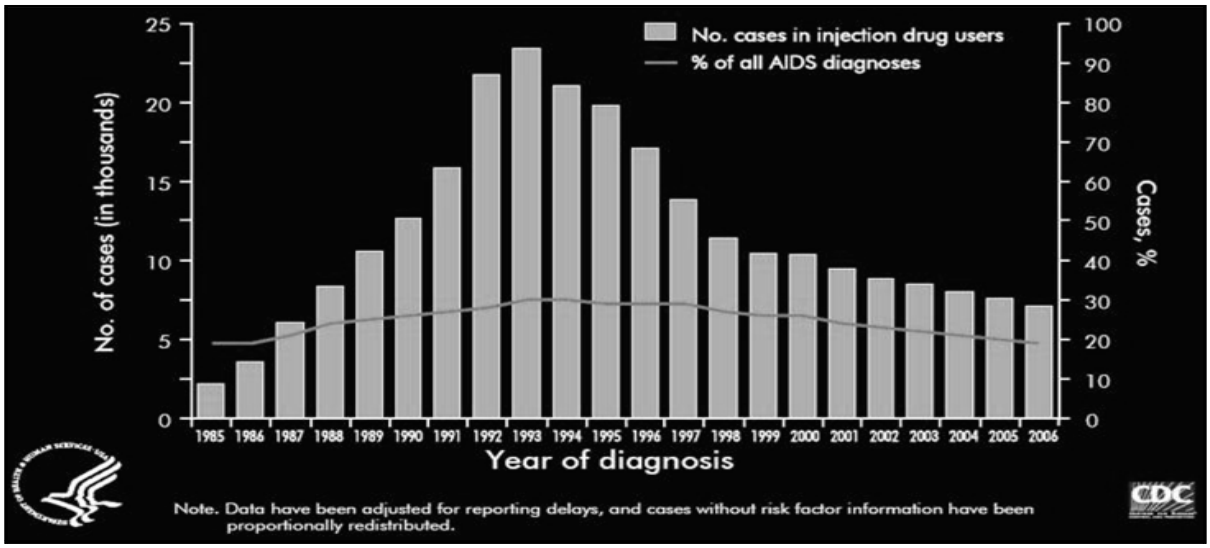


* Proportion among AIDS cases in countries not reporting HIV data

Sources: the European Commission; EuroHIV; Council of Europe; and Dr. Chris Beyrer's "The Next Wave: The Emerging HIV Epidemics of Eurasia."

In the U.S., the CDC estimates that 20% of all AIDS cases are related to IDUs, as shown in Figure 17, with the total number of national AIDS cases linked to IDUs averaging 8,266 per year from 2002 to 2006. The CDC further postulates that there are an estimated 35,000 adults and adolescent IDUs living with an HIV infection (not AIDS) in the U.S. The state of New York alone comprises 9,000 cases. 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.

Figure 17
ESTIMATED NUMBER AND PROPORTION OF AIDS CASES AMONG ADULT AND ADOLESCENT IDUs
1985-2006—U.S. AND DEPENDENT AREAS



Source: the CDC <www.cdc.gov/hiv/idu/resources/slides/>.

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. From 1991 to 2000, **needle and syringe programs (NSPs)** prevented more than 20,000 cases each of HIV and hepatitis C, thus saving 4,500 lives and approximately A$7.7 billion in direct treatment costs.

However, evidence suggests that the widespread provision of standard syringes to IDUs is not sufficient to contain the transmission of bloodborne diseases within this population. For example, in Australia, there are approximately 16,000 new cases of hepatitis C diagnosed each year, with the government's estimated lifetime treatment costs (50 years) rising by A$46.6 million for every 1,000 new infections (Source: Australia's *National Hepatitis C Strategy 2005-2008*). Altogether, Australian researchers predict that total direct healthcare treatment costs could exceed A$4 billion if there are at least 10,000 new hepatitis C infections in IDUs in Australia each year for the next 60 years (Source: the *Australian and New Zealand Journal of Public Health* May 2008). The Australian government estimates that 90% of new hepatitis C cases are associated with IDUs and more than half of all IDUs are infected with hepatitis C.

A key reason why countries that support harm reduction programs, such as Australia, have been successful in containing HIV epidemics but still largely fail to reduce hepatitis C epidemics is the continued sharing of injecting equipment by IDUs. Hepatitis C is a more infectious disease than HIV, and thus is more readily transmitted through bloodborne contact with a contaminated needle. Despite the widespread availability of standard syringes in Australia, a significant proportion of the national IDU population continues to reuse and share these products due to convenience, habit, and social behavior.

The Australian government examined the provision of retractable syringes to IDUs between 2002 and 2006 (prior to the production of Unilife's Unitract™ syringes). This trial found that while there was interest in the use of retractable syringes by IDUs, there was a reluctance to engage the non-controlled needle retraction mechanism inside the body due to the risk of vein damage. However, when IDUs removed the needle from the body and activated the safety mechanism in the open air, visible aerosol was generated. Due to the potential infections associated with this bloodborne disease transmission route, the Australian government suspended the trial until new technology emerged to overcome these safety concerns.

In addition to Australia, other countries leading the use of harm reduction programs to combat the spread of disease via IDUs include New Zealand, the UK, Canada, Spain, Switzerland, and Germany. Many governments have implemented NSP sites, safe injection centers, mobile vending units, pharmacies, and prison exchange programs that supply IDUs with sterile syringes either for free or at a reduced cost.

Regardless, Unilife anticipates that there will likely always be a segment of the IDU population that will continue to try to reuse needles. Thus, the supply of syringes such as those provided by Unilife—which cannot be used more than once and automatically protect those at risk of needlestick injury from unsafe disposal—is critical. As the market adoption of safety syringes continues to increase, the Company expects to also see continued expansion of national and regional initiatives to supply these syringes to IDUs and other places where drug use is a problem, such as prisons and indigenous populations.

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 virtually eliminates 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.

Unitract™ 1mL Insulin and Safe Syringes

Unilife's Unitract™ 1mL syringes have been designed to enhance injection safety outcomes in healthcare, harm reduction, and self-administration of prescribed medication (diabetes) markets. For IDUs, the Company offers a Safe Syringe that can be provided to the government to eliminate the sharing of needles, thus providing a significant savings in healthcare costs associated with disease transmission. In addition, the 1mL size is commonly used by diabetics to inject insulin.

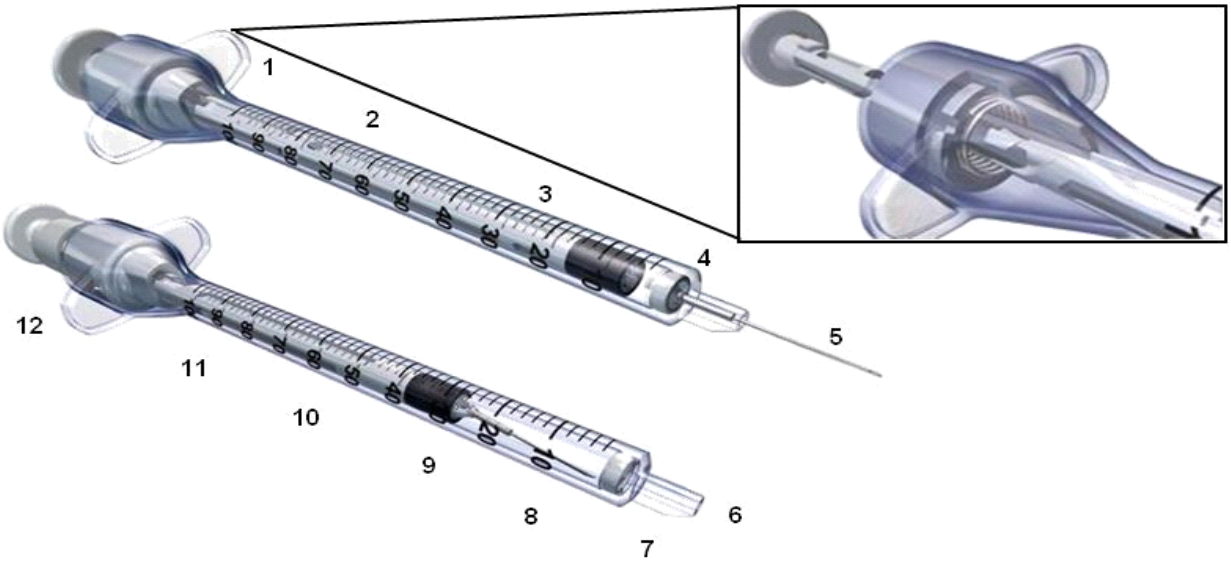
Unilife commenced production and commercial release of its Unitract™ 1mL Insulin and Safe Syringes in 2008 at the Shanghai facilities of its channel partner and licensee, KDL (overviewed on page 17). U.S. production is expected to commence shortly at Unilife's IBS facility. By the end of 2009, annual production capacities are expected to exceed 40 million units. To optimize levels of product reliability, the 1mL automated assembly line features state-of-the-art robotic processes and visual quality tracking equipment. Figure 18 (page 50) illustrates the Unitract™ range of 1mL syringes, depicting the key characteristics of the design. Additional details specific to each of the syringe applications in this category—the Insulin Syringe and the Safe Syringe—follow Figure 18.

Figure 18

Unilife Medical Solutions Limited

THE UNITRACT™ RANGE OF 1ML SYRINGES

Designed for functionality and ease of use with integrated, fully passive safety features to provide effective, reliable protection during all stages of the injection process



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 (100 units or 1cc) in volume
4 Low dead space
5 Permanently attached (fixed) needle with standard bevel
6 Passive (automatic) needle retraction mechanism to virtually eliminate risk of needlestick injury
7 Audible, tactile prompt signals activation of safety mechanism upon full dose delivery
8 Operator-controlled rate of needle withdrawal direct from body to minimize infection risk of aerosol
9 Automatic locking of plunger upon full retraction of needle into the barrel to prevent reuse
10 Tilting of needle to one side within the barrel to prevent product tampering and needle re-exposure
11 All safety features are fully integrated (internal) to the device
12 Compact design for comfortable handling, intuitive use, and convenient, compact disposal

Sources: Unilife Medical Solutions Limited and Crystal Research Associates, LLC.

Unitract™ Insulin Syringe

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 top. 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 on page 51, 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.

In October 2008, Unilife received 510(k) clearance from the FDA for its Unitract™ 1mL Insulin Syringe. This clearance enables Unilife to market and sell this syringe within the U.S. As such, the Company is now initiating product launch activities, which entail product evaluation trials within its target market sectors and the finalization of discussions with interested distributors. In essence, Unilife seeks to begin generating market demand in anticipation of the full commissioning of the automated assembly system at IBS' facilities (fully detailed on pages 52-53), after which the Company can promote the syringe as a U.S.-made product. Globally, Unilife has already secured regulatory approvals for its 1mL range within Canada, Europe, and Australia. Distribution partners, many of which have committed to minimum annual orders, have been appointed in almost 40 countries, including Canada, Switzerland, Germany, Taiwan, and China.

Pharmaceutical companies also purchase non-prefilled (standard) safety syringes as part of procedural kits for the administration of injectable drugs that are still supplied in vials or ampoules. Unilife is also investigating opportunities to supply the Unitract™ Insulin Syringe to pharmaceutical companies.

Unitract™ Safe Syringe

The Unitract™ Safe Syringe, intended for use by IDUs, is distinguished from the Company's other 1mL syringe by its gray top. This syringe is at the forefront of Unilife's 1mL product line's commercialization.

For an injection, such as that performed by IDUs, the normal process entails first drawing a small amount of blood to ensure that the needle is in the vein and then injecting. Unilife's safety syringes do not allow the operator to pull back on the plunger once the injection has been initiated. By not being able to pull the plunger back, it ensures that the syringe cannot be loaded more than once, thereby eliminating 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.

In line with Unilife's market-driven approach to product development, the Company took its original 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. This design now accommodates the needs of the target population, which the Company believes is likely to assist market adoption of the product versus competing products among the end users, and still retain its integrated non-reuse feature—making the product favorable for government programs that seek to enhance harm reduction programs by virtually eliminating the risk of needle sharing.

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. The Company has secured regulatory approval of the Safe Syringe in Australia, Canada, and Europe, with a submission to the FDA seeking U.S. certification pending.

Unitract™ Clinical Range

Currently at the advanced design and prototype stage, the Unitract™ Clinical Range is intended to complete the Unilife portfolio of clinical safety syringes for use at acute care facilities and other sites where intramuscular injections are common. This project has been slowed in order to focus the Company's efforts on development of the Unilife Prefilled Syringe. Yet, ultimately, the Unitract™ Clinical Range products are expected to be available in 3mL and 5mL sizes to meet the injection safety needs of healthcare workers and their patients. The design and method of operation is intended to complement the Unilife Prefilled Syringe to maximize levels of device functionality, user familiarity, and occupational safety. Unilife is taking steps to commence full commercialization of its Clinical Range.

Based on its 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.

INTEGRATED BIOSCIENCES INC. (IBS)

Beyond producing patented Unilife products, Unilife's wholly owned U.S. subsidiary, IBS, is a full-service medical device contract manufacturing partner for a number of international healthcare and pharmaceutical suppliers. IBS designs and operates automated high-volume clean room assembly systems for the large-scale production of medical devices (as illustrated in Figure 19). Through this subsidiary, Unilife is able to provide a total package of medical device commercialization services, including device design and development, prototyping, regulatory submissions, clinical support, and the development and operation of automated assembly systems (as depicted in Figure 20).

Figure 19
Unilife Medical Solutions Limited
IBS CLEAN ROOM

Source: Unilife Medical Solutions Limited.

Figure 20
Unilife Medical Solutions Limited
MANUFACTURING

Source: Unilife Medical Solutions Limited.

Some of the core services provided by IBS include those listed below and on page 53.

- *Quality Management Systems.* In keeping with the pursuit of excellence in the design, development, production, and supply of medical devices, Unilife has established a Quality Management System (QMS), which is fully certified to the international Good Manufacturing Practices (GMP) standard ISO 13485:2003. IBS has also secured and continues to maintain certification to ISO 13485:2003, and operates an FDA-registered manufacturing facility with **Class Six** clean rooms.

- *Device Design and Prototype Development.* Unilife has received international acclaim for its expertise in the design and development of innovative medical devices. Its staff in the U.S. and Australia have significant expertise in product development, specializing in areas such as the creation of formal design specifications and the development and verification of prototypes.

- *Development and Operation of Automated Assembly Systems.* The IBS division of Unilife has world-class knowledge in the design, construction, and operation of automated assembly systems. IBS has dedicated design teams that identify the most suitable production platform and assembly process for many types of medical devices. These high-precision automation systems can be supplied in a modular turnkey format.

- *Two-stage Production Process.* Unilife has pioneered a two-stage strategy to help fast-track the commercialization of innovative medical devices onto global healthcare and pharmaceutical markets. Initially, Unilife can develop semi-automated assembly systems for installation at the facilities of KDL in China to support the production of stock volumes that are satisfactory to obtain regulatory approval and generate initial market demand. At the same time, Unilife can design and develop fully automated robotic assembly systems at its U.S. facilities that can be brought online to support high-volume commercial sales.

Current Projects

The $75 billion global medical device market is experiencing rapid growth, driven by an aging population and the continued demand for novel and better product offerings. Multinational healthcare companies are increasingly seeking to outsource the production of their proprietary products to specialist contract medical device manufacturers to help streamline operational efficiencies. More than 20% of U.S.-made medical devices are manufactured under outsourced contract agreements, with this figure expected to increase steadily in coming years. IBS has contracts for the production of a number of medical devices that are marketed within North America by healthcare and pharmaceutical industry leaders, including those summarized below.

- *B.Braun USA.* IBS maintains a solid long-term relationship with B.Braun for the production of a range of syringe products under contract, where IBS manufactures approximately 50 different parts for B.Braun, for a total of approximately six million per year. Primarily hand assembled, these specialty syringes have custom printing and a low volume, custom mix environment. Following a successful supplier audit conducted by B.Braun in 2007, when IBS secured a 100% quality rating, the two companies began negotiating the terms of a new and expanded four-year contract.

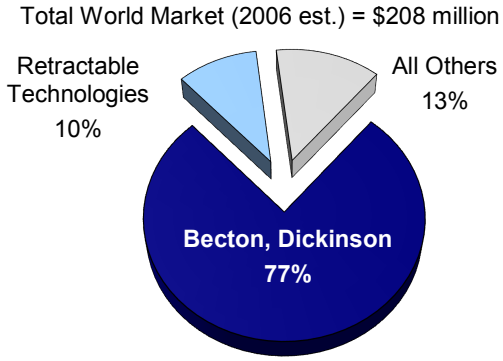
- *Sterile Prefilled Orthopedic Device.* For use within the U.S. orthopedic market, IBS supplied an initial batch of a packaged and sterile prefilled device to one of the world's largest pharmaceutical companies for use in clinical trials. These trials were recently successfully completed, with IBS scheduled to commence full production of the device during the second half of 2009.

- *Insulin Pump Device.* IBS has begun clinical trial production of a device on behalf of an undisclosed U.S. company to be used in the large and fast-growing U.S. diabetes market for insulin delivery devices. IBS is currently in the process of completing the build for this and is currently shipping product for sterility validations, with this launch expected to occur in early 2009. This program was transferred to IBS from another manufacturing group that was not able to satisfy the need. An aggressive production ramp-up plan is scheduled to commence in the second quarter 2009. Final shipment of the product is expected to take place to one of the world's largest diabetes suppliers.

- *Hemostatic Gauze Pad.* IBS has a contract with a U.S. company that has secured an initial order for the production of a hemostatic gauze pad to be tested by the U.S. military in battlefield conditions. IBS is now in discussions with this company regarding opportunities for high-volume production.

Competition

Figure 21
RETRACTABLE SYRINGES - MARKET SHARE BY COMPANY (2006)



Source: Greystone Associates' Retractable Safety Syringes (January 2007).

As illustrated in Figure 21, Becton, Dickinson and Company and Retractable Technologies, Inc. present competition to Unilife in the retractable syringe marketplace based on the respective market share of these two entities in 2006. In addition, Unilife could encounter competition from other medical device manufacturers as well as large pharmaceutical and biotechnology companies that have device divisions, as these companies may develop enhanced or alternative injectable technologies, such as injection pens or needle-free techniques, or may offer customized development services that could compete with the Company's business model. Moreover, 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 ridden with safety and regulatory concerns, still remain in the healthcare mainstream, particularly in developing economies (Source: Greystone Associates 2007).

The list of companies in Table 5 is not an exhaustive summation of potential competitors or competitive products, but it is believed to be representative of the type of competition that Unilife may face as it strives to commercialize its products and technologies globally. A profile of each competitor follows Table 5 on pages 55-56.

Table 5
Unilife Medical Solutions Limited
POTENTIAL COMPETITION

Company Name	Ticker (Exchange)	Last Trade (01/02/09)	52-week Range	Avg. Vol. (3 month)	P/E	Market Cap.
Becton, Dickinson and Co.	BDX (NYSE)	$69.86	$58.14 - $93.24	1,952,480	15.66	$16.98 B
Retractable Technologies, Inc.	RVP (AMEX)	$0.79	$0.45 - $2.00	8,964	—	$18.8 M
Safety Syringes, Inc.	*Closely held*	—	—	—	—	—
Covidien, Ltd.	COV (NYSE)	$37.37	$32.27 - $57.00	4,558,500	13.87	$18.82 B
Inviro Medical Devices	*Closely held*	—	—	—	—	—
Terumo Corporation (Terumo Medical Corporation)	45430 (TSE)	¥4,170.00	¥2,905 - ¥6,260	—	18.93	¥879.4 B
Smiths Group plc** (Smiths Medical)	SMIN (LON)	£937.50	£655.50 - £1,181.00	2,058,960	13.53	£364.7 B
Unilife Medical Solutions Ltd.***	UNI (ASX)	A$0.25	A$0.18 - A$0.49	134,592	—	A$54 M

* Traded on the Tokyo Exchange. At 01/02/09, ¥1 = ~US$0.01.

** Traded on the London Exchange. At 01/02/09, £1 = ~US$1.39.

*** Traded on the Australian Exchange. At 01/02/09, A$1 = ~US$0.70.

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

Becton, Dickinson and Company (BD)

BD is headquartered in New Jersey with offices in at least 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 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 and 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 disease. 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. In March 2007, Queensland Health awarded RTI a one-year contract to supply its VanishPoint® syringes to all of Queensland Health's 202 acute care facilities. However, while RTI maintains such agreements with many organizations for the distribution of its products in foreign markets, domestic sales in the U.S. still account for approximately 80% of RTI's revenues.

Safety Syringes, Inc.

Safety Syringes was founded in 1991 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, 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. (COV-NYSE). Covidien operates under eight brand names derived from its four strategic business segments: (1) medical devices; (2) medical supplies; (3) imaging solutions; and (4) pharmaceutical products. Covidien's Kendall brand manufactures and distributes medical products used in various clinical settings, such as healthcare facilities and in patients' homes. The company's line of MONOJECT™ safety syringes is currently available prefilled with insulin for diabetes patients or with tuberculin for tuberculosis testing. The MONOJECT™ line of 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, which are also intended to protect healthcare workers from needlestick injuries. As such, Magellan™ syringes incorporate a needle-based safety device that is intended to keep clinicians safe while providing clinical flexibility.

Inviro Medical Devices

Founded in 1988, Inviro Medical is a medical device company focused on the development and marketing of medication delivery systems that emphasize sharps safety. Headquartered in Atlanta, Georgia, Inviro Medical is presently positioned to target U.S., Canadian, and European safety syringe markets. The company's patented InviroSNAP!® Safety Syringe was developed using end-user feedback to optimize its features and performance. To properly use the InviroSNAP!® syringe, operators administer the medication and then manually pull back on the plunger with their hands to withdraw the needle into the barrel. Consequently, this causes the needle to retract back into the barrel where the plunger is subsequently broken off by the operator to prevent needlestick injuries or reuse of the device. In mid-2006, Inviro Medical reached an agreement with the IMD Group in Australia, electing IMD as the preferred supplier of the company's medical devices. In addition, in late 2006, Inviro Medical announced an exclusive agreement with SafePro USA Inc. and its parent company, Formosa Medical Devices Inc., for the sale, marketing, and distribution of SafePro safety syringes in the U.S. and Canada.

Terumo Medical Corporation (TMC)

Parented by the Terumo Corporation (45430-TSE), 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. While some of TMC's products and devices are currently produced in Japan, the company is transitioning to full-scale manufacturing operations in its Elkton, Maryland, facility. 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

One of four divisions 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. To address global market needs relating to anesthesia, respiratory care, critical care, and infection control, Smiths Medical manufactures and distributes disposable medical products under its Portex, Inc. division, which is headquartered in Keene, New Hampshire. Through Portex, 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

Table 6 is a summary of Unilife's corporate and operational milestones, as well as the expected or actual completion date of each.

Table 6
Unilife Medical Solutions Limited
MILESTONES

Recent Milestones	Completion Date
▪ Initial supply of the Unilife Prefilled Syringe to sanofi-aventis	April 2008
▪ Commenced production of Unitract™ 1mL syringes in China	April 2008
▪ Exclusive License Agreement with sanofi-aventis	July 2008
▪ Receipt of $13.9 million (€10 million) exclusivity fee	July 2008
▪ Started Industrialization Program	July 2008
▪ Commenced commercial sales of the Unitract™ 1mL syringes	July 2008
▪ Appointed KDL as an international distribution partner	July 2008
▪ U.S. FDA clearance for the Unitract™ 1mL Insulin Syringe	October 2008
▪ Receipt of first industrialization payment	October 2008
Potential Milestones	**Expected Completion Date**
Corporate	
▪ Industrialization Agreement with sanofi-aventis	Early 2009
▪ U.S.-qualified production of Unitract™ 1mL Syringes	Mid-2009
▪ Listing on respected international exchange	Mid-2009
▪ Site selection for EU manufacturing facility	Third Quarter 2009
▪ Supply Agreement with sanofi-aventis	End 2009
Operational	
▪ Commence appointment of suppliers for Unilife Prefilled Syringe	2009
▪ New medical device manufacturing contracts by IBS	2009
▪ Start of supply of the Unilife Prefilled Syringe	2010
▪ Completion of Industrialization Program	2011

Sources: Unilife Medical Solutions Limited and Crystal Research Associates, LLC.

Key Points to Consider

Unless stated otherwise, all monetary amounts are in U.S. dollars. At 01/02/2009, US$1.00 = ~A$1.43 and €0.72.

- Unilife has developed and patented an innovative portfolio of clinical and prefilled retractable syringes with a novel automatic, user-controlled needle retraction system that is fully integrated within the device. The Company is in a solid position to supply a 'best-in-class' range of safety syringes into target healthcare and pharmaceutical markets that increasingly mandate use of such devices. Unilife has secured a highly competitive position within the pharmaceutical market specifically for prefilled syringes—the most profitable and fastest-growing sector of this industry.

- In 2008, Unilife signed an Exclusive Licensing Agreement with sanofi-aventis, the world's fourth largest pharmaceutical company and largest consumer of prefilled syringes. Sanofi-aventis paid Unilife $13.9 million (€10 million) for five-year exclusivity to purchase the Unilife Prefilled Syringe.

    - Under an Industrialization Agreement, expected to be signed in early 2009, sanofi-aventis has agreed to fund Unilife's Industrialization Program of between $20.8 million and $23.6 million (€15 million and €17 million) to develop production systems capable of supplying a minimum of 40 million units of the Unilife Prefilled Syringe in 2011.

    - To help lower the risk involved in the industrialization process, Unilife has also signed an Exclusive Business Development Agreement with Gerresheimer Bünde, the world's second largest manufacturer of prefilled syringe systems.

    - A Supply Agreement, which is expected to be signed between Unilife and sanofi-aventis toward the end of 2009, is intended to commit to long-term orders at a unit price still to be negotiated. The Company expects that annual production volumes for the Unilife Prefilled Syringe could reach 400 million units in 2014 and up to one billion units per year beyond 2017.

- The Unilife Prefilled Syringe has been engineered for high-volume production and designed for compatibility with standard filling and packaging systems. All safety features are fully 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 disposal space. By removing the need to purchase and attach clip-on safety products to a standard prefilled syringe, Unilife can significantly reduce the costs to a pharmaceutical company in areas such as assembly, packaging, storage, and transport.

- In October 2008, Unilife received U.S. 510(k) clearance of its Unitract™ 1mL Insulin Syringe, enabling the Company to continue with the commercialization of this product in target U.S. markets.

- Unilife's wholly owned subsidiary, Integrated BioSciences Inc. (IBS), is a U.S.-based contract medical device manufacturer with expertise developing and operating automated assembly systems. IBS brings key industrial and engineering requirements in-house. The expertise of IBS in the development of pilot production systems for the Unilife Prefilled Syringe has had a key role in the signing of the Exclusive Licensing Agreement with sanofi-aventis. Via IBS, Unilife successfully initiated pilot production of its prefilled syringes during 2008 at its FDA-registered and ISO 13485-certified facility.

- There is a requirement in the marketplace to provide a safety syringe. To date, nearly all of Unilife's competitors have been *technology driven*. What differentiates Unilife in this market is that rather than being technology driven, Unilife is *market driven*, where the Company actually enters the market to discover the market's specific needs.

- Unilife has been able to secure world-class medical device and pharmaceutical experts to its team, including the former head of medical devices at the World Health Organization (WHO), who was responsible for the development of international standards for single-use syringes.

- At September 30, 2008, Unilife's cash position was roughly $10.6 million (A$13.4 million) with no need to raise further capital at that time, as the Company is now cash flow positive. Unilife estimates that revenues beyond 2014 may be in excess of $400 million per year. Additionally, there is current revenue from IBS that may increase as its programs expand.

Historical Financial Results

Tables 7 and 8 (page 60) provide a summary of Unilife's key historical financial statements—its Income Statements and Balance Sheets for the fiscal year ended June 30, 2008. The individual parent entity referenced in Tables 7 and 8 is Unilife Medical Solutions Limited. The economic entity encompasses Unilife Medical Solutions Limited and its controlled businesses, Unitract™ Syringe Pty Ltd. and IBS. In addition, Table 9 (page 61) contains the Company's Consolidated Statement of Cash Flows for the quarter ended September 30, 2008.

Each of these financial statements (Tables 7, 8, and 9) are presented in Australian dollars (A$), the functional and presentation currency of the parent entity. As of the date of this Income Statement, June 30, 2008, A$1.00 was approximately US$0.96. The historical exchange rates referenced for Tables 7, 8, and 9 differ from the current rate used throughout the rest of this report.

Table 7
Unilife Medical Solutions Limited
INCOME STATEMENTS FOR THE YEAR ENDED JUNE 30, 2008

	Economic Entity		Parent Entity	
	2008	2007	2008	2007
	A$	A$	A$	A$
Revenue from continuing operations	3,708,655	2,292,389	436,379	224,181
Other income	461,511	996,400	333,072	776,504
Cost of good sold	(3,098,651)	(1,924,355)	—	—
Employee expense	(3,250,097)	(2,831,756)	(668,104)	(643,995)
Depreciation and amortization expenses	(803,881)	(270,660)	(417,017)	(144,662)
Other expenses	(4,485,808)	(5,255,263)	(1,958,450)	(3,030,694)
Loss on sale of non-current assets	—	(2,046,178)	—	(1,971,319)
Finance costs	(387,065)	(319,108)	(146,838)	(125,749)
Impairment of property, plant, and equipment	—	(697,102)	—	(506,737)
Expense associated with issue of Convertible Note	(124,300)	(364,682)	(124,300)	(364,682)
Share-based payments	(681,217)	(634,558)	(681,217)	(634,558)
Provision for loan non-recovery	—	—	(6,077,503)	(5,024,590)
Loss before income tax expense	(8,660,853)	(11,054,873)	(9,303,978)	(11,446,301)
Income tax benefit	43,615	148,797	—	—
Loss attributable to members of the Company	(8,617,238)	(10,906,076)	(9,303,978)	(11,446,301)
	Cents	Cents		
Basic earnings per share (cents per share)	(4.4)	(7.8)		
Diluted earnings per share (cents per share)	n/a	n/a		

Source: Unilife Medical Solutions Limited.

Presented in Australian dollars (A$). As of the date of this Balance Sheet, June 30, 2008, A$1.00 was approximately US$0.96.

Table 8
Unilife Medical Solutions Limited
BALANCE SHEETS FOR THE YEAR ENDED JUNE 30, 2008

	Economic Entity		Parent Entity	
	2008	2007	2008	2007
	A$	A$	A$	A$
Assets				
Current Assets				
Cash and cash equivalents	3,002,277	4,225,131	2,930,957	3,492,035
Trade and other receivables	1,069,942	1,181,353	6,423,852	4,798,898
Inventories	1,107,515	486,619	—	—
Other current assets	36,286	38,822	4,564	5,338
Total Current Assets	5,216,020	5,931,925	9,359,373	8,296,271
Non-current Assets				
Other financial assets	—	—	7,464,595	7,464,595
Property, plant, and equipment	8,111,437	8,019,884	2,093,283	2,449,671
Intangible assets	6,849,797	6,872,275	—	—
Other non-current assets	7,108,866	6,482,208	—	—
Total Non-current Assets	22,070,100	21,374,367	9,557,878	9,914,266
Total Assets	27,286,120	27,306,292	18,917,251	18,210,537
Current Liabilities				
Trade and other payables	1,912,742	2,113,182	672,261	583,396
Borrowings	4,333,621	923,257	4,234,490	575,093
Total Current Liabilities	6,246,363	3,036,439	4,906,751	1,158,489
Non-current Liabilities				
Borrowings	3,162,656	4,096,486	—	16,677
Total Non-current Liabilities	3,162,656	4,096,486	—	16,677
Total Liabilities	9,409,019	7,132,925	4,906,751	1,175,166
Net Assets	17,877,101	20,173,367	14,010,500	17,035,371
Equity				
Issued capital	72,254,862	66,783,726	72,254,862	66,783,726
Reserves	2,604,297	1,754,461	2,556,943	1,748,972
Accumulated losses	(56,982,058)	(48,364,820)	(60,801,305)	(51,497,327)
Total Equity	17,877,101	20,173,367	14,010,500	17,035,371

Source: Unilife Medical Solutions Limited.

Presented in Australian dollars (A$). As of the date of this Consolidated Statement of Cash Flows, September 30, 2008, A$1.00 was approximately US$0.79.

Table 9
Unilife Medical Solutions Limited
CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE QUARTER ENDED SEPTEMBER 30, 2008

			Current quarter (ended Sept. 30, 2008) $A'000
	Cash flows related to operating activities		
1.1	Receipts from customers		18,307
1.2	Payments for	(a) staff costs	(2,148)
		(b) advertising and marketing	(65)
		(c) research and development (refer to item 1.13)	—
		(d) leased assets	(175)
		(e) other working capital	(2,686)
1.3	Dividends received		—
1.4	Interest and other items of a similar nature received		161
1.5	Interest and other costs of finance paid		(63)
1.6	Income taxes paid		—
1.7	Other		
	- Grants Received		—
	Net operating cash flows		13,331
1.8	Net operating cash flows (carried forward)		13,331
	Cash flows related to investing activities		
1.9	Payment for acquisition of:	(a) businesses	—
		(b) equity investments	—
		(c) intellectual property	—
		(d) physical non-current assets	(57)
		(e) other non-current assets	—
1.10	Proceeds from disposal of:	(a) businesses	—
		(b) equity investments	—
		(c) intellectual property	—
		(d) physical non-current assets	—
		(e) other non-current assets	—
1.11	Loans to other entities		—
1.12	Loans repaid by other entities		—
1.13	Other – cash on acquisition of subsidiaries		
	Other – payments for research and development		(230)
	Net investing cash flows		(287)
1.14	**Total operating and investing cash flows**		13,044
	Cash flows related to financing activities		
1.15	Proceeds from issues of shares, etc.		120
1.16	Proceeds from sale of forfeited shares		—
1.17	Proceeds from borrowings		—
1.18	Repayment of borrowings		(2,799)
1.19	Dividends paid		—
1.20	Other – share issue (costs) / refunds		—
	Net financing cash flows		(2,679)
	Net increase (decrease) in cash held		10,365
1.21	Cash at beginning of quarter/year to date		3,002
1.22	Exchange rate adjustments		—
1.23	**Cash at end of quarter**		13,367

Source: Unilife Medical Solutions Limited.

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 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 primarily from information available to the public released by the Company through news releases, Annual Reports, 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 Unilife. 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.

General Economic Conditions

Changes in the general domestic and international climate may adversely affect the financial performance of the Company and its products. Factors that may contribute to a change in the general economic climate include industrial disputes, inflation, and political and social reform.

Evolving Corporate Status

The Company is subject to all of the usual risks encountered by evolving organizations, including capital adequacy, cash flow, product development and regulatory approval, market penetration and market growth, and continuity of core personnel. Notwithstanding, Unilife anticipates significant growth over the next few years. Such growth may place considerable strain on management, particularly given the international nature of the Company's operations and the marketing of its products. There can be no assurance that Unilife will be able to manage this growth in the future.

Core Technology

The Company's future revenues are highly dependent on the commercialization of products based on its technology. To commercialize its technology, the Company intends to form alliances with key distributors, partners, and manufacturers. Unilife's future revenues rely on the achievement of these goals as well as the required regulatory approvals. However, no assurance can be given that the Company will succeed in the commercialization of its technology.

In addition, the markets in which Unilife operates are characterized by the continual search for technological advances that deliver improved reliability and reduced cost. The Company's growth and future financial performance will depend on its ability to enhance its existing technology and develop and introduce new products on a timely basis to keep pace with technological developments and evolving industry requirements. If Unilife is unable to do so, there may be a material adverse effect on its business.

The research and development required for technology enhancements and new products are complex, uncertain, and require significant investment and high levels of innovation. If Unilife fails to anticipate or respond adequately to technological developments or customer needs, or if it experiences any significant delays in product development or introduction, the Company's products may become obsolete and it may not be able to sustain or grow its business. Furthermore, there is no assurance that new products introduced by Unilife will gain widespread market acceptance.

Intellectual Property

The Company relies on a combination of patents, trade secrets, trademarks, copyrights, licenses, and non-disclosure and confidentiality agreements to establish and protect its proprietary rights in its technologies. If Unilife is unable to adequately protect its intellectual property rights or becomes subject to a claim of infringement, its business may be materially adversely affected. The Company currently has patents that have been granted and are under application. The Company cannot be certain that patents will be issued with respect to any of its pending or future patent applications. In addition, the Company does not know whether any issued patents will be upheld as valid or proven enforceable against alleged infringers or that these patents will prevent the development of competitive patents.

Regulatory Approvals

The business of manufacturing and distributing medical devices is increasingly exposed to significant legislative compliance issues and regulatory requirements, such as Therapeutic Goods Administration (TGA) approval in Australia, Food and Drug Administration (FDA) approval in the U.S., and Medical Device Directive compliance (CE Mark) in the EU. The Company is required to comply with all applicable regulatory requirements with respect to the manufacturing, supply, and distribution of its safety syringes.

There is no guarantee that Unilife's products will obtain regulatory approvals from the TGA, EU, or the FDA. Even if such approvals are granted, there is no guarantee as to the time taken or cost involved. Sales of the Company's products in other jurisdictions are subject to foreign regulatory requirements that vary from country to country. The federal, state, and foreign laws and regulations regarding the manufacture and sale of Unilife's products are also subject to future changes, as are administrative interpretations and policies of regulatory agencies. If the Company fails to comply with applicable federal, state, or foreign laws or regulations, it could be subject to enforcement actions—product seizures, recalls, withdrawal of clearances or approvals, and civil and criminal penalties—that may materially harm its business.

Manufacturing

Unilife depends on a number of suppliers to successfully manufacture commercial quantities of its products. If any supplier does not deliver for any reason, contractual or otherwise, the business may be seriously financially harmed. Additionally, Unilife may experience problems or delays in its manufacturing process, which may also harm the financial status or reputation of the Company.

The Company's business plan is predicated on entering into agreements with one or more external parties to manufacture components of the Company's technology. If Unilife is unable to secure agreements with these manufacturers on favorable terms or at all, then its ability to commercialize its technology and expand its operations may change from that currently envisioned.

Product Liability

Product liability claims could damage the Company's reputation and financial results. The Company's business will be exposed to an inherent risk of potential product liability claims related to the trials, manufacturing, marketing, and sale of human medical devices. Unilife believes that it possesses satisfactory product liability insurance coverage and intends to increase its coverage during 2009 to support full product launch. However, there is no guarantee that insurance will be maintained or increased on acceptable terms, and that such insurance will provide adequate coverage against potential liabilities.

A successful claim brought against the Company in excess of, or outside of, its insurance coverage could seriously harm its financial condition and operations. Claims, regardless of merit or potential outcome, may also reduce Unilife's ability to expand its business or obtain physician endorsement for its products.

Market and Competition

The safety medical device industry is a rapidly growing, immature industry that can be highly competitive. The Company faces competition from other syringe developers that may have greater research and development, management, financial, technical, manufacturing, marketing, sales, and other resources than those currently available to Unilife. There can be no assurance that the Company will be able to compete successfully against its current and future competitors, some of which are profiled on pages 54-56.

Sales Channels

The Company will rely on a number of distributors and partners to sell its product. If these distributors or partners fail to assist in distributing the product, revenues and growth will be limited.

Foreign Market and Exchange Rate Fluctuation

The Company intends to continue with its plan to conduct some of its business on a global scale. There are risks inherent in doing business internationally, such as changes in regulatory requirements, tariffs, customs duties and other trade barriers, longer payment cycles, problems in collecting accounts receivable, political instability, war and other political risks, fluctuations in currency exchange risk, foreign exchange controls, export and import restrictions or prohibitions, seasonal reductions in business activity, and an unfavorable tax regime, any of which could adversely impact the success of the Company's international operations. There is no assurance that one or more of these factors will not have a materially adverse effect on Unilife's business, operating results, and financial condition.

As a consequence of the international nature of its business, Unilife will be exposed to risks associated with changes in foreign currency exchange rates. Movements in foreign currency exchange rates may have an impact on the Company's reported results of operations, financial position, and cash flows.

Reliance on Key Personnel and Need to Attract Quality Staff

The Company's success depends to a large degree on the continued services of its senior management and key personnel. The loss of their services, particularly to a competitor, could disrupt the Company's operations and harm its business. Unilife believes that responsible management processes, an emphasis on people management, the use of an employee share scheme, and good employment practices and benefits within its employment arrangements reduce the likelihood of such personnel terminating their employment with the Company and/or setting up in competition.

Legislation

If the Company's technology or products based on its technology do not comply with applicable laws or if the Company is exposed to liability claims, its business and financial results could be seriously harmed. Any imposition of liability that is not covered by Unilife's insurance or is in excess of its insurance coverage could have a material adverse effect on the business, results of operations, and financial condition. Furthermore, changes in legislation and government policy could also negatively impact the Company. No assurance can be given that Unilife will be able to obtain any necessary license required in the future or that future changes in laws or government policies affecting its technology or products will not impose additional regulatory requirements on the Company, intensify competition in the industry, or otherwise have a material adverse effect on its business, financial condition, and results of operations.

Catastrophic Disasters

The occurrence of a catastrophic disaster or other similar events could cause damage to the Company's facilities and equipment, which could require cessation or curtailing of operations. The Company may be vulnerable to damage from various types of disasters, including earthquakes, fires, terrorist acts, floods, power losses, communications failures, and similar events. The insurance maintained may not be adequate to cover the losses resulting from disasters or other business interruptions.

ASX Share Investment Risk

There are various risks associated with investing in any form of business and with investing in the stock market generally. The value of shares will depend upon general stock market and economic conditions as well as the specific performance of the Company. Investors should be aware that an investment in the Company involves risks that may be higher than the risks associated with an investment in other companies. Unilife's share price may be subject to significant volatility similar to many technology-based companies that have experienced significant share price volatility in recent times. There is no guarantee of profitability, dividends, return of capital, or the price at which the shares will trade on the ASX. There can also be no guarantee that an active market in shares will develop or will remain.

Additional Financing Requirements

Unilife can give no assurances that its business objectives will be met without future borrowings and/or further capital raisings. If such borrowings and/or capital raisings are required, the Company cannot guarantee that they can be obtained on terms favorable to Unilife. An inability to raise additional financing may have a material adverse effect on the Company's business, financial condition, and performance.

Recent Events

Unless stated otherwise, all monetary amounts are in U.S. dollars. At 01/02/2009, US$1.00 = ~A$1.43 and €0.72.

11/28/2008—Unilife Medical Solutions Limited posted to its website a copy of the chairman's address and chief executive officer (CEO) presentation delivered at its 2008 Annual General Meeting in Sydney.

11/26/2008—Announced the following key executive appointments (biographies on pages 20-23): (1) Mr. Bernhard Opitz as senior vice president of operations; (2) Mr. Mark Iampietro as vice president of quality and regulatory affairs; and (3) Dr. Graham Purches as RTFS (Unilife Prefilled Syringe) operations director.

10/24/2008—Announced that it received U.S. Food and Drug Administration (FDA) clearance of the Unitract™ 1mL Insulin Syringe. FDA clearance of the 510(k) submission for the Unitract™ 1mL Insulin Syringe gave Unilife permission to market and sell the Unitract™ 1mL Insulin Syringe within the U.S. Unilife now intends to initiate its launch plan for the evaluation and commercial release of the product within target U.S. healthcare, diabetes, and harm reduction markets.

10/03/2008—Announced the strengthening of its Strategic Business Plan to further position the Company for continued global expansion. Since the start of its current financial year, Unilife has signed an Exclusive Licensing Agreement with sanofi-aventis for the exclusive right to purchase the Unilife Prefilled Syringe (also called the Unilife Ready-to-Fill Syringe [RTFS]) for five years and received payment of an exclusivity fee from sanofi-aventis. Both parties are currently negotiating in good faith to finalize an agreement to complete industrialization of the licensed product, under which the pharmaceutical partner will likely bear the industrialization costs. In addition, Unilife fully committed its corporate and operational resources toward the high-volume industrialization of its proprietary range of prefilled and clinical safety syringes, the strengthening of relationships with pharmaceutical and medical device partners, and the continued expansion of the Company within the U.S. and Europe. The Company's Board of Directors also ratified agreements to terminate certain contracts with MedPro Safety Products and agreed in principle to terminate an agreement with Carpe DM, Inc. that no longer fit Unilife's business model.

08/04/2008—Announced the receipt of the $13.9 million (€10 million) exclusivity fee from sanofi-aventis. To support its goal of becoming a profitable multinational leader in the development and supply of innovative safety medical devices, the Board initiated a consolidation program to further streamline global business activities. This program was intended to be focused on the cost-efficient delivery of core internal projects, such as the Unilife Prefilled Syringe, which may generate significant and profitable revenue streams in the future.

In addition, the Company announced that it was expanding its industrial capabilities for the Unilife Prefilled Syringe, which includes expanding engineering and operational resources at Integrated BioSciences Inc. (IBS), establishing a European base, and commencing recruitment activities to fill a number of positions important to the industrialization of the Unilife Prefilled Syringe. Further, the Company announced that a number of key corporate and operational functions at Unilife were expected to be transferred from Australia to IBS' facilities in Pennsylvania. The centralization of key corporate and operational functions at IBS was hoped to further strengthen the overall cost efficiency of Unilife and help ensure that the industrialization of the Unilife Prefilled Syringe remained on-track. Unilife's CEO was to be among a small number of executives relocating to IBS. Unilife is expected to continue to maintain a business presence within Australia to support the fulfillment of essential business reporting functions.

07/15/2008—Reported the completion of another significant corporate milestone: the start of commercial sales for the Unitract™ range of 1mL Safe Syringes. To support the global rollout of the Unitract™ 1mL syringes, the Company announced that its strategic partner in China, Shanghai Kindly Enterprise Development Group Co., Ltd ("KDL"), was appointed as a distribution partner for a number of international regions.

07/07/2008—Released its annual shareholders' letter.

07/01/2008—Announced that it entered into a global license agreement with sanofi-aventis for the exclusive rights to the Unilife Prefilled Syringe for a period of five years in exchange for a license fee that was to be paid by July 31, 2008, among other terms.

06/25/2008—Updated shareholders with regard to previous announcements concerning the Company's potential expansion in the U.S. Since late 2006, Unilife had been exploring the possibility of a redomiciliation to the U.S. through a scheme of arrangement (such as a reverse merger) transaction. Over the past few months, the Company discussed such a transaction in detail with an interested third party. These discussions contemplated an acquisition by the third party of all of the Company's issued shares, founder shares, and Options in return for the issue of Shares/Options in the third party and also the issue of a suite of incentive options in the third party for key management of the Company. After exhaustive negotiations with these interested parties and careful consideration of the benefits of such a transaction, the Board of Directors decided not to proceed with the strategy of a redomiciliation to the U.S. through a scheme of arrangement transaction. In making this decision, the Board took into account a variety of relevant factors and, in particular, considered that the position being presented by the interested party in respect of the proposed transaction (including any premium that the party would be prepared to pay) did not sufficiently take into account the true intrinsic value and significant growth prospects of the Company. Instead, the Board believed that it was at that time in the best interests of the Company and its shareholders to pursue a global strategy for organic growth.

Unilife also announced the appointment of Mr. William Galle (biography on page 19) as a non-executive director.

06/04/2008—Announced that Unilife entered into discussions with the Croatian government to evaluate the establishment of a proposed €90 million medical device manufacturing facility. Unilife selected Croatia as a potential location due to its anticipated entry into the EU during 2009 or 2010. Up to 500 local jobs could be created through the establishment of the proposed facility in Croatia. The selection of the site may ultimately be determined by a number of factors, including incentives, access to key markets, and the skills base of the labor force. Mr. Jim Bosnjak (biography on page 18), Unilife's non-executive chairman, presented Unilife's investment proposal to the Croatian government and held several meetings with the Prime Minister Ivo Sanader and other senior ministers.

06/03/2008—Advised that certain Options would expire at 5:00 pm (WST), June 30, 2008, unless exercised beforehand.

04/07/2008—Announced that it commenced delivery of prefilled syringes to its pharmaceutical partner to support the completion of product verification activities. Initial verification testing indicated that the syringes exceeded the functional performance requirements set for the product. Production of the prefilled syringe was carried out at IBS using an automated assembly system capable of manufacturing up to one million units per year to support completion of product validation and initial sales. The provision of this production batch within the timeframe required under the Exclusive Development Agreement with Unilife's pharmaceutical partner triggered a further payment to Unilife.

04/03/2008—Announced that production of the Unitract™ range of 1mL Safe Syringes commenced in China. In addition, Unilife reported that it lodged its 510(k) submission with the FDA for U.S. regulatory approval of the Unitract™ 1mL Insulin Syringe.

01/08/2008—Announced the extension of its exclusive agreement with one of the largest pharmaceutical groups in the world to support the ongoing development of the RTFS. To support the agreement with its pharmaceutical partner, Unilife obtained a Freedom to Operate (FTO) report from its patent attorneys. The FTO gave Unilife confidence that the patents filed for the prefilled syringe did not infringe on other international patents, and further strengthened Unilife's ability to commercialize the product.

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.

Antithrombotic—A type of anticoagulant drug therapy that prevents the formation of blood clots by inhibiting the action of the blood protein thrombin, one of the elements needed in clot formation.

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 all 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.

Class Six—A Class Six clean room is an environment that has a low level of environmental pollutants. Clean rooms are classified by ISO standards 14644-1 and Federal Standard 209 according to the number and size of particles permitted per volume of air. An ISO Class Six clean room (equivalent to a Federal Standard 209E Class 1000) has no more than 35,200 particles per cubic meter equal to and larger than 0.5 microns. ISO classification spans Class One (the most stringent) to Class Nine.

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.

FDA 21 CFR 820—Title 21 Part 820 of the Code of Federal Regulations (21 CFR 820), also known as the Quality System Regulation (QSR), outlines current Good Manufacturing Practices (GMP) regulations. These requirements are meant to ensure that medical devices are safe and effective. Medical device manufacturers undergo FDA inspections to ensure QSR compliance. See entry for *Good Manufacturing Practices (GMP)* below.

Federal Register—A publication of the federal government that includes official transactions of the U.S. Congress as well as all federal agencies.

First-Pass Metabolism—The decrease in bioavailability or concentration of an oral drug due to metabolism and excretion before the drug reaches the systemic circulation (also known as first-pass effect or presystemic metabolism).

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 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.

Fully Integrated—When two or more components or functions are combined and incorporated into a single package or device.

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.

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.

Hepatitis C—Previously known as non-A, non-B hepatitis, hepatitis C is an inflammation of the liver that causes fever, jaundice, abdominal pain, and weakness. Unlike other forms, hepatitis C is largely caused by blood transfusions, needles, and in rare cases, sexual contact.

Human Immunodeficiency Virus (HIV)—The virus that causes Acquired Immune Deficiency Syndrome (AIDS). It replicates in and kills the helper T-cells.

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

Intramuscularly—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 13485:2003—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.

ISO 9001:2000—Specifies requirements for a quality management system for any organization that needs to demonstrate its ability to consistently provide products that meet customer and applicable regulatory requirements and aims to enhance customer satisfaction. For further details, visit www.iso.org.

Lipodystrophy—A disorder of fatty tissue characterized by a selective loss of body fat. Patients with lipodystrophy have a tendency to develop insulin resistance, diabetes, a high triglyceride level, and fatty liver. There are numerous forms of lipodystrophy that are genetic or acquired.

Low-Molecular-Weight Heparin (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 Lock—A type of connector with a locking mechanism, used extensively for medical and laboratory applications. Luer taper is a standardized system of small-scale fluid fittings used for making leak-free connections between a male-taper fitting and its mating female part on medical and laboratory instruments, including hypodermic syringe tips and needles.

Microtrauma—A microscopic injury usually affecting connective tissue.

Multiple Sclerosis (MS)—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.

Myelosuppressive Chemotherapy—Chemotherapy involving the use of anticancer drugs to intentionally decrease the bone marrow's production of blood cells.

Needle and Syringe Programs (NSPs)—A public health measure to reduce the spread of bloodborne viral infections among injecting drug users (IDUs). These programs provide a range of services, including the provision of injecting equipment (needles and syringes, swabs, vials of sterile water, and sharps bins for the safe disposal of used injection equipment), education and information on the reduction of drug-related harms, referral to drug treatment, medical care, and legal and social services. The aim is to prevent the shared use of injecting equipment and to address the potential for transmission of infection via sexual contact by providing condoms and safer sex education.

Needlestick Injuries—Penetrating wound 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 Act—A U.S. federal law that requires employers to provide employees with a workplace that is relatively free of hazardous conditions.

Occupational Safety and Health Administration (OSHA)—A Federal agency under the U.S. Department of Labor responsible for establishing and enforcing safety and health standards in the workplace for most businesses and industries in the U.S.

Patent Cooperation Treaty (PCT)—A unified procedure for filing patent applications to protect inventions in 139 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.

Polysomnographer—A technician trained in polysomnography, which is the continuous recording of specific physiologic variables during sleep. Polysomnography typically records brain wave changes (electroencephalogram), eye movements (electrooculogram), muscle tone (electromyogram), respiration, electrocardiogram (EKG), and leg movements.

Prophylaxis—The prevention of disease, or a medication or treatment that is used to prevent a disease.

Provisional Patent Applications—Interim patent applications that provide a one-year period for product development. A Provisional Patent Application is not examined but can serve as the basis of priority for an application filed later.

Pulmonary Embolism—The lodgment of a blood clot in the lumen of a pulmonary artery, causing a severe dysfunction in respiratory function.

Six Sigma—A quality management and process improvement methodology. A professional certified as a Black Belt in Six Sigma is expected to be able to explain Six Sigma philosophies and principles, including supporting systems and tools, demonstrate team leadership, understand team dynamics, and assign team member roles and responsibilities. Black Belts have a thorough understanding of all aspects of the DMAIC model in accordance with Six Sigma principles. They have basic knowledge of lean enterprise concepts, are able to identify non-value-added elements and activities, and are able to use specific tools.

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

Thimerosal—An organomercury compound (approximately 49% mercury by weight) used as an antiseptic and antifungal agent.

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

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

Vial—A small container for holding liquids. A small bottle that contains a drug (especially a sealed sterile container for injection by needle).

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