



INITIATION REPORT

Medical Device Industry • August 19, 2009

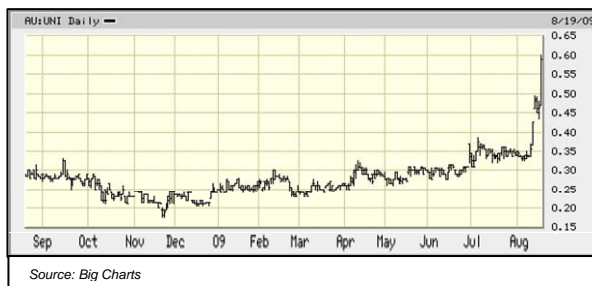
UNILIFE MEDICAL SOLUTIONS (ASX: UNI)

- **Unilife has disruptive drug delivery technology and a sound strategy for entering international needle & syringe markets, including North America and Europe.**
- **Sanofi-aventis, the largest consumer of prefilled syringes, is investing \$38 million in fees and industrialization payments for rights to Unilife's safety syringes. Negotiations for exclusivity by therapeutic class are ongoing.**
- **Additional supply agreements are expected with other pharmaceutical companies and in other therapeutic areas, starting in 2010.**
- **Preparations are well under way for the U.S. registration of the Company's stock.**
- **We are initiating coverage on Unilife (ASX: UNI) with a BUY rating and a target price of \$3.00 (or A\$3.65) per share.**

Unilife Medical Solutions is a medical device company with a disruptive safety-syringe technology in sync with global trends in drug delivery. Its principal feature is a needle retraction mechanism activated automatically to prevent needlestick injuries and reuse. This proprietary technology is elegant in the way in which all safety features are fully integrated within the device to retain the simplicity of traditional syringes that everyone is accustomed to using. Moreover, Unilife's products offer pharmaceutical companies a means of differentiating their drugs and vaccines, while also helping healthcare providers to meet new regulations requiring the use of safety syringes.

Investors can anticipate several value-driving milestones in the coming 12 to 18 months. For one, Unilife and sanofi-aventis are scheduled to complete the framework for supply contracts for ready-to-fill syringes under an industrialization agreement signed on July 1st. In addition,

Share Price (08/19/09)	A\$0.59
52-Week Price Low / High	A\$0.17-\$0.60
Mkt. Capitalization (issued)	A\$128 M
Shares Outstanding (issued)	216.68 M
12-month Target Price	A\$3.65
Website	www.unilife.com



commercial launch of a 1ml safety syringe from a fully automated U.S. production line is about to commence under the Unitract™ brand, and the Company will soon register its stock on a major U.S. exchange.

KEITH A. MARKEY, PH.D.
 212-514-7914
 KMARKEY@GRIFFINSECURITIES.COM

INVESTMENT HIGHLIGHTS:

DISRUPTIVE SAFETY SYRINGE TECHNOLOGY ATTRACTS INTEREST FAR AND WIDE. Unilife has developed an elegant syringe design that returns full control of injections to healthcare workers and self-administering patients, while offering a virtually fool-proof system to protect against needlestick injuries and prevent needle & syringe reuse. Unlike today's most advanced ready-to-fill (prefilled) syringe models, the Company's proprietary designs incorporate all safety features within the barrel, thereby eliminating the need for special manufacturing equipment, extra packaging, and adaptation by users to any unusual handling of the injection system.

CLOSE RELATIONSHIP WITH SANOFI-AVENTIS DE-RISKS UNILIFE'S STRATEGIC PLAN. The Company has been collaborating with the international pharmaceutical giant since 2003, first in an informal relationship involving the design and test-production of glass ready-to-fill syringes. That led sanofi-aventis to provide financial support for the installation and qualification of an automated manufacturing line at the Company's U.S. headquarters. The work has progressed ahead of schedule, and completion of the project has been moved up by 12 months, to the end of 2010. At the end of June, the two partners signed an industrialization agreement that establishes a mechanism for determining therapeutic areas in which sanofi-aventis will have exclusive rights to Unilife's ready-to-fill syringes. We believe the final list, which is due by late December according to the agreement, will yield a number of areas that afford the Company considerable profit potential. Just as important, it will free Unilife to pursue supply contracts with drug companies in other therapeutic areas. Indeed, one near-term goal is to sign such a deal with another pharmaceutical company in early 2010. Regardless, Unilife has chosen its partner well, for sanofi-aventis purchases, by our estimation, 40% of all ready-to-fill syringes sold globally.

SEVERAL FACTORS FAVOR READY-TO-FILL SYRINGE USE.

- **REGULATIONS.** With the passage of the Needlestick Safety & Prevention Act in 2000, the United States set a global precedent for reducing needlestick injuries among healthcare workers. Enforcement has gradually tightened, resulting in adoption of safety needles & syringes by an estimated 70% of acute-care hospitals and around 50% of all other healthcare providers today. Hence, the domestic market has not matured fully, and overseas markets are at even earlier stages of adoption. The European Union's parliament is expected to vote on a measure this October that will be used by member countries as a template for national legislation. It probably will reflect a regulation that Germany instituted in 2007, requiring an adoption of new technologies and measures that force employers in the healthcare industry to protect their workers without reducing the standard of care provided to patients. We believe the new regulatory environment will begin to take hold in Europe in 2012.
- **DEMOGRAPHICS.** An ageing baby boom population is going to significantly increase the demand for healthcare services over the next few decades. To ensure adequate care and minimize costs, efforts are under way to expand the number of therapies that can be self-administered or provided by a caregiver in the home. Devices that simplify drug administration under these conditions should gain wide acceptance. We believe prefilled safety syringes will fit the bill by providing a simple delivery device ready for use that also protects against needlestick injuries.
- **NEW PHARMACEUTICAL AGENTS.** The introduction of biological therapies for such diseases as arthritis and multiple sclerosis has increased the demand for prefilled syringes over the past decade. These drugs are expensive, which makes prefilled syringes an appealing alternative to vials that can result in up to 20% of their contents being wasted through inefficient transfer to a delivery device. As a result, demand has outstripped supply, which has left many drug companies seeking new sources, particularly for compounds in clinical trials. Over the next decade, demand for prefilled syringes is only going to accelerate, given the number of monoclonal antibodies and other injectable therapies now under development worldwide.

MANAGEMENT HAS A WELL-CONCEIVED COMMERCIALIZATION PLAN. From its early years, Unilife has been committed to a global commercialization strategy that has led to partnerships with large multinational corporations. Its relationship with sanofi-aventis, for instance, is facilitating Unilife's penetration of the established North American and European markets by providing an entry that avoids direct competition with today's major needle and syringe manufacturers. Meanwhile, its partnership with Shanghai Kindly Enterprise Development Group Company Ltd (KDL), the second-largest medical device manufacturer in China, is providing manufacturing capacity in Asia and marketing support for its technologies in 32 countries. Unilife's strategic plan is also the reason its entire base of operations was moved from Australia to the United States. That move was important for two reasons: First, it brought the Company closer to its key clientele, international pharmaceutical manufacturers. And second, it was executed through an acquisition that garnered an FDA-registered medical device manufacturing plant, thereby facilitating commercialization of its safety syringes from a regulatory perspective. We believe Unilife's strategic plan is also behind efforts that are under way to register its stock on a major U.S. exchange, since that will add credibility to the corporate story and attract a broader group of investors than it has garnered on the Australian stock market.

THE COMPANY HAS STRENGTHENED ITS MANAGERIAL TALENT SINCE MOVING TO THE UNITED STATES. Unilife has hired more than 30 senior managers in the last year, the majority of which have more than 20 years of experience within related fields working with companies such as Baxter International, Medtronic, Teva, Safety Syringes Inc, Resmed, MEDRAD, Biotronik, Tyco, Dentsply, Boston Scientific and Kimberley Clark. Thus, they bring expertise in the design, development, production, and supply of medical devices to pharmaceutical companies, and they are already playing instrumental roles in the recent progress made in preparing for the commercialization of Unilife's novel technologies.

UNILIFE SHARES CONSTITUTE AN ATTRACTIVE INVESTMENT OPPORTUNITY. We believe the Company is rapidly approaching an inflection point that will transform it into an acknowledged leader in the safety device market. For one, its future relations with the largest user of ready-to-fill syringes, sanofi-aventis, should be cemented by late December upon the expected agreement of a list of therapeutic drug classes for which sanofi-aventis will be granted exclusive rights to purchase the ready-to-fill syringe. With that in hand, the Company will move into partnering negotiations with other pharmaceutical manufacturers from a position of strength, as its technology has no equal. The industrialization program is scheduled to be completed in late-2010 (one year ahead of schedule) whereby Unilife will commence the supply and sale of the product to pharmaceutical customers. Moreover, commercial production recently commenced of a 1ml syringe, which will help to familiarize healthcare providers around the world with the simple, user-friendly design of Unilife's products. Finally, listing on a major U.S. exchange will probably generate new interest in Unilife shares. Purchases made prior to that event may also benefit fully from the exchange rate difference between the U.S. and Australian dollar. Our valuation models indicate that Unilife shares merit a price of \$3.00 apiece. **(Note that all financial data in this report are in U.S. dollars, unless specified otherwise.)** Accordingly, we are initiating coverage of Unilife Medical Solutions with a BUY recommendation and a price target of \$3.00 (or A\$3.65) per share.

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CORPORATE HISTORY

June '04	Completed successful test of an assembly line in Australia for producing a 1 ml Unitract syringe pursuant to obtaining certification of the facility and regulatory approval of this safety device.
Nov '04	Entered into a strategic partnership with Shanghai Kindly Enterprise Development Group Company Ltd (KDL), the second largest medical device manufacturer in China and distributor of medical devices in 50 countries worldwide.
2004	Received awards for the Unitract syringe design and international business strategy.
Nov '05	Changed the corporate name to Unilife Medical Solutions from Unitract Ltd to reflect a strategy to provide various technology solutions for healthcare providers.
March '06	Transferred semi-automated assembly line to KDL in China.
June '06	Submitted documentation to regulatory authorities for the Unitract 1ml syringe, which resulted in approvals in Europe, Canada, and Australia.
Dec '06	Signed a A\$500,000 exclusive agreement to design a ready-to-fill syringe incorporating Unilife's retractable needle technology for sanofi-aventis.
Jan '07	Acquired Integrated BioSciences to gain a U.S. operating base, FDA-registered medical device manufacturing facility, and expertise in automated manufacturing.
April '08	Initiated shipment of ready-to-fill syringes to sanofi-aventis from automated pilot production line in the United States.
July '08	Appointed KDL as distribution partner in China and 32 countries in the Pacific Rim, South America, Eastern Europe, the Middle East, and Africa.
Aug '08	Completed agreement giving sanofi-aventis exclusive rights to purchase ready-to-fill syringes in exchange for a €10 million upfront fee and up to €17 million in milestones.
Oct '08	Received FDA certification of the Unitract 1ml syringe via a 510k application.
Jan '09	Consolidated operations in the United States.
June '09	Entered into industrialization agreement with sanofi-aventis for ready-to-fill syringes.

NEAR-TERM MILESTONES

Q3, '09	Locate a site for a new manufacturing plant in Pennsylvania.
Q3, '09	Sign sourcing agreement for an automated manufacturing line (60 million units/year).
Q4, '09	Complete exclusivity list discussions with sanofi-aventis for certain drug classes.
Q4, '09	List Unilife Medical Solutions stock on a major U.S. stock market.
Q4, '09	Launch Unitract 1ml syringe in the United States and Europe.
Q2, '10	Sign a ready-to-fill syringe supply agreement with a second drug company.
H1, '10	Raise funds via an equity offering to help finance manufacturing equipment, inventory, and possibly a small acquisition.
Q3, '10	Order equipment for first high-volume (150 million units/year) manufacturing line.
H2, '10	Move into new manufacturing plant.
Q4, '10	Complete work under the industrialization agreement for the ready-to-fill syringe.
Q4, '11	Begin commercial shipments of ready-to-fill syringes to sanofi-aventis.

MANAGEMENT

Alan Shortall, Chief Executive Officer & Director

- Joined Unilife at its inception and has served in his current capacities since September 2002.
- Has extensive marketing and commercialization experience.
- Named one of the top 100 Notable People in the medical device industry by *Medical Device & Diagnostic Industry* magazine in 2008.

Dan Calvert, Chief Financial Officer

- Appointed to his current position in December 2008 with more than 25 years of experience in financial, strategic, and operational management in diversified U.S. and international corporations.
- Has working knowledge of SEC registration and compliance requirements.

Bernhard Opitz, Sr. Vice President of Operations

- Appointed to his current position in November 2008.
- Has 28 years of experience in various senior management positions with Bayer AG, Well's Dairy, Ikonisys, and Nanosphere.
- Is an internationally recognized engineer for his work in productivity improvements and rapid-response engineering that includes extensive use of high-speed robotic equipment.

Eugene Shortall, Sr. Vice President

- Assumed his position as a liaison with sanofi-aventis in 2008 and has played a key role in establishing the industrialization agreement.
- Has two decades of experience managing complex projects in Europe and the Middle East, including the reconstruction of more than a dozen government and major private facilities in Kuwait following the 1991 U.S.-led liberation.

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

- Assumed his current position with Unilife in 2003 after nearly 20 years in the health care industry, with such companies as Johnson & Johnson, Nycomed International, and GlaxoSmithKline.
- Served as the head of the World Health Organization's medical device division, was responsible for creation of the International Organization for Standardization (ISO) standards for auto-disable syringes, and worked with the World Bank for worldwide access to safe injection technologies.

Mark Iampietro, Vice President of Quality & Regulatory Affairs

- Appointed to his current position in October 2008, after more than 30 years with pharmaceutical, biotechnology, and medical device companies, including Spherics, Cynosure, C.R. Bard, Summit Technology, and Tambrands.
- Has launched two ISO 9000/13485 quality programs, is a senior member of The American Society for Quality with certifications as a quality and reliability engineer, and has published in *Quality Magazine*.

Stephen Allan, Vice President of Communications

- Joined Unilife in 2002 prior to its listing on the Australian Stock Exchange.
- Has over 15 years of experience in media, government, and public relations, having established his own consulting business that worked with various trade groups, governmental agencies, and private corporations.

BOARD OF DIRECTORS**Jim Bosnjak, Non-executive Chairman**

- Joined Unilife's Board of Directors in February 2003 and assumed his current position in April 2006.
- Has been involved in numerous commercial enterprises in the transportation, manufacturing, funds management, advertising, hospitality, and tourism industries.
- Serves as chairman of the media company Ultimate Outdoor Ltd, which he cofounded; was chairman of one of Australia's largest bus companies, Westbus Ltd; and served as chairman of the Tourism Council of Australia and Bus 2000, which coordinated transportation services for the Sydney 2000 Olympic Games.

Alan Shortall, Chief Executive Officer and Director**William Galle, Non-executive Director**

- Has been a member of Unilife's Board of Directors since June 2008.
- Serves as president of Diversified Portfolio Strategies LLC, a consulting firm that provides alternative investment advisory services for institutions and investors; and is a managing director of American Marketing Complex, which helps companies implement balance sheet enhancement strategies and develop strategic business plans.

Jeff Carter, Non-executive Director

- Has served as a Unilife Director since April 2006 and was appointed the corporate secretary in March 2007.
- Relinquished the position of chief financial officer with Unilife to enable the Company to hire someone (Dan Calvert) experienced in meeting U.S. SEC regulatory requirements.
- Has experience as chief financial officer with Ambri Ltd and Agenix Ltd in Australia, as well as various managerial positions with Coca-Cola Amatil, Santos Ltd, CIBC Australia and Touche Ross.

THE NEED FOR SAFETY NEEDLES & SYRINGES

Injuries among healthcare workers and the risk of acquiring blood-borne pathogens such as HIV prompted the enactment of the U.S. Needlestick Safety & Prevention Act in November 2000. At the time, an estimated 600,000 to 800,000 needlestick or other percutaneous injuries from medical “sharps” (e.g., needles, scalpels, and lancets) occurred annually to healthcare providers in all settings (e.g., hospitals, clinics, physicians’ offices, long-term care facilities, and individual homes). The introduction of various safety products and greater awareness on the part of healthcare workers had already reduced the incidence of percutaneous injuries significantly during the 1990s. Following passage of the Needlestick Safety & Prevention Act, increased surveillance by the Occupational Safety and Health Administration (OSHA) helped to lower the incidence rate somewhat further, as shown in Figure 1.

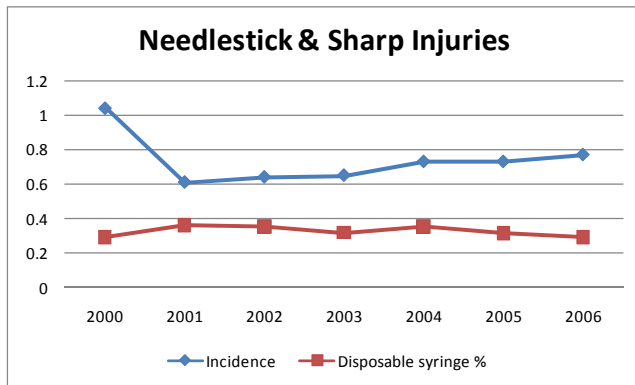


Figure 1. The number of percutaneous injuries declined as a result of various measures to protect healthcare workers. Incidence of injuries was calculated based on annual data from U.S. hospitals reporting to the Exposure Prevention Information Network (EPINet) and is displayed as the number of injuries reported per 1,000 patient-days. As such, it does not take into account such differences as reporting rates or the severity of illnesses treated between years, which probably trended upward. The percentage of injuries attributed to disposable syringes is plotted as calculated by EPINet.
 Source: Exposure Prevention Information Network¹

We think the data depicted in Figure 1, which was collected by the Exposure Prevention Information Network, merits consideration.¹ Passage of the Needlestick Safety & Prevention Act in late 2000 generated considerable awareness of the threat still posed by medical sharps. This probably alerted healthcare workers to be more careful. Since then, the annual incidence rate has increased modestly, but this does not take into consideration possible increases in reporting rates or the level of care administered, which may have risen between 2001 and 2006, the most recent year for which injury data is available. More interesting is the relatively stable proportion of injuries attributed to disposable syringes, because it suggests that even though utilization of safety syringes increased as OSHA took action to enforce adoption of medical safety devices, no obvious benefit was observed.² (See Figure 2.)

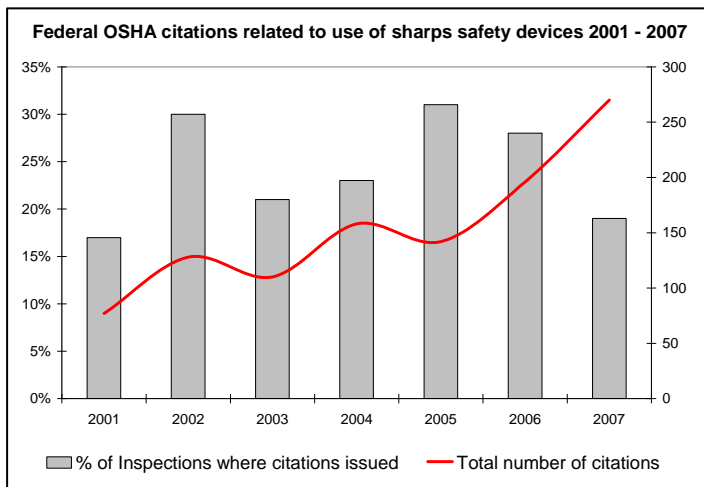


Figure 2. Federal OSHA citations for failing to use sharps safety devices rose substantially between 2001 and 2007, as the agency took steps to enforce compliance with the provisions of the Needlestick Safety & Prevention Act.
 Source: Perry, J and Jagger, J.²

¹ Official summary report for needlestick & sharp object injuries, published by the Exposure Prevention Information Network (EPINet), 2000 – 2006 annual data obtained from www.healthsystem.virginia.edu/internet/epinet/epinetdatareports.cfm.

² Perry, J and Jagger, J. OSHA enforcement activity on BPS: an update. MLO Med Lab Obs 2008; 40(3): 46.

The apparent lack of benefit may have to do with the needle/syringe designs on the market, as many have been less than ideal, requiring manual activation, two-handed use, or an unusual manipulation to activate the safety mechanism. Indeed, a 2006 survey of “sharps” injuries to healthcare workers in Massachusetts found that hypodermic needles accounted for 31% of the total reported and that within this group (where it was known whether or not the product featured a safety device), hypodermic needles with safety features were responsible for 63% of the injuries, while needles lacking a safety design accounted for only 33%.³

Other countries have begun to take action. In 2005, the European Parliament adopted a resolution promoting health and safety in the workplace, partly through implementation of preventive measures to protect healthcare workers from injuries caused by needles and other sharps. This was followed by a similar, but more specific resolution the following year, and subsequent efforts are ongoing. The likely result will be passage of legislation later this year outlining employers’ obligation to use safety needles and syringes, modify work practices where necessary to make them safer, put an end to the recapping of needles, train workers in the use and safe disposal of needles and other medical sharps, and record all injuries from needles and sharps in a special register. This act will serve as a guide for the drafting of national laws by EU members. Germany has already acted via a regulation issued in August 2007, mandating protection from needlestick injuries in hospitals and physicians’ offices. Among the performance requirements of safety needle/syringe devices are: one-handed activation, support of normal healthcare techniques by caregivers, and prevention of re-use. We believe implementation of medical safety laws will take one to two years to enact at the national level, which means that use of safety syringes will likely be mandatory across much of Europe by late 2012.

Elsewhere, governments are taking notice of the threat posed by needles/syringes that lack safety features, particularly because of the socioeconomic burden that infections from needlestick injuries and needle sharing among street-drug users impose. The risk of acquiring an infection is lower in developed countries, where immunizations are common, some diseases are less prevalent than in the developing world, and quick intervention can prevent seroconversion (e.g., administration of hepatitis B vaccine or post-exposure prophylaxis with zidovudine for HIV exposures).⁴ Nonetheless, the threat is real, as evidence indicates that up to 35%-40% of people exposed to the hepatitis B or C virus develop the disease.⁵ Overall, up to 500 million people are infected with hepatitis B or C globally, and 1.5 million lose their lives to these infections per annum.⁶ The rate of seroconversion from HIV exposures is much lower via needlestick injuries (up to 4.4%). But the burden inflicted upon mankind is still considerable, as an estimated 2.7 million people were newly infected with HIV in 2007 (the latest year for which data is available), bringing the total number infected to 33 million worldwide.⁷ It is statistics such as these that have convinced the World Health Organization to promote needle exchange programs and the use of safety needles/syringes to prevent reuse and accidental injuries.

Needlestick injuries also impart an economic toll. A recent assessment involving four U.S. healthcare facilities (a 600-bed public hospital, 244-bed Veterans Affairs medical center, 437-bed rural tertiary care hospital, and 3,500-bed healthcare system) found that direct costs ranged from \$71 – \$4,838 (in 2003 US dollars) for hepatitis B, hepatitis C, and HIV. The lowest amount was for an exposure to blood from a

³ Davis, LK, and DeMaria, A. Sharps injuries among hospital workers in Massachusetts, 2005; published by Massachusetts Department of Public Health Occupational Health Surveillance Program (2008).

⁴ Jagger, J. Caring for healthcare workers: A global perspective. *Infect Cont Hosp Epidemiol* 2007; 28(1): 1.

⁵ Pruss-Ustun, A, et al. Estimation of the global burden of disease attributable to contaminated sharps injuries among health-care workers. *Am J Ind Med* 2005; 48(6): 482.

⁶ World Health Statistics 2009, published by the World Health Organization.

⁷ Mathers, BM, et al. Global epidemiology of injecting drug use and HIV among people who inject drugs: a systematic review. *Lancet* 2008; 372(9651): 1733.

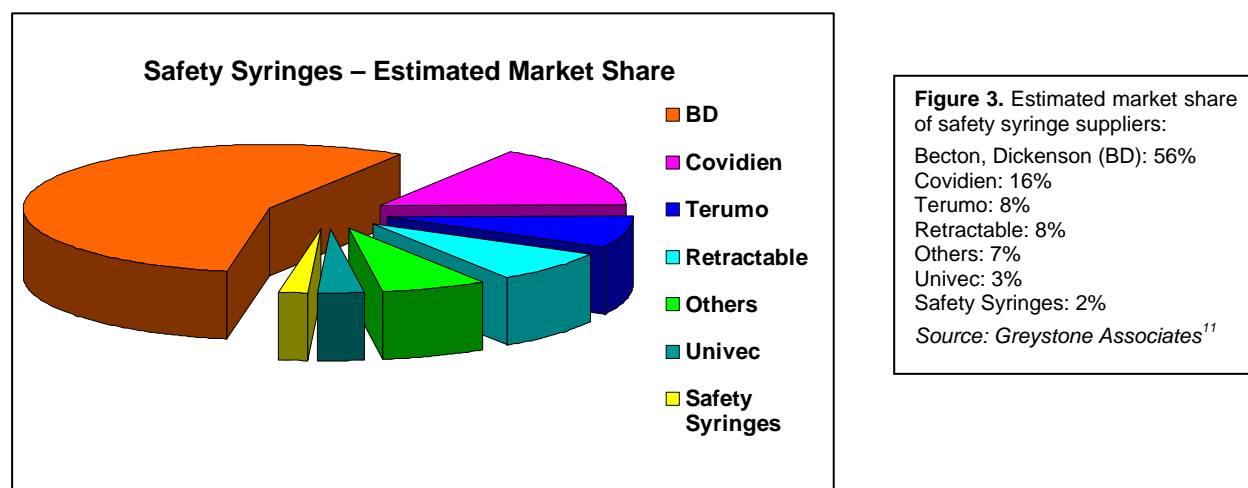
patient with no infection, while the highest amount was to treat a healthcare worker exposed to blood from a patient co-infected with HIV and hepatitis B and/or C.⁸

THE MARKET FOR SAFETY NEEDLES & SYRINGES

An estimated 35 billion injections were used to administer drugs and vaccines worldwide in 2003, with the United States accounting for 47% of the market and Europe, 24%.⁹ The most common delivery device is the 1ml disposable syringe used for subcutaneous administration of insulin and other drugs, intramuscular injections, and vaccinations.¹⁰ However, another design, the ready-to-fill syringe with a glass barrel has been rapidly gaining in popularity, with sales reaching 2.2 billion units in 2008.

MARKET SHARE OF SUPPLIERS

The traditional market for plastic needles & syringes is dominated by three players, Becton, Dickinson (71%); Covidien (22%), and Terumo (7%). Yet, the safety needle/syringe market is considerably more fragmented, as companies have used technological innovations to garner share, as shown in Figure 3:¹¹



Future changes in market share will be determined at least partly by the preferences of healthcare workers. Indeed, the U.S. Needlestick Safety & Prevention Act placed the responsibility for choosing preferred needle/syringe models in the hands of committees that include caregivers. We believe healthcare workers elsewhere will be given a similar role. Regardless, several features will likely play a part in determining the favored models: (i) Passive safety mechanisms that are initiated automatically upon completion of the injection, versus active mechanisms that require a separate action by the caregiver to protect against an unwanted needlestick. (ii) The type of protection used: sheaths that afford protection through a tube that extends from the barrel of the syringe to cover the needle, versus retraction systems that draw the needle into the barrel of the syringe. (iii) Ease of use, as determined by such factors as the need for any pre-assembly or post-injection manipulation, the overall feel of the device, and reliability. (iv) Familiarity to the healthcare worker, since that could minimize training and expedite both patient care and worker safety during medical emergencies. (v) Price, given continuing efforts to restrain the growth of medical costs. Hence, it isn't surprising that many suppliers of safety needles/syringes to the healthcare industry offer more than one model with different features and at different price points.

⁸ O'Malley, EM, et al. Costs of management of occupational exposures to blood and body fluids. *Infect Cont Hosp Epidemiol* 2007; 28(7): 774.

⁹ International Association of Safe Injection Technology presentation at the Uganda Safe Injection Meeting, April 24, 2004.

¹⁰ Greystone Associates. Prefilled syringes: drugs, devices, and disease therapeutics, February 2008.

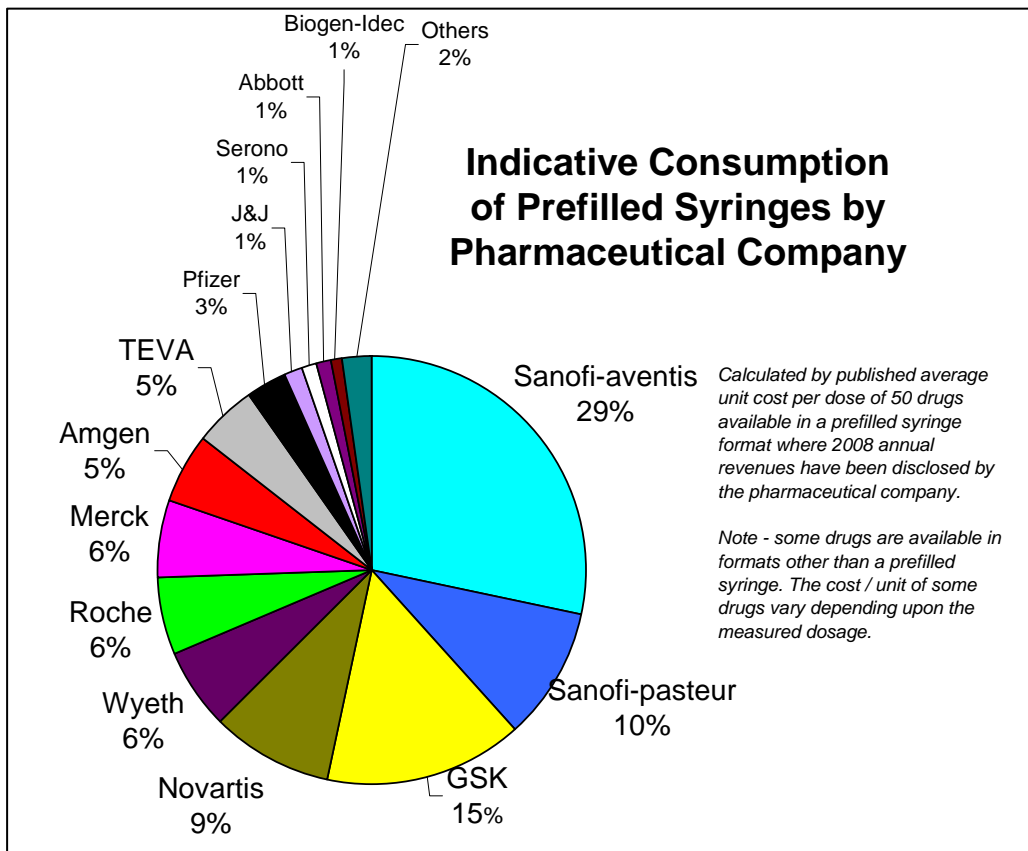
¹¹ Greystone Associates. Safety syringes: players, products, and prospects, May 2004.

THE READY-TO-FILL SYRINGE MARKET

Within the safety syringe market, the ready-to-fill sector is an important and rapidly growing area in which the syringe manufacturer’s customer is not the healthcare provider, but pharmaceutical companies. The use of prefilled syringes dates to World War II, though it was sanofi-aventis that more recently saw prefilled syringes as a means to gain a competitive edge in the delivery of anti-coagulants and vaccines. (Prefilled syringes are supplied to pharmaceutical companies ‘ready-to-fill’ with a measured dose of drug. Hence, prior to them containing a dose, they are referred to as a Ready-to-Fill Syringe.)

In recent years, other drug companies have chosen to offer their products in prefilled syringes, ready for use with drugs for multiple sclerosis, fertility, osteoporosis, hepatitis, rheumatoid arthritis, oncology, anemia, hemophilia, hemolytic disease, and antithrombotic therapy. Today, many pharmaceutical companies employ prefilled syringes, as depicted in Figure 4. (The chart was prepared from publicly available prefilled-syringe drug sales and average doses.)

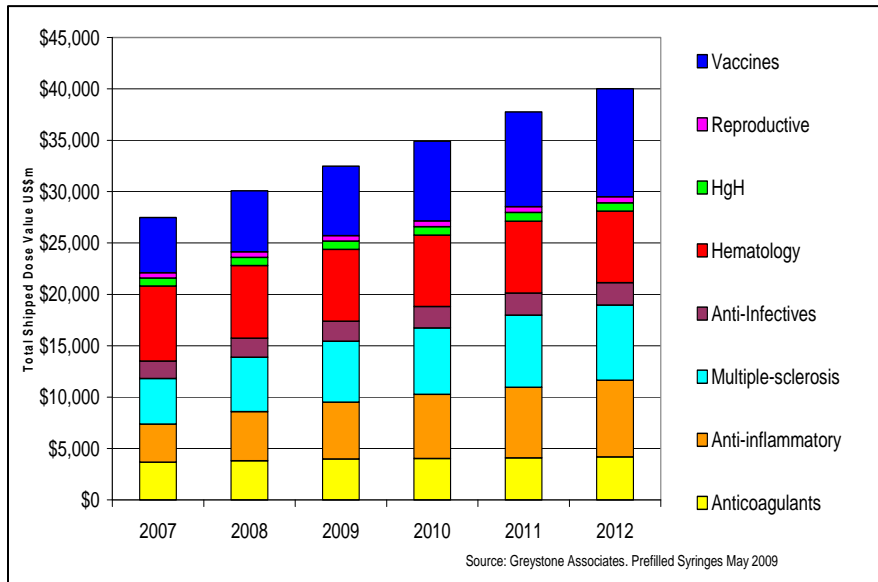
Figure 4. Purchasers of Ready-to-Fill Syringes



Source: Griffin Securities and Unilife Medical Solutions

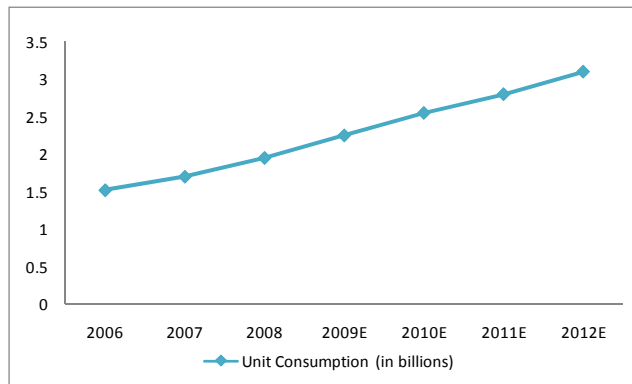
Sanofi-aventis is still the leading user (purchaser) of ready-to-fill syringes worldwide, accounting for nearly 40% of the market, by our estimates. The relative importance of each company will likely change over the coming decade as more biotechnology drugs (i.e., peptides, monoclonal antibodies, and other proteins) and vaccines emerge from corporate R&D pipelines. Figure 5 (see next page) presents the projected changes graphically, but note that the graph is based on drug sales supplied in a prefilled syringe format and not ready-to-fill syringes themselves. The difference is that some products, such as vaccines and anti-coagulants, are sold at a fraction of the price of therapeutic agents, including drugs for multiple sclerosis, hematological conditions, and inflammatory diseases. Nonetheless, the graph provides a reasonable basis for tracking relative changes in demand by therapeutic category.

Figure 5. Drug Sales in Prefilled Syringes by Therapeutic Class, 2007-2012



There are several reasons why prefilled syringes are favored for use with these products. For one, they must be delivered parenterally, and many are administered at a standardized dose that is not dependent upon the patient’s weight. Then, too, many of the current therapies and drug candidates are intended for use by patients with chronic conditions that may be treated via self-administration, and patients have demonstrated a preference for prefilled syringes and similar delivery devices. We note, for instance, that following the introduction of Copaxone, Avonex, and Betaseron in prefilled syringes, 85% or more of the users switched from vials within six months.¹² Prefilled syringes also enable pharmaceutical companies to save money by reducing drug waste associated with vials and to differentiate their products from the competition with user-friendly packaging. When prefilled syringes come with safety features, the pharmaceutical industry is also able to help their customers meet the safety requirements now being enforced or enacted worldwide. Prefilled syringes even give pharmaceutical companies another approach to manage a product’s life-cycle to gain and/or retain market share. These factors, plus the growing needs of an ageing world population, are projected to expand the ready-to-fill syringe market from 1.7 billion units in 2007 to more than 3 billion units by 2012, as shown in Figure 6.¹³

Figure 6. Consumption of READY-TO-FILL Syringes



¹² French, D. Advances in parenteral drug delivery devices. Presented at the Pharmaceutical Technologies Arden House Conference, January 21-26, 2007.

¹³ Greystone Associates. Prefilled syringes, May 2009.

UNILIFE'S SAFETY TECHNOLOGY

Unilife has a unique portfolio of safety syringe technologies which can be applied to all types of plastic and prefilled syringes used in the market today. The key inventions are the ability for operators to control the speed of passive (automatic) needle withdrawal directly from the body into the barrel, and the automatic locking and tilting of the needle to prevent it from being reused or re-exposed. These fully integrated safety features enable the Company's syringes to meet all of the requirements and safety device preferences set forth by the U.S. Needlestick Safety & Prevention Act, OSHA and the FDA, as well as those set forth in discussions of future laws by the European Union that are likely to be based on current German regulations.

For users of Unilife's line of clinical and ready-to-fill safety needle/syringe models, the basic features are unequalled. The device is operated with a single hand, exactly like any traditional needle and syringe. Hence, no special training is required for its use. The safety mechanism automatically engages upon discharge of the syringe contents, but it does so in a manner that gives the user full control over the rate of retraction. This is important for two reasons: First, the user does not have to exert any unusual pressure to activate the safety mechanism, either while the needle is still imbedded in the skin or after it has been withdrawn. (Both situations are required with different competitors' devices.) And second, by enabling the user to control the rate of retraction, the device does not cause blood splatter that accompanies the rapid retraction of uncontrolled needle retractors. (Aerosolized blood and/or minute tissue particles are a means by which infections may be spread from patient to healthcare worker.) In addition, Unilife has built two technologies into its devices that prevent reuse. Upon retracting into the syringe, the needle is tilted so that it is no longer aligned with the hole through which it was withdrawn. And the plunger is designed to lock once the retraction is complete, so that it is not possible to expel the needle with force or to tamper with the device by pulling out the plunger. Thus, a used device cannot harm anyone, regardless of how it is discarded, and it cannot be reused, possibly contaminating a drug vial or passing an infectious agent from one person to another.

THE READY-TO-FILL SAFETY SYRINGE

The single most important product in Unilife's pipeline is its ready-to-fill syringe. That's because this device should generate higher sales volumes and wider gross margins than related models to be sold into the more price-sensitive healthcare provider market. And the Company's technology should help it to win supply contracts with established pharmaceutical companies, particularly for drugs in their R&D pipelines. That should enable Unilife to fill its clients' orders on time, as it builds out its own production capacity.

SEVERAL FACTORS TO UNDERPIN ACCEPTANCE OF THE UNILIFE READY-TO-FILL SYRINGE

Incentives for the pharmaceutical industry: For drug companies, the Unilife ready-to-fill syringe will offer cost savings of up to 70% on packaging and logistics compared with competitors' products, since it is the same size and shape as traditional needle/syringe devices. Indeed, these traits should also permit savings on manufacturing equipment, since Unilife's syringes are shipped in standard trays that allow their manipulation, filling, assembly, and packaging on existing production lines without modification. The Unilife syringe will also enable drug companies to avoid the waste associated with overfill required for vials. (Overfill of less than 5% is typical on ready-to-fill syringes, versus up to 20% for vials.) Thus, pharmaceutical companies will have ample incentives to use the Unilife's syringe, even before they consider the benefits to healthcare workers (e.g., convenience, accuracy of the dosages, and safety).

Competitive advantages: Unilife's ready-to-fill syringe is shown beside three competitors' devices in Figure 7 on the next page. It is obvious that the Company's syringe is the slimmest model. (Note that it is virtually the same size as the traditional ready-to-fill syringe.) In contrast, the three competitors are much bulkier, as the safety devices must be attached onto a standard prefilled syringe. They are thus incompatible with standard drug filling lines and increase pharmaceutical costs for packaging, storing, and shipping. Moreover, their extra bulk gives them a different feel than traditional ready-to-fill syringes, and healthcare workers may require some training to become acquainted with the distinct technologies of

these safety devices – the three competitors use a sheath that is deployed around the needle after use, in contrast to the needle retraction performed by the Unilife syringe. And as evident from the photo, the compact size of the Company’s product means that it occupies less disposal space, which is another source of savings for high-volume users.

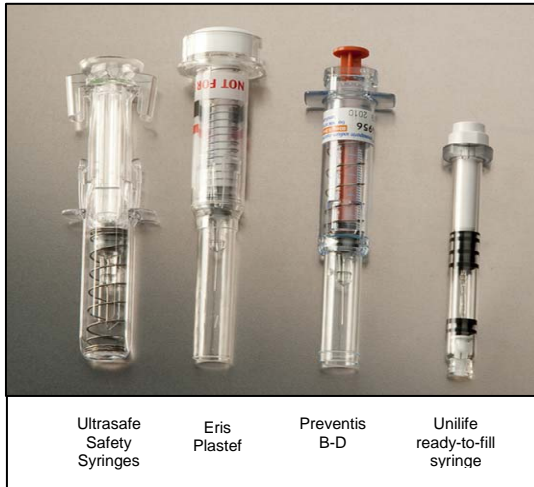


Figure 7. A comparison of different ready-to-fill syringes yields obvious differences. The devices pictured are, from left to right: Ultrasafe syringe from Safety Syringes, Inc.; Eris from Plastef (recently acquired by West Pharmaceuticals); Preventis from Becton, Dickinson; and Unilife’s ready-to-fill syringe. All are displayed with their safety mechanisms deployed: The Ultrasafe, Eris, and Preventis have safety sheaths covering the used needles, while the Unilife has its needle retracted.
Source: Unilife Medical Solutions

A comparison of the features of ready-to-fill safety syringe technologies, including the four depicted in Figure 7, are presented in the schematic below. (See Figure 8.) Three basic technologies are presented: a needleguard, sold on interchangeable needles by Becton, Dickinson that is manually operated; an active safety technology that requires the user to remember to deliberately trigger the safety mechanism (a guard or sheath); and a passive technology that requires no specific action by the user to initiate the safety mechanism (guard, sheath, or needle retraction). Note that the passive safety guard and shields are deployed without user control and after the needle is withdrawn from the skin.

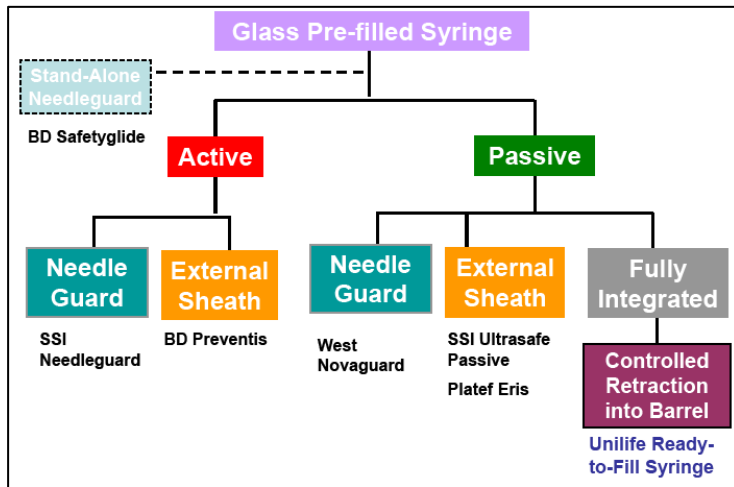


Figure 8. Various modifications to the traditional glass ready-to-fill syringe have been made to provide protection against needlestick injuries, tampering, and reuse. Only the Unilife syringe offers all three features, while giving the user complete control over needle retraction.
Source: Unilife Medical Solutions

Pricing flexibility: We calculate that pharmaceutical companies currently spend between \$0.50 and \$1.20 per unit on a prefilled syringe with an attached safety device depending upon the type of device and the annual volume purchased. The design features offer Unilife another advantage in penetrating the ready-to-fill syringe market, and that is in pricing flexibility, thanks to a fully-automated production system. Indeed, the Company’s production engineers expect its manufacturing costs to be competitive on a global basis, which means that the syringe will be able to compete based on its features and its price. The ready-to-fill syringe is shipped in three parts, the glass barrel with needle assembly in place, the safety plunger mechanism, and the rubber stopper, which is consistent with industry manufacturing

requirements. The components consist of the same materials found in traditional ready-to-fill syringes, which should enable Unilife’s customers to receive regulatory approval for the drug/syringe combination readily. (Note that the Company’s pharmaceutical customers will be responsible for the simple tests required for obtaining approval of the drug-syringe combination from regulatory agencies.) We estimate that Unilife’s ready-to-fill syringe will garner an average price of approximately \$0.80, which is at a premium to safety products in use today, but near the bottom of the price range of needle-free injectors.¹⁰

Scalable production capacity: Unilife has automated its production process on a pilot assembly line, and preparations are under way for the purchase of equipment capable of producing 60 million units per year in 2010. That system will be used to manufacture the first commercial volumes of ready-to-fill syringes, which are expected to be launched in 2011. The next production upgrade that is planned will involve a 100-150 million unit capacity line, which is scheduled to commence operation in 2012. Thereafter, that assembly line will be duplicated as needed to meet demand. This should maximize returns on capital investments and minimize expenses for training personnel on the equipment. The Company should also be able to build capacity as demand for specific drugs increases and to add production in a simple modular fashion, even adjacent to its clients’ manufacturing facilities. Corporate plans call for the start-up of three production lines by 2014 (one annually between 2012 and 2014), followed by another in 2015 and two in 2016. This capacity should enable Unilife to increase its penetration of the ready-to-fill market gradually, reaching 20% in 2016, as depicted in Figure 9. (Note, however, that our valuation models include only one of the two production lines scheduled for 2016.)

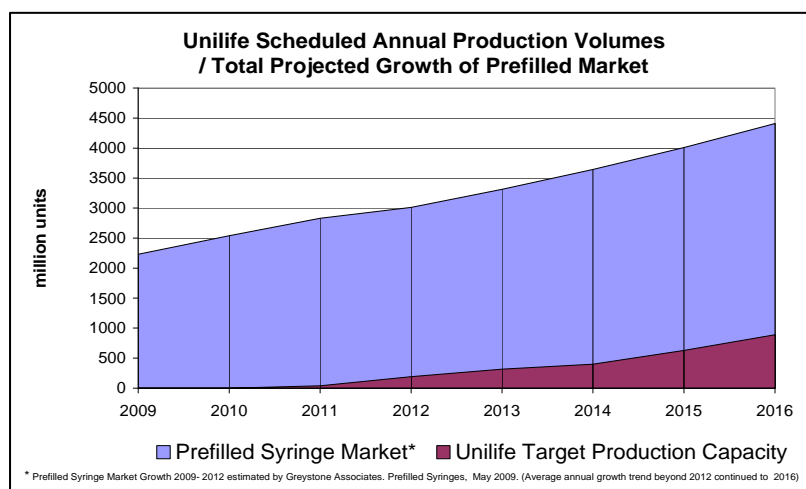


Figure 9. Unilife’s planned expansion of ready-to-fill syringe production will support an approximate 20% share of the market in 2016. At that time, its production capacity will approach 900 million units per year, or roughly double its 2014 capacity.
 Source: Unilife Medical Solutions

SANOFI-AVENTIS – A SOLID PARTNER

Unilife and sanofi-aventis have a business relationship that dates back to 2003. It started as an informal collaboration that brought together the first company to utilize the prefilled syringe as a competitive advantage and an innovative designer of ready-to-fill syringe technology. A design and pilot supply contract for a ready-to-fill syringe gradually evolved into a tighter, more financially rewarding partnership under which sanofi-aventis basically agreed to defray the cost of establishing an automated production line at the Company’s corporate headquarters in Pennsylvania. Quarterly payments based on achievement of various milestones are ongoing under this agreement, and the production line is now so far ahead of schedule that completion was recently moved up by one year, to the end of 2010. That event will conclude the industrialization program, at which point sanofi-aventis will have invested \$38 million in Unilife via upfront fees and milestone payments. This significant investment by sanof-aventis gives them the right to negotiate the purchase of the product for use in particular therapeutic sectors.

On July 1st, a new agreement was signed giving sanofi-aventis four months to submit a list of therapeutic areas in which it would like to have exclusive rights to Unilife’s ready-to-fill syringe. The two companies will then have two months to agree to a final exclusivity list that will form the basis of future supply

negotiations through at least 2014. If an acceptable exclusivity list is not completed within the 60 day period, sanofi-aventis will have exclusive rights to the syringe in all therapeutic categories, but only until July 2012. We believe such an outcome is extremely unlikely, given the mutually beneficial collaboration that the two companies have had. Instead, we think the two partners will identify an appropriate list of therapeutic areas within the specified period and that they may even sign the first supply contract for the ready-to-fill syringe with a drug that sanofi-aventis either has on the market or in late-stage development.

Coming to terms on the exclusivity list will also open new opportunities for Unilife. Specifically, the Company will be able to negotiate with other pharmaceutical corporations for therapeutic areas that are not of interest to sanofi-aventis. This will diversify Unilife's client base, and it will reward sanofi with a 5% royalty on Unilife's sales to these clients. (The royalty payments will end when sanofi-aventis has recouped its €17 million financial support for the development of the first ready-to-fill syringe production line; that is, when Unilife's cumulative sales to other drug companies reach €340 million.) Unilife has presented its technology at trade shows to generate interest, and based upon public information about sanofi-aventis's areas of therapeutic expertise, it has identified and is in discussions with a number of other potential customers that would complement a deal with its long-standing partner. Indeed, one near-term goal is to complete a deal with another pharmaceutical company in the first quarter of 2010.

Financial implications: The partnership with sanofi-aventis has the potential to generate enormous financial rewards for Unilife, though much will depend on the timing of the supply agreements and the drugs involved. For now, we estimate that Unilife will receive \$18 million in calendar 2010 from sanofi-aventis, largely in the form of milestones under their existing agreements, and \$34 million in 2011, primarily from the first shipments of ready-to-fill syringes. (Note that the Company is switching from a fiscal year, ending on June 30th, to a calendar year for financial reporting purposes, and that all of our estimates reflect a calendar-year accounting period.) For 2012 through 2016, we have used corporate plans for manufacturing capacity additions to guide our revenue projections, while taking into consideration potential variations in capacity utilization.

PRODUCTION OF THE UNITRACT 1ML SYRINGE COMMENCES

Unilife has another syringe that has been approved by regulatory agencies around the world – it is the Unitract 1ml syringe. This product uses the same basic safety technology as the ready-to-fill syringe, and like its counterpart, it is intended for subcutaneous drug administration. However, it is not designed to be prefilled, but sold to end-users (i.e., healthcare providers and patients). Unilife initially set up a semi-automated production facility for this product, but subsequently transferred the equipment to its partner in China, Shanghai Kindly Enterprise Development Group Company Ltd (KDL), when the corporate strategy shifted to devote greater internal resources to development of the ready-to-fill syringe. The Company just began production of this syringe at its Pennsylvania manufacturing plant for sale in its primary geographic markets, North America, Europe, and Australia. The goal of the initial sales will be to increase awareness of the Company and its products' features.

KDL is the second largest medical device manufacturer in China and has an extensive international distribution network that reaches 50 countries. Unilife first entered into a strategic partnership with KDL in November 2004, granting its partner rights to manufacture, distribute, and sell the 1ml syringe locally. Commercial production of the 1ml syringe began in April 2008 in preparation for Unilife granting its partner international distribution rights in 32 countries a few months later.

Financial implications: We estimate that the Unitract 1 ml syringe will generate revenue of \$9 million in 2010 and \$11 million in 2011, with KDL accounting for a large proportion of these sums. That is consistent with Unilife's intent to invest its resources in commercialization of the ready-to-fill syringe.

CONTRACT MANUFACTURING

Unilife transferred its base of operations to the United States through its 2007 acquisition of Integrated BioSciences, which was a privately owned contract manufacturer of medical devices. The deal was important because it gave the Company a manufacturing facility (FDA registered and ISO 9001 and 13485 certified) and experienced personnel in automated medical device production. Since then, the Company has built a strong management team with significant experience in all sectors associated with the design, development, production, and supply of medical devices to pharmaceutical companies. The Company has hired more than 30 senior managers in the last year, the majority of which have more than 20 years experience within related fields working with companies such as Baxter International, Medtronic, Teva, Safety Syringes Inc, Resmed, MEDRAD, Biotronik, Tyco, Dentsply, Boston Scientific and Kimberley Clark.

Medical device manufacturing contracts Unilife has inherited and built upon from its acquisition of Integrated BioSciences' include the production of a reservoir for an implantable drug delivery pump and a variety of syringe products for B.Braun USA, the U.S. subsidiary of a multinational medical device manufacturer. We think these continuing relationships are noteworthy, since one involves a drug delivery technology that could complement Unilife's safety needle/syringe products and the other validates the Company's expertise in syringe manufacturing.

Financial implications: Contract manufacturing is not expected to become an important part of Unilife's business portfolio. Yet, it may have strategic importance in establishing relationships with others in the medical device industry and in providing the Company with experience in new technologies that could be applied to its own areas of interest. For 2010 and 2011, we estimate contract manufacturing will generate \$3 million and \$5 million in revenue, respectively.

UNILIFE'S R&D PORTFOLIO

The ready-to-fill and 1 ml syringes were designed with a fixed needle that is appropriate for subcutaneous drug administration. The former is like most other ready-to-fill syringes, in that its barrel is made of glass, while the latter is constructed of plastic. Hence, the Company is experienced with both types of materials. In fact, Unilife has demonstrated that its safety technologies may be adapted to a variety of syringes having interchangeable needles and with longer fixed needles for intramuscular injections. Thus, the Company has already conducted the basic research required for expanding its product line through these types of additions. Prototypes have also been created for a line of safety syringes with different volumes that Unilife calls its Clinical Range syringes, as well as a model suitable for harm reduction programs (i.e., needle/syringe exchange programs for injecting drug users).

INTELLECTUAL PROPERTY

Unilife has filed for and/or received patents covering its basic technologies, as summarized in the Table 1 below:

Table 1. A Representative Sampling of Patents Filed and/or Granted on Unilife's Technology

Patent	Status	Claim(s)
US 6,083,199	Granted 2000	Single use retractable syringe, in which the needle is retracted into the barrel after use and tilted to prevent reuse
US 7,500,967	Granted 2009	Single use retractable syringe that has gates in the plunger and barrel that restrict plunger movement to prevent reuse
US2008/0255513	Published	Automatic system for retracting the needle into the barrel of the syringe after the contents of the syringe have been discharged
US2008/0208143	Published	Disabling mechanism that prevents the withdrawal of the plunger after depression of the plunger to prevent reuse
US2008/0097337	Published	Sheath that covers the needle after delivery of the syringe contents
US2009/0093759	Published	Syringe and plunger mechanism that permits the user to control the rate of retraction of the needle into the syringe
WO 2009/003234 A1	Published	Ready-to-fill syringe with automatically activated, user controlled needle retraction system

The patents listed in Table 1 are representative of the intellectual property that the Company has built around its technology. We have selected mostly patents filed in the United States as examples, because they are more readily accessible than those filed in Australia and appear to cover the same technologies. However, the Company has filed for protection for this intellectual property under the Patent Cooperation Treaty and as such, it is building a broad international patent estate around its technologies. The one international patent that we've cited is for the ready-to-fill syringe with a retractable needle and plunger assembly, which is not yet published in the United States. Note that most of the patents protect products that Unilife intends to commercialize, while a small number were probably filed to block would-be competitors from using a similar, but slightly different technology as a basis for their products. This intellectual property estate is complemented by Freedom to Operate reports from U.S. and Australian patent attorneys indicating that the Unilife syringes do not infringe on other companies' patents. Overall, we believe the Company has developed a unique platform to create a variety of injection devices and that it is protected as such by multiple patents worldwide.

INVESTMENT CONCERNS AND RISKS

For a complete description of risks and uncertainties related to Unilife Medical Solutions business, see Unilife's Annual Reports, which can be accessed directly from the Company's website, www.unilife.com. Potential risks include:

- **Stock risk and market risk:** There is a limited trading market for the Company's common stock. There can be no assurance that the Company's shares will be registered in the United States and that an active and liquid trading market will develop or, if developed, that it will be sustained, which could limit one's ability to buy or sell the Company's common stock at a desired price. Investors should also consider technical risks common to many small-cap or micro-cap stock investments, such as small float, risk of dilution, dependence upon key personnel, and the strength of competitors that may be larger and better capitalized.
- **Competitive risk:** The medical device market continues to evolve, and research and development are expected to continue. Other companies are already established players in the needle & syringe market and are actively engaged in the development of new safety devices that may directly or indirectly compete with those being pursued by Unilife. These companies may have substantially greater research and development capabilities, as well as significantly greater marketing, financial, and human resources than Unilife.
- **Products still in development phases:** The Company's ready-to-fill syringes and many other models are still at a precommercialization stage. Such products may appear to be promising, but may not reach commercialization for various reasons, including failure to achieve regulatory approvals with customers' drugs, reliability concerns, and/or the inability to be manufactured at a reasonable cost. And even if its products are commercialized, there can be no assurance that they will be accepted, which may prevent the Company from becoming profitable.
- **Funding requirements:** It is difficult to predict Unilife's future capital requirements. The Company may need additional financing to continue funding the development of its products and their production. There is no guarantee that it can secure the desired future capital or, if sufficient capital is secured, that current shareholders will not suffer significant dilution.
- **Regulatory risk:** There is no guarantee that Unilife's products will be approved by the U.S. Food and Drug Administration (FDA) or international regulatory bodies for marketing in the U.S. or abroad.
- **Patent risk:** The medical device industry is one in which patents have not always provided sufficient protection against competition. Moreover, the sector has had sizable patent disputes that have resulted in large settlement awards. There can be no assurance that Unilife's patents will provide sufficient protection against competitors and that patent litigation will not become a financial burden.

FINANCIAL FORECASTS & VALUATION

We have applied two valuation methods in assessing Unilife's business prospects. Both are based on the assumptions regarding the Company's planned build-out of its manufacturing capacity through 2014. One model is our traditional discounted cash flow (DCF) valuation in which we ascribe probabilities to certain key events occurring as we have assumed. (The probabilities, which are modeled from academic research of success rates in the drug industry, are then used to weight the profit contribution from each production line.) The second valuation method follows another common approach, in which a suitable P/E ratio is applied to corporate earnings in 2014 to determine a future price of Unilife shares and then discounts that price back to mid-2009. **NOTE: All estimates are in U.S. dollars.**

SALES PROJECTIONS

Our sales projections are built off of Unilife plans for seven manufacturing lines to support commercial shipments of its 1 ml and ready-to-fill syringes. Our estimates reflect the manufacturing capacities of the following planned additions and their approximate start-up times as shown in Table 2:

Table 2. Projected Production Line Additions **

Start-up Date	Working Capacity (in millions of units/yr)	Probability Weighting for our DCF model
2009**	40	95%
Late 2010	60	65%
Late 2011	150	35%
Late 2012	150	25%
Early 2014	150	10%
Mid 2015	150	10%
Late 2016	150	10%

** The 2009 start-up refers to the Unitract 1 ml production line. All other start-up dates are for ready-to-fill syringe production lines.

Each line's working capacity (as shown in Table 2) takes into account an inability to operate the equipment at full speed continuously and time required for maintenance. We have assumed that each line will be run in 24/7 mode to optimize utilization. Finally, we've assumed that the prices of the Unitract 1 ml syringe and ready-to-fill syringe are \$0.40 and \$0.80 upon launch, respectively. The ready-to-fill syringe price is an average approximation, though, since we expect sanofi-aventis will receive preferential pricing for high-volume purchases, while other clients will likely pay a higher price (20% to 50% higher) for smaller orders. A modest, 2% annual price increase for each of the syringes is applied to offset higher supply costs incurred by Unilife.

For 2010 and 2011, we've assumed revenues (in millions) are generated from the following sources:

	2010	2011
sanofi agreements	\$8	\$3
Ready-to-fill syringe sales		\$34
Unitract 1 ml sales	\$9	\$11
Contract mfg.	\$3	\$5

Note: Unilife is switching from a fiscal year ending on June 30th to a calendar-year reporting basis as of January 1, 2010. During the interim six months, we estimate that the Company will book revenue of roughly \$7.5 million and a loss of about \$3.5 million.

INCOME STATEMENT (All data are in thousands of U.S. dollars, except per-share figures.)

(Fiscal 2009 ended on June 30, 2009. Thereafter all accounting periods will close on a calendar-year basis.)

	2009	2010	2011	2012	2013	2014
Total revenue	\$ 32,000	\$ 20,000	\$ 52,945	\$ 165,390	\$ 256,553	\$ 388,187
COGS	-	9,000	31,750	90,188	138,699	208,457
Gross profit	\$ 32,000	\$ 11,000	\$ 21,195	\$ 75,202	\$ 117,854	\$ 179,730
Operating expenses						
R&D	\$ 2,000	\$ 2,000	\$ 2,000	\$ 2,500	\$ 2,500	\$ 2,500
Selling & marketing	2,000	2,000	3,000	6,000	7,000	7,000
General & administrative	22,500	14,000	17,000	17,000	17,500	17,500
Total expense	22,500	18,000	21,000	22,000	26,000	27,000
Operating profit	\$ 9,500	\$ (7,000)	\$ 195	\$ 53,202	\$ 91,854	\$ 152,730
Non-operating income/expense						
Interest expense	-400	-170	-250	-2400	-2300	-1875
Interest income	400	400	400	700	1250	1250
Other						
Total non-operating	-	230	150	(1,700)	(1,050)	(625)
Pretax profit	\$ 9,500	\$ (6,770)	\$ 345	\$ 51,502	\$ 90,804	\$ 152,105
Income tax				6,695	34,505	57,800
Net income	\$ 9,500	\$ (6,770)	\$ 345	\$ 44,807	\$ 56,298	\$ 94,305
Earnings (loss) per share	\$ 0.04	\$ (0.03)	\$ 0.00	\$ 0.18	\$ 0.23	\$ 0.38
Diluted shares outstanding	217000	230000	245000	247000	247500	248000

Expense Assumptions**□ Cost of Goods Sold:**

We have used the following ranges for production costs related to the two syringes:

- Unitract 1ml: 62% initially and declining gradually to 57%.
- READY-TO-FILL syringe: 58% initially and gradually declining to 50% over 14 years.

The reason for the improvement in gross profit margins stems from an assumption that the Company will receive better supply prices as its own production volumes increase. Another factor weighing in its favor is the use of glass tubing as a starting material for its ready-to-fill syringes, rather than sourcing completed glass barrels. This probably ensures better pricing, since there are only a few suppliers of barrels, but numerous suppliers of tubing to medical device manufacturers worldwide.

□ R&D Expense:

For 2010 and 2011, we estimate that development costs amount to \$2 million per year, since Unilife has already created its prototypes. Starting in 2015, our projections reflect an assumption that the company engages in the development of new products, with annual costs amounting to 2% of sales.

□ **Selling & Marketing Expense:**

Unilife is targeting a select group of potential clients, pharmaceutical corporations, which have experienced purchasing managers. As such, the Company is not going to incur marketing costs associated with large advertising campaigns initially. Our model allocates \$2 million per annum to this activity in 2010 and 2011, followed by increases that bring the 2014 expenditure to \$8 million. Thereafter, we've adjusted that figure upward by 10% per year.

□ **General & Administrative Expense:**

Our estimate of expenses for fiscal 2009, which ended June 30th, are a combined number that is based on preliminary estimates from the company.¹⁴ Unilife has added experienced staff to its headquarters in the past 12 months, and in 2010, the Company is planning to move into a new, leased facility, which will likely require extra costs to be incurred. As a result, we expect general & administrative costs to total about \$14 million in 2010 and \$17 million in 2011. We estimate these expenses will remain relatively stable through 2014 before rising 3% per annum, starting in 2015.

□ **Non-operating Income/Expense:**

We've assumed that Unilife raises capital via equity financing(s) in the next 12 to 18 months, which is reflected in higher interest income. This should be offset by interest expense on a capital lease on the new headquarters/manufacturing plant. In sum, we're not expecting any large, net changes in non-operating items.

□ **Tax Liabilities:**

Our estimates reflect tax liabilities booked for financial reporting purposes, not tax purposes. As such, we've applied an initial tax rate of 13% to the first year in which operations turn profitable and a 38% rate to subsequent years. Unilife will not pay these full amounts, though, as it has net operating loss carryforwards in Australia, where its patents are "domiciled" and much of its corporate income will be recorded. The NOL offsets, approximating \$40 million at the end of fiscal 2008, are taken into consideration in calculating annual cash flows for our DCF model, but not presented in the Income Statement.

¹⁴ Unilife press release: Chariman's letter to shareholders. Issued August 18, 2009.

HISTORICAL BALANCE SHEET # (All data are in thousands of U.S. dollars, except per-share figures.)
 # Pro forma for conversion to U.S. GAAP and U.S. dollars.

ASSETS	3/31/2009
Current Assets	
Cash & equivalents	5,622
Accounts Receivable	3,588
Inventory	1,756
Other	434
Total Current Assets	\$ 11,400
Property & equipment	\$ 8,910
Intangible assets	5,752
Other	1,301
Total Assets	\$ 27,363
LIABILITIES	
Current Liabilities	
Accounts payable	\$ 644
Debt due	1,584
Other	830
Deferred revenue	2,684
Total Current Liabilities	\$ 5,742
Long-term debt	\$ 3,345
Other	10,736
Total Long-Term Liabilities	\$ 14,081
Shareholders Equity	
Equity	68,892
Accumulated Deficit	(61,352)
Treasury Stock	-
Total Shareholders Equity	\$ 7,540
Total liabilities & equity	\$ 27,363

CASH FLOW REQUIREMENTS

□ Capital Expenditures

Our estimates are based largely on Unilife's plans to add six production lines for its ready-to-fill syringes between 2010 and 2016, as presented in Table 2. Equipment for the first, with an annual capacity of 60 million units/year, has been evaluated and orders should be placed soon. These machines will comprise most of the Company's capital expenditure budgets through 2016, aside from normal maintenance costs. That's partly because the new headquarters/manufacturing plant will be leased. The State of Pennsylvania is providing financial incentives to help defray the costs of the plant and the equipment as a means of encouraging Unilife to remain in the state.

Our cash flow model includes annual capital expenditures of \$10 million, \$14 million, \$24 million, \$18 million, and \$22 million in 2010 through 2014, respectively, largely to reflect the investments in production equipment. Note that we have included only one of the two production lines planned for 2016 in our discounted cash flow (DCF) valuation model.

□ Equity Transactions

As described in the section "Sales Projections," Unilife has several sources of revenue for the near term. However, we expect the company will raise money to help finance its capital expenditures in the near term, the move to the new headquarters/manufacturing facility, and working capital needs. The financing(s) will likely take place in association with the registration of its stock on a major U.S. exchange. Another related event that is reflected in our estimates is a 1-for-5 stock split in Australia and the exchange of its common shares outstanding there for the equivalent of an American Depository Receipt, or ADR (a right to a certain number of shares of a foreign company held in deposit).

DISCOUNTED PRICE MODEL

We have used two approaches to valuing Unilife shares a discounted price model and a DCF valuation model. In the discounted price model, we applied a price/earnings ratio of 34 to our estimate of the Company's earnings in 2014 (\$0.38 per share) and discounted that price back to mid-2009 (or 5.5 years), using a discount rate of 30. This approach yielded a share price of approximately \$3.00, which is consistent with the results obtained from our DCF valuation model, shown on the next page.

DISCOUNTED CASH FLOW ANALYSIS (All data are in thousands of U.S. dollars, except per-share figures.)

	2009	2010	2011	2012	2013	2014
Revenue	\$ 7,500	\$ 20,000	\$ 52,945	\$ 165,390	\$ 256,553	\$ 388,187
Operating income	-3500	-7000	195	53202	91854	152730
Net income	-3500	-6770	345	44807	56298	94305
Depreciation/amortization	400	1900	4450	7100	10000	12750
Stock-based compensation	400	1000	1000	1000	1000	1250
Tax loss carryforwards	0	0	0	6695	33305	0
Capital expenditures	-500	-10000	-14000	-24000	-18000	-22000
Asset purchases						
Other						
Total cash flow adjustments	300	(7,100)	(8,550)	(9,205)	26,305	(8,000)
Free cash flow	\$ (3,200)	\$ (13,870)	\$ (8,205)	\$ 35,602	\$ 82,603	\$ 86,305
Risk-adjusted free cash flow	\$ (3,200)	\$ (13,870)	\$ (8,205)	\$ 25,106	\$ 51,507	\$ 44,430

Discount Rate	Discounted Cash Flows (2009 - 2024)	PV of Terminal Value at a Perpetual growth rate of rFCF					
		Enterprise Value			Value per Diluted Share		
		2.0%	3.0%	4.0%	2.0%	3.0%	4.0%
7.5%	\$679,261.24	\$ 1,103,573	\$ 1,362,035	\$ 1,768,190	\$1,782,835	\$2,041,297	\$2,447,451
10.0%	\$527,326.47	\$ 537,416	\$ 620,211	\$ 730,605	\$1,064,742	\$1,147,538	\$1,257,931
12.5%	\$413,491.09	\$ 292,290	\$ 326,224	\$ 368,144	\$705,781	\$739,715	\$781,635
15.0%	\$327,273.05	\$ 169,777	\$ 185,729	\$ 204,580	\$497,050	\$513,002	\$531,853
17.5%	\$261,294.94	\$ 103,131	\$ 111,325	\$ 120,732	\$364,426	\$372,620	\$382,027

Discount Rate	Net Debt	Total Equity Value			Value per Diluted Share		
		2.0%	3.0%	4.0%	2.0%	3.0%	4.0%
		7.5%	\$ (693)	\$1,783,528	\$2,041,990	\$2,448,144	\$ 7.19
10.0%	(693)	\$1,065,435	\$1,148,231	\$1,258,624	\$ 4.30	\$ 4.63	\$ 5.08
12.5%	(693)	\$706,474	\$740,408	\$782,328	\$ 2.85	\$ 2.99	\$ 3.15
15.0%	(693)	\$497,743	\$513,695	\$532,546	\$ 2.01	\$ 2.07	\$ 2.15
17.5%	(693)	\$365,119	\$373,313	\$382,720	\$ 1.47	\$ 1.51	\$ 1.54

Discount Rate	Terminal Value as % Enterprise Value			Implied EBITDA Multiple		
	2.0%	3.0%	4.0%	2.0%	3.0%	4.0%
	7.5%	61.9%	66.7%	72.2%	11.62	14.35
10.0%	50.5%	54.0%	58.1%	7.99	9.22	10.86
12.5%	41.4%	44.1%	47.1%	6.09	6.80	7.67
15.0%	34.2%	36.2%	38.5%	4.92	5.38	5.93
17.5%	28.3%	29.9%	31.6%	4.12	4.45	4.83

Assumptions related to the Discounted Cash Flow Analysis:

- The DCF model projects cash flow through 2024, discounted back at multiple annual rates (7.5%, 10.0%, 12.5%, 15.0%, and 17.5%) to demonstrate the potential variability related to this assumption. It also includes three perpetual growth rates (2%, 3%, and 4%) to show the impact on the present value of the company's terminal value. The rates used in calculating the per-share value for Unilife Medical Solutions are a 12.5% annual discount rate and a perpetual growth rate of 3%. The number of fully-diluted shares estimated to be outstanding in 2014, 248 million, is used in the per-share calculation. (Note that the 2009 estimates are for the 6-month period between fiscal years.)
- The cash flows are risk adjusted, based on the proportional gross profit contribution by each production line on an annual basis and the probability of that line starting up as projected.

DISCLOSURES

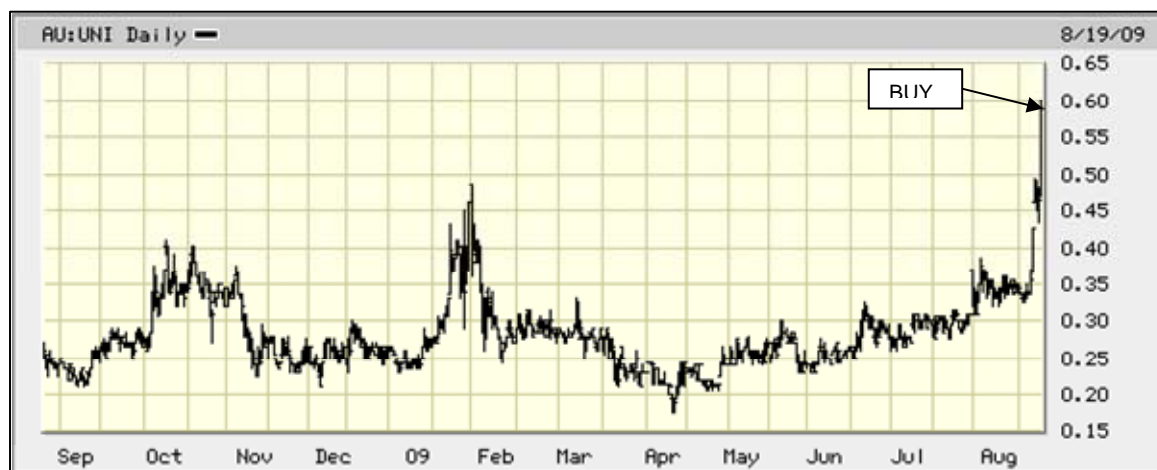
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2-YEAR PRICE CHART



Source: Big Charts

Initiated coverage: 8/19/2009; share price, A\$0.59; rating, BUY; 12-month target price, A\$3.65

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