

# Alan D Shortall

BUSINESS CONSULTANT



A transformative leader and entrepreneur whom successfully revolutionized the injectable drug delivery industry through disruptive innovation and pioneer deal making.

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## Experience

### OVERVIEW

I helped change the mind set of major pharmaceutical and biotech companies such as Sanofi, Amgen and Astra Zeneca from the industry norm of one year supply agreements by securing ten and fifteen year supply commitments, thus locking in long term recurring revenue streams once commercial launch commenced. I have also successfully negotiated up-front cash payments in excess of US\$150 million. These up-front cash commitments and supply agreements validated my vision and the technology while creating hundreds of millions of dollars of potential annual revenue to be built into the Company's pipeline.

I have built and led highly efficient cross functional innovation teams which delivered successful rapid product development and in doing so established a new life sciences benchmark for innovation. I have negotiated and raised in excess of US\$350 million through the issuance of equity in the capital markets in the U.S.A. and Australia.

Having founded and led the growth, as CEO of a publicly listed company for sixteen years in the highly regulated life sciences industry, I have a broad and deep understanding of all elements of leading a successful business. From the seamless integration of quality control, regulatory, rapid product development, operations, finance and marketing to cutting edge innovation. I am a veteran dealmaker, empowering leader, innovator and passionate entrepreneur.

I won the Ernst & Young Entrepreneur of the Year Award in Greater Philadelphia in 2015 "Honoring those who see past the present to define the future".

## Expertise

### DEEP UNDERSTANDING OF;

- *Drug Delivery Systems*
- *Healthcare*
- *Life Science Markets*
- *All Elements of Business*
- *The Seamless Integration of;*
  - Quality Control*
  - Regulatory*
  - Rapid Product Development*
  - Operations*
  - Finance*
  - Marketing*

## ENTREPRENEUR

In 2002, I founded Unilife, a medical device company, in Sydney, Australia based on a technology concept for a plastic, automatically retractable, safety “fill at time of use” (from a vial) syringe. I went on to list Unilife on the Australian Stock Exchange (ASX) in late 2002 taking on the roles of Director and CEO. I led the successful development of the original product concept right through high volume, fully automated manufacturing and US FDA & EU regulatory approval. In 2010, through a complex redomiciliation process I led the Company’s transition from the ASX to a NASDAQ listing while continuing and thereafter maintaining a dual listing. I retired as Chairman and CEO of Unilife in February 2016.

- In 1989, I immigrated to Australia from Ireland having sold my successful marketing consultancy in a management buyout. Through 2002, I bought, built and sold a number of businesses.
- In 2005-6, I was approached by Sanofi to develop a prefilled, glass retractable syringe with the same automatic retraction features as the plastic safety syringe. At that time conventional thinking was that it would be impossible to integrate a safety mechanism into a primary drug container and maintain the integrity of the drug during its shelf life and achieve regulatory approval. My product development team proved conventional thinking to be wrong. I negotiated a US\$40 million agreement with Sanofi in June 2009 to finalize the product design and industrialize the product. It was challenging closing such a transformative deal during the height of the Global Economic Recession (GER).
- In 2007, I negotiated the purchase of an FDA registered medical device manufacturer in Pennsylvania, USA so as to minimize the risk that many companies face when transitioning from a technology development company to an industrial producer. In 2008, Unilife relocated key personnel from Australia to Pennsylvania.
- At the height of the GER in 2009, I led the design and construction of a state of the art medical device, 165,000 sq.ft. manufacturing facility with a mortgage in place guaranteed by the US Government. Within one year of the initial clearing of the 35 acre site, the Company moved into the new facility that included operational cleanrooms. Along with the successful completion of a major manufacturing facility project in a highly regulated industry, I navigated the Company through the GER, a remarkable achievement for a pre-revenue, technology development company, which I believe is a testament to my resilience and determination.

## INNOVATION

In 2011, I recognized that the global healthcare market was shifting from a volume/priced based system to one based on outcomes/value. With the global pharmaceutical/biotech industries’ drug pipelines filled with highly viscous complex biologics, 90% of which required injection, my vision was to create highly differentiated pre-filled drug delivery systems which would empower patients to very simply, safely and conveniently self-inject these complex biologics in their home, office or anywhere. Avoiding having to visit the doctor’s office or healthcare facility would ensure better patient adherence, therefore better health outcomes and reduce healthcare costs. At the same time creating an opportunity for our pharmaceutical customers to leverage the benefits of our products, taking market share from their competitors and increasing their revenue, Win/Win. My vision was validated by the unprecedented supply agreements I executed with major Pharmaceutical partners.

During the succeeding four years, I built cross functional product development teams, which developed five new categories of differentiated delivery systems. This quantum and level of successful, rapid product development in the medical device industry had never previously been achieved.

The new categories are;

- 1) A platform of prefillable wearable injectors (wearable injector pump) for delivery of high volume dose biologics (this is the fastest growing sector in medical devices). In particular the wearable injector (WI) technology created by my innovative teams has become the market leader in wearable injector pump technology in the pharmaceutical industry with supply agreements in place with Astra Zeneca, Sanofi and Amgen. The Company’s WI is currently the only WI technology that can be delivered to the patient prefilled with the drug and preassembled which enables the simplest possible user interface. According to an independent research report issued by Roots Research, the WI

## Skills

*Skilled Negotiator*

*Creative Dealmaker*

*Innovator*

*Agile Thinker*

*Empowering Leader*

global market is a whole new category that is expected to grow from almost zero revenue currently to over US\$8 billion annually within ten years, and that does not include the insulin market. The development of the Company's wearable injector technology was based on my successful concept of innovation, simple to use, saves time, enhances peoples' lives and is cost competitive.

- 2) A platform of prefilled syringes with integrated, automatic needle retraction.
- 3) A platform of electronic auto-injectors, Bluetooth connected, both single use and re-usable.
- 4) A platform of prefilled ocular delivery injection devices for precision injection into the eye reducing the industry standard for dose accuracy from up to 40% uncontrollable variation to a 2% variation.
- 5) A platform of prefilled drug reconstitution delivery systems enabling a drug to drug or a liquid/powder mixing in an easy to use single device into a primary drug container and maintain the integrity of the drug during its shelf life and achieve regulatory approval. My product development team proved conventional thinking to be wrong. I negotiated a US\$40 million agreement with Sanofi in June 2009 to finalize the product design and industrialize the product. It was challenging closing such a transformative deal during the height of the Global Economic Recession (GER).

## TRANSFORMATION

By encouraging and empowering my teams to think "outside the box" to create highly differentiated delivery systems, I was responsible for transforming the pharmaceutical industry and how they conducted their business in three significant ways.

- 1) By creating innovative delivery systems that are introduced into the market by the Pharma partner prefilled with the drug, I created a B2B model which eliminates almost all sales and marketing costs for Unilife. This could only be achieved through innovative design to overcome industry perceived barriers of regulatory biocompatibility because of the interaction of the drug and the materials used in manufacturing the drug container.
- 2) Through this business model, I changed how deals were constructed in the Pharma/Device industry. The drug delivery systems my teams created were so differentiated that they created an opportunity for Pharma partners to leverage the benefits to patients thereby increasing their market share and revenues. The delivery systems were unique and patented; thus once the Pharma partner had committed and gone through the regulatory process, they had no alternative supplier for the duration of our agreements. I built into the supply contracts supply-chain risk mitigation protection for our customers. I negotiated eight, ten and fifteen year supply agreements (in some cases exclusive commitments from the Pharma partner) from some of the largest companies in the world. The unprecedented long term supply commitments set up a business model with built-in recurring revenue for ten to fifteen years from the date commercial release was achieved.
- 3) I secured significant up-front, lump sum payments for exclusive access, or non-exclusive access, early in the product development cycle from Pharma companies such as Sanofi US\$40 million and Amgen US\$90 million, due to the innovation and uniqueness of the delivery systems that were developed under my leadership.

## PIONEER DEALMAKING

Part of my unique talent is my ability to quickly assess the possibilities presented and to make the most of innovation in order to negotiate unprecedented agreements with long established leaders in the market. This invariably involved dealing with strong negotiators who are accustomed to dictating conditions to potential partners or suppliers and I established terms that had been previously thought impossible. My philosophy in deal making is based upon the understanding of the art of negotiation and collaboration. If just making a deal is the intended outcome of negotiation it tends to create a winner and a loser whereas insightful negotiating can lead to successful winner/winner outcomes which then become sustainable and repeatable.

## Achievements

### E&Y ENTREPRENEUR OF THE YEAR AWARD

*The Ernst & Young (EY)  
Entrepreneur of the Year  
Award in Greater Philadelphia  
2015. The world's most  
prestigious business award for  
entrepreneurs. As the First  
and only truly global award of  
it's kind, Entrepreneur Of The  
Year celebrates those who are  
building and leading successful,  
growing and dynamic  
businesses.*

### NAMED IN TOP 100 NOTABLE PEOPLE

*Medical Device and Diagnostic  
Industry Magazine 2008*

#### Sanofi (Prefilled Syringes)

In 2008, I negotiated an exclusive license along with an Industrialization Agreement with Sanofi (3rd-5th largest Pharma in the world) for US\$40 million. An upfront payment of \$10 million was received and the balance was paid on milestone achievements over the following two years. As part of the Industrialization Agreement, Sanofi also committed to sign a Supply Agreement for the product which included significant, minimum annual volumes. All milestones were met on time and all US\$40 million was paid by Sanofi. This deal was based on a functioning prototype of "Unifill" a highly differentiated, pre-filled glass syringe with fully integrated automatic and controlled needle retraction which eliminated the risk of needle stick injuries and was to be used for delivering Sanofi's blood thinning drug Lovenox. At that time market estimates were that Sanofi was selling in excess of 400 million doses of Lovenox per annum.

I seized the initiative when due to unforeseen issues relating to Sanofi's business model costs, the supply agreement which had been expected to be signed in late 2010, was delayed. I instructed my team to create a completely new iteration of Unifill with the same core features and functionality. Through efficiency of design for high volume automated manufacturing, we were able to reduce the production costs by 30%. The Unifill Finesse was developed from user input requirements and went from initial design to automated high volume manufacturing within two years. This is a perfect example of my "never quit" attitude in driving a business. In 2013, my perseverance was rewarded by the execution of a long term Exclusive Supply Agreement for the Unifill Finesse with Sanofi that contained minimum annual purchase volumes of 150 million units. Sanofi paid an additional US\$10 million in upfront fees.

#### Hikma

In late 2013, I negotiated a fifteen year exclusive supply agreement with Hikma, a leading generic drug company, for the exclusive supply of two Unifill platform products for an annual unit volume commitment of 170 million units. Hikma agreed to pay US\$7 million in upfront payments with a further US\$20 million to be paid in milestone payments.

#### Sanofi (Wearable Injectors)

In 2014, I negotiated and executed a fifteen year Exclusive Supply Agreement with Sanofi for the Company's wearable injector (WI) technology. In that agreement, Sanofi committed to exclusively purchase all of its WI requirements from the Company for fifteen years. The exclusive commitment was a one way commitment as it enabled the Company to sell its WIs to any other Pharma. In a public announcement released by the Company and approved by Sanofi, it was estimated that Sanofi would have five to ten biologics that would require delivery by WI; it was further estimated that each of those biologics would use an average of five million WIs annually and that the average cost to the Pharma would be \$25 per unit. For a major Pharma to commit exclusively to a single source supplier for a complete category of device for fifteen years was unprecedented.

#### Abbvie

In early 2015, I negotiated and signed a Strategic Partnership Agreement with AbbVie with an upfront payment of US\$5 million.

#### Amgen

In early 2016, I architected, negotiated and signed a US\$90 million agreement with Amgen (the largest biotech company in the world) which included Licensing, Strategic Alliance and Supply Agreements. Amgen agreed to pay US\$65 million up-front with an additional US\$25 million to be paid within two years. The US\$90 million commitment was to secure license access to Unilife's wearable injector technologies for some of Amgen's biologics. Upon commercial release of the Amgen products, the contract has the potential to generate hundreds of millions of dollars in annual revenues from WI unit sales for Unilife, in addition to the \$90 million. This is potentially the largest medical device supply agreement in the history of the pharmaceutical industry validating the technology along with my vision for the healthcare and life sciences markets.

## Media

TV INTERVIEWS AS LIFE

SCIENCES & INDUSTRY

EXPERT

*CNBC "Mad Money" Jim Cramer*

*CNBC "Fast Money"*

*Bloomberg*

*Fox Business*

*And numerous others*

PUBLISHED ARTICLES

*7 Articles in Drug Development  
& Delivery Magazine.*

*Life Science topics such as;*

*Healthcare market shift  
from price/volume driven to  
outcomes/value based system.*

*Patient empowerment  
driving better adherence and  
compliance therefore better  
health outcomes.*

## SUMMARY

Upon my retirement as Chairman and CEO from the Company it was ideally positioned to; capitalize on its strong financial position (US\$65 million plus in the bank); the multiple long term agreements that I negotiated and signed; more than US\$240 million market cap on NASDAQ; the impending shipments of the first high speed production line Unifill products and the financial commitments from customers for further investment. I am now ready to utilize all of my experience, my deep understanding of the market, along with my vision and tenacity, to help drive other companies.

## OTHER INTERESTS

In 2000, I founded a not-for-profit organization to support men in the community through experiential weekends based on the following values; love, compassion, congruence, accountability and integrity. Over 60,000 men have now gone through the experiential weekend process globally and it has helped with the ultimate goal of keeping the women and children in our communities safer. Along with the Australian organization I have had the honor of helping to grow the organization in South Africa, Ireland, New Zealand and the USA.

In my free time and using the facilitation skills I learned on the experiential weekends, my passion now is in using the success derived from these processes to support US military retired Special Forces Operators to help them with their challenging re-integration back into society by helping to re-set their moral compass which in many cases were compromised in order to carry out their mission.

Through;

- Increased empathy
- Strengthened social connection
- Focused attention
- Decreased isolation
- Emotional de-compression
- Stress reduction
- Trauma recovery

The processes have shown to help reduce alcohol abuse, illicit drug abuse, prescription drug abuse, violence and most importantly suicide reduction.

I have participated at international level in competitive sports all my life including representing Australia and winning the team silver medal in the pistol shooting World Championships.