

Federal Treasurer Josh Frydenberg Opens New ST Headquarters

August 2018: Australia's new Federal Treasurer Josh Frydenberg officially unveiled ST's new Melbourne headquarters, an event coinciding with the company's 10 year anniversary.

The deputy Liberal Party leader joined staff and other local dignitaries at the celebration, praising ST's commitment to innovation and recognising it's contribution to Australian healthcare.

10 Years of Giving





Montagner Zembrzuski

— FAMILY —
FOUNDATION

Being philanthropic is important to us and STA has a long history of giving. In the past 10 years, we have donated more than \$21 million worth of medicine to patients on compassionate grounds and delivered more than \$3.5 million to research and development. But one of our greatest achievements has been the establishment of the Montagner-Zembrzuski Family Foundation. Here's an insight.

Click on the link above to watch the video.

10 Years of Giving



It was three years ago that our family decided we wanted to give and support causes beyond our local community.

After making this decision, we were made aware of the struggles facing the people of Timor-Leste.

While this region is geographically close to Australia - it's faster to travel by plane from Darwin to Dili than it is to journey between Sydney and Melbourne - the nations are poles apart, in terms of basic services, infrastructure and health and education.

When we first travelled from the capital Dili to the township of Maliana - about a five-hour journey by road - it was glaringly obvious that this community remains emotionally and physically scarred by the country's battle to achieve independence.

But there was still a feeling of great hope and a determination to rebuild. We could also see that with the right support, young people here could be given an opportunity to really flourish.

Maliana



Our attention was drawn to the Don Bosco Technical School, which was established in Maliana to educate both boys and girls in Years 10, 11 and 12 in electrical trades.

It is proudly run by the Salesian Christian Brothers and has been purpose-built to equip young Timorese people with vital trade skills that will benefit the country's planned gas refinery operations - seen as an integral part of the country's rebuild.

We were immediately struck by the teenagers on campus. Many of them are from very poor families and travel from many parts of Timor to board. They have overcome enormous obstacles to acquire an education and take none of it for granted. They are so obviously proud to be at school, praying daily in gratitude for the simple joy of three meals a day, companionship, and the opportunity to learn.

What they were missing on campus was a place to congregate and shelter. While there were some very basic outdoor recreational facilities, these structures provided no protection from the searing heat and monsoonal rains.

We knew that simple, but solid buildings could make a real difference to the experience of these young people and their teachers.

So, after consulting with the school principal, Brother Marcal, a Salesian Brother, we set about facilitating a build of this "hall without walls" - a structure that would shelter the exposed basketball court and provide a natural hub for community events.



Just weeks ago, we traveled back to Maliana as a family to join the students and local community for the official opening of this building (see main photo above).

We felt so privileged to be involved, and to watch as this school creates its own history.

We were genuinely humbled by the generous hospitality provided to us by this community and consider ourselves lifelong friends.

The building looks fantastic and the project is beautifully aligned with our own philanthropic goals: it is sustainable for the long term and it has the backing of the Timorese Government.

In addition, the Salesian Brothers have a long history in Timor-Leste and have committed to operating this school for the next fifty years.

We will continue to support this school because we believe it represents the best of what Timor-Leste's future can be.

There is so much more we can do and are planning for Timor-Leste.

We look forward to providing further updates shortly of another project in the region working with younger children.





10 Years of Compassion



Linda Wilson is an Australian mother, wife, grandmother and nurse who was diagnosed with pancreatic cancer five years ago.

She had surgery, but was devastated when her cancer recurred.

While she was given just months to live, she has steadfastly refused to abandon hope.

She says, "I don't consider I am dying from pancreatic cancer, I consider I am living with pancreatic cancer." This is her story.

Please click on the following video link above to view Linda's story.



10 Years of Giving



ST is committed to providing and leaving an enduring legacy, not only in Australia but overseas. Sustainable healthcare and education are among our philanthropic passions. We were intrigued when we first heard about the work of Specialists Without Borders (now Pangea). This not-for-profit group, founded in 2008, ensures large contingents of Australian medical professionals are able to travel to developing countries to train and educate their peers. In reality, it translates to improved healthcare for the people and patients in these resource-poor nations, like Rwanda. Royal Melbourne Hospital Director of Neurosurgery Associate Professor Kate Drummond is Pangea's Chair.

Here, she explains how ST has made a difference.



“I don’t think we would have been able to survive from SWB into Pangea without the support of Specialised Therapeutics. They have been our biggest donors and our most supportive and regular donors and basically, that money has allowed us to run our programs, feed our participants, buy our teaching materials and transport our people. It has been absolutely vital. It has meant we can have a little bit of admin support. As you can imagine, trying to organise 350 people right across the world, having a little bit of admin support has been fantastic – it has basically allowed us to survive.

None of the products that Specialised Therapeutics have are of any use in Africa, or in any of the countries we go to. This is true philanthropy.

What is has allowed is education of people who really are going to benefit from the upskilling we can give them, to provide more sophisticated and more safe health care in the areas they are working. They are very senior doctors and nurses going across from Australia to provide tailored education programs.”

Associate Professor Kate Drummond shared these insights in August 2018. To hear her discussion, please click on the video link above.



10 Years of ABRAXANE in Australia



STA was founded in 2008 with a single oncology product, a chemotherapy drug called ABRAXANE. It was not yet approved to treat pancreatic cancer anywhere in the world, but Perth oncologist Dr Andrew Dean had heard promising data about this new medicine at an international scientific meeting. At the same time, he was quietly contemplating one of his patients, a Perth grandmother called Margaret Thompson. She had been diagnosed with progressive pancreatic cancer and in his opinion, had only weeks to live.

Dr Dean was considering her case when he stepped into his waiting room and saw an unfamiliar face.

“Hello,” said the stranger. “You don’t know me, but my name is Carlo Montagner from a company called Specialised Therapeutics.”

It was a serendipitous meeting. Within hours, Dr Dean had secured an agreement to provide Margaret Thompson with ABRAXANE on compassionate grounds. She

was the first pancreas patient outside the US to be treated with this agent.

In this piece, Andrew Dean discusses how in his opinion, STA and ABRAXANE have changed the Australian oncology landscape.

“ABRAXANE was STA’s foundation product and to my mind, the company’s founder and CEO Carlo Montagner showed great foresight and vision introducing it to Australians.

STA has been exceptionally generous in its support of our treatment endeavours, by enabling early compassionate access of this medicine to many, many people who could not otherwise have afforded it. STA’s support meant we were able to offer both public and private patients access to ABRAXANE when and where appropriate, more than five years before this medicine was available on the Pharmaceutical Benefits Scheme.

Following on from that, I would say it has been the single drug that has had the most impact on the modern treatment of pancreatic cancer in the past 10 years.

Since it was introduced into this country, we have seen a dramatic improvement in the



prognosis for metastatic pancreatic cancer patients.

I can tell you that at our centre in Western Australia, the median survival time for pancreatic patients with metastatic disease is now 19 months, compared to a

global average of 11 months. It is my opinion that ABRAXANE has played a huge role in that. We have had patients who have survived four, five and six years with metastatic disease, and that was previously unheard of. We have also had many patients who were initially considered inoperable, but treatment has enabled their tumours to shrink to such an extent that we have been able to successfully operate. Many of those people are still alive.

In addition, we have recently published the successful use of ABRAXANE re-treatment as third-line therapy for pancreatic cancer, and also its marked success as single-agent therapy for anaplastic thyroid cancer.¹

And Margaret Thompson? It's been nine years since she was provided ABRAXANE on compassionate grounds. She was what we call an exceptional responder. Her tumour shrank by 90% within 6 weeks. Today, she remains in remission, having never had surgery.

Ultimately, for patients, the introduction of this medicine has meant more time with families and children that would otherwise not have been possible.”

*August 2018.

References:

1. *Journal of Clinical Oncology* 33, no. 15 suppl - published online before print.

10 Years of Innovation

ST prides itself on being innovative and entrepreneurial. We set a new pharma industry benchmark in Australia when we decided to stop

bonus payments to our in-field representatives based on sales volumes in their territories. We wanted them to focus on their customers, build real relationships and educate, rather than sell. We think it's worked. Our CEO Carlo Monaghan explained his rationale behind the decision in this opinion piece published in a national Australian newspaper.



“I recently bought a red Tesla. It’s a battery operated, engineering marvel that doesn’t require petrol, can be recharged via a rooftop solar panel, is sleek, modern and chivalrous to boot - with doors that open automatically on the owner’s approach.

While I’m an unapologetic and long standing motor car tragic, what really clinched the deal was the way this beautiful piece of machinery was sold to me.

Tesla does have showrooms in Australia, but you can’t actually buy these cars from a showroom.

When you go to a Tesla showroom, expert staff - obvious car enthusiasts like me - demonstrate and provide all manner of information about these cutting edge vehicles.

Our “sales” conversation was educational, informative and involved a pleasant exchange of information that ultimately, led to me purchasing a Tesla product online. At the showroom, I felt no sales pressure but was provided with enough information to make my own decision.

By being informed and well-educated by the representative, in a ‘non-salesy’, low pressure environment, I was free to consider the actual merits of the Tesla without the distraction of the typical car sales process. I knew the various Tesla representatives I had spoken to in the showroom were not receiving sales commissions, so the information provided was passionately, factually and legitimately delivered.

I tell this story because, as the CEO of Australia’s largest independent pharmaceutical company, I have made the decision that from February 1, 2017 our in field company representatives who call on current and potential prescribers of our therapies will no longer be incentivised by the volume of prescriptions written in their territories.

Instead, financial rewards achieved by our people will be based on other performance measures - like the extent of their product and therapeutic knowledge, their level of customer service and engagement, their commitment and dedication to ensuring the patients who would most benefit from our therapies are given the best chance of accessing them.

Why are we doing this? Because if you motivate frontline representatives with a financial carrot, then it is commonsense that those frontline staff are going to prioritise selling products instead of focusing on the specific needs of the patients the product can treat.

Like Tesla, I want doctors to know that when our field force representatives approach them about our therapies, they can engage in a legitimate and genuine exchange of information that is educational and informative.

I want them to feel comfortable in the knowledge that our representative is not being financially rewarded for ‘shifting more units’.

Conversely, I want our people to be truly engaged and to make customer and patient care paramount. I want them to engage and educate without the pressure of sealing a deal.

I want them to strive to achieve – but not sales targets. Success can be measured in other ways that are still tangible.

This approach does fly in the face of how most pharmaceutical companies in Australia and around the world typically operate.

But I am convinced this is the most transparent approach. Our customers – predominantly oncologists and haematologists – can see through a sales pitch. Most consumers can, in whichever industry you work.

This is not about taking an ‘airy fairy’ approach to sales. Quite the contrary. As an entrepreneur with a strong commercial bent, I care passionately about the business I founded, the pharmaceutical industry and the bottom line. Without profitability, there is no pharmaceutical industry, which is able to underpin breakthrough and life saving therapies and technologies.

I staunchly believe this approach will translate to desirable commercial outcomes, because success begins with a great product that fulfils a marketplace need.

Sales are achieved when customers are educated about a product’s merits and benefits. If you have the right product, then the outcome is assured.

When there is an inherent confidence in a product, there is no need to reiterate and ram home tired sales messages.

Our products are medicines that fulfil unmet medical needs. They are not ‘me-too’ products, but are carefully selected for in-licensing to our regions (Australia, New Zealand and South East Asia) because they are innovative and different. Like the battery operated Tesla car, they are not mainstream, but niche-market. The right people will prescribe them if they have the right information and there is a genuine medical need in the community.

Interestingly, my sales tactic sentiments are being echoed in other industries.

In recent weeks, consumer groups have called on the banking industry to come clean on how staff bonuses really work.

These groups warned that some consumers felt bullied into buying bank products by over-zealous sales people who were chasing their own bonuses, instead of providing real, transparent and legitimate information that might actually

improve a customer's financial prospects instead of their own.

The customer should always come first and in the pharmaceutical industry, I would say it is even more important.

Our customers are doctors and ultimately, the patients they care for. Their health is their most prized possession. Our sales should only be made when it's right for them, based on the best information available, imparted by an expert, educated field force.

When the basics are in place, the rest will follow. Just ask Tesla."

****This opinion piece was published in the Herald Sun on February 10, 2017***

10 Years of Meeting Unmet Needs



ST was founded with a mission of meeting unmet medical needs. In line with this ethos, we are passionate about helping all patients access new and innovative medicines that can change lives. In the past decade, we have worked closely with Rare Cancers Australia to ensure that new, innovative and potentially life-changing therapies are available to all patients who can most benefit. Here's RCA Chief Executive Officer Richard Vines.

“In 10 years, ST has done an amazing amount of work in areas that would otherwise be neglected by multi-national pharmaceutical companies.

One example of this would be introducing ABRAXANE to patients with pancreatic cancer, which has been a remarkable breakthrough. Bringing this medicine to Australians was done with great energy and compassion from everybody at ST.

But I think the greater point here is ST's contribution overall to Australian healthcare.

Without ST doing the work it is doing and in-licensing novel medicines for the Australian market, we would be denied access to a whole range of medicines where the originating company does not have offices in Australia.

ST's ability to license products, bring them to Australia and put them through the regulatory and reimbursement processes so they can be delivered to patients is just absolutely unique and invaluable.

As a company, it is as close to a national treasure for cancer patients as we can possibly find.

On a personal level, ST's CEO Carlo Montagner is a remarkable man and it has been a joy to work with him.

I have worked with him on the Cancer Drugs Alliance and now, we will be working with him on the National Oncology Alliance. He brings a unique energy and passion to the Australian cancer community. Without his vision and effort, there would be a lot of cancer patients that would potentially, have died prematurely or unnecessarily. He has extraordinary energy.

In the next decade, I would really like to see STA's continued growth, so it can bring more new therapies to Australians. Of course, we would like to see its focus

on rare cancers continue so it can provide next-generation cancer medicines, like becombination therapies, targeted therapies, and different types of immune oncology drugs.

STA is well placed to bring these medicines to Australians with the same energy and passion it has shown in the past 10 years.

I wish STA a very happy birthday and a very successful next decade.”

Video: Celebrating 10 Years



Celebrating 10 Years | Success is a culmination of our people, and our products. But it is patients who are at the heart of everything we do. Click on the link above to see a snapshot of what we've achieved in the last decade and some of the people who've made an impact along the way.

Where it all began: How 007 became ABRAXANE

It was 1992. The year that the space shuttle Endeavour made a successful mission to space, when the Cold War came to an end and when a Frenchman called George Charpak took out a Nobel prize in Physics for his inventions of particle detectors.

It was also the year a new cancer drug called Taxol emerged on the global cancer stage. Chemical engineer Dr Neil Desai was working alongside world-renowned surgeon, philanthropist and entrepreneur Dr Patrick Soon-Shiong. Together, they attended a scientific meeting about Taxol (paclitaxel), which had just received marketing approval. They heard that this life-saving compound, discovered in the bark of the Pacific Yew Tree, had been formulated with a castor oil derivative known as Cremaphor (CrEL) to make it water soluble for infusion into cancer patients. The accomplished scientists knew that in patients, Cremaphor had been known to cause life-threatening allergic reactions¹, and were adamant there must be another way to deliver the compound to patients. And so they set to work. Thousands of lab hours later, they contested that emerging nanoparticle technology, in combination with natural human albumin, would enable delivery of the same important medicine in a more efficient way, but this time, without the side-effects of Cremaphor.

This was a meeting of like minds, and of science. The Desai/Soon-Shiong version of paclitaxel without Cremaphor was originally known as ABI 007 (license to kill cancer), and their unique method of combining drug molecules with new technology was the *nab* platform.

Despite the demonstrated improvement in breast cancer treatment over paclitaxel², the medical community initially scoffed, calling it 'old wine in a new bottle'. Dr Desai and his scientific partner insisted it was 'new wine in a new bottle' and persisted. Many technology, monetary and regulatory hurdles later, their new drug that began life as ABI 007 became ABRAXANE (nanoparticle

albumin-bound paclitaxel).

To date, it has been used to treat ~600,000 patients around the world,³ and is regarded a standard of care in some settings. Dr Neil Desai discusses the ABRAXANE story and reveals what's next.



Tell us about the ‘Eureka Moment’ that led to the development of ABRAXANE.

I would not say there was one particular Eureka moment, but there were a couple of instances along the way. The first moment was when we came up with the idea of combining a drug with human albumin. That had never been done before, so conceptually, that was a Eureka moment. Then, we had to translate the concept into reality. We had to figure out how to bring together thousands of molecules of paclitaxel and albumin and convert them into a form that was suitable for putting into a patient. Nanotechnology was a new field. It is the science of assembling a structure at the molecular level and creating objects so tiny, they cannot be seen under an optical microscope. There were no reference materials and we were in the lab, tinkering under the microscope and trying to develop a technique to

create particles so small, that they were no longer visible. When that finally happened, that was the all-important second Eureka moment.

What do you say now to those who initially called it “old wine in a new bottle”?

I would say that those medical professionals probably didn't fully understand the nature of the drug. True, it was paclitaxel, but I think that is where the similarity ended. I would say it is new wine ... and probably in a new bottle as well.

From my interactions with physicians over many years, when they use ABRAXANE they can see how patients feel when they are being treated with this drug. And I think that is an important factor, although it doesn't usually get factored into the clinical trial setting. We need to get clinical information about how a patient feels. If we were able to get that kind of information, it might add to the body of existing evidence. There may be a lot of side effects that result from solvent-based paclitaxel. And, in some cancer settings, our delivery system has been shown to improve how the drug works.

How can the nanoparticle albumin-bound (*nab*) platform be further leveraged? Tell us about next-generation nab - ABI-009.

We have taken the *nab* platform and put another drug into the same type of technology that was used to develop ABRAXANE. The drug in this case is rapamycin. We call this drug ABI-009. It is not a new drug, as rapamycin was originally approved in the transplant setting for prevention of rejection. It has not really been used in the cancer setting. What is exciting is that we have found that combining rapamycin with the nab platform helps to leverage its activity and its ability to penetrate tumours. We are exploring that in the cancer setting and so far, the results are promising.

We are currently conducting a registration trial for a rare sarcoma, called PEComa (perivascular epithelioid cell tumor). which we hope to complete enrolment for this year. Outside of the cancer setting, we are also trialling the technology in pulmonary hypertension, where we are seeing some interesting

results in the first few patients. Other indications - including epilepsy and mitochondrial disease - are also being investigated.

Rapamycin targets the mTOR pathway, which is a pivotal biologic pathway. When activated, this pathway drives the spread of cancers and promotes other proliferation. And so, if you are able to block that pathway effectively, you are able to stop that proliferation. In the case of pulmonary hypertension for example, pulmonary arteries get clogged because of proliferation in the blood vessels. We look forward to seeing more data emerge from our trial programs, but things are looking promising.

Why is rapamycin synergistic with the *nab* platform?

The way the molecules bind together is unique and we are actually able to create these nanoparticles with rapamycin that are even smaller than those we created with ABRAXANE.

In animal models it works very effectively. We are now translating our research into the clinic and beginning to see results now.

Our technology opens a new opportunity, potentially in terms of how side effects are managed, as well as drug activity. The *nab* platform enables drugs to be used in a space where they may not be active, or marginally active without the *nab* platform. Ultimately, at the end of the day it is about quality of life for patients who are prescribed these medicines.

What advice would you give to entrepreneurs about when to persist?

There are many good ideas and many intelligent people come up with great ideas.

Often there are technology hurdles, as was the case with us. We did persist, although admittedly, funding is a big part of it.

I would say that when hurdles seem insurmountable, if you know your idea is good, you must persist.

In your view, is chemotherapy becoming outdated, with the advent of immunotherapy agents? Or do you think that chemotherapy drugs will still remain a backbone of cancer therapy?

There are new approaches with immune modulators and genetic modulators. Chemotherapy agents ultimately may phase out, but I can't see that happening for a while.

I think chemotherapy agents will remain a backbone of cancer treatment, also because of the regulatory framework in which we operate. Scientists must demonstrate that newer agents offer an improvement over standard therapy, in order to obtain approvals. I think often the easiest way is to trial combination therapies using the older standard of care.

What is the future of ABRAXANE and how do you feel about your scientific legacy?

The future of ABRAXANE is not in my hands, unfortunately. It remains to be explored in different indications and I suspect there may be new benefit. There is data in ovarian cancer, as well as a few other cancer types. It is always a challenge for a large company to see if it makes economic sense to pursue those indications, taking into consideration other factors like patent expiry times and new agents on market.

Having said that, I am proud of what ABRAXANE has achieved and the role I played in bringing it to people. Developing this technology was a team effort, and I congratulate everyone who participated. It was a new approach, perhaps a bit radical at the time. It became one of the first drugs approved using nanotechnology. Our persistence paid off.

Dr Desai shared his insights in June 2018.

To hear Dr Neil Desai discuss ABRAXANE's 'eureka moment', please click on the following video.



References:

1. Taxol Product Information
2. J Clin Oncol. 2005 Nov 1;23(31):7794-803.
3. Data on file, Celgene 2018.