



March 2017



### ITL Limited (ASX: ITD)

#### Company Overview

ITL Ltd (ASX:ITD) is a diversified medical technology company that develops and manufactures blood banking and laboratory sampling systems, blood pressure monitoring devices and custom procedure packs. ITL sells into over 50 countries and a number of its products have sold many millions of units with long and successful track records. ITL's subsidiary, MyHealthTest, develops direct to consumer pathology tests for the monitoring of chronic diseases such as diabetes.

#### The ITL Story

ITL Ltd was founded in 1994 by Bill Mobbs (current Executive Chairman and largest shareholder) and Dr Jag Dillon in Canberra. In the SC there was a rapidly growing awareness of the need to protect against transmittable diseases and the founders saw opportunity in developing products that would protect both patients and healthcare practitioners. The company's first product, DonorCare – a container that provided safe storage of needles immediately upon withdrawal from the patient – was developed to help solve this need and has since gone on to sell hundreds of millions of units.

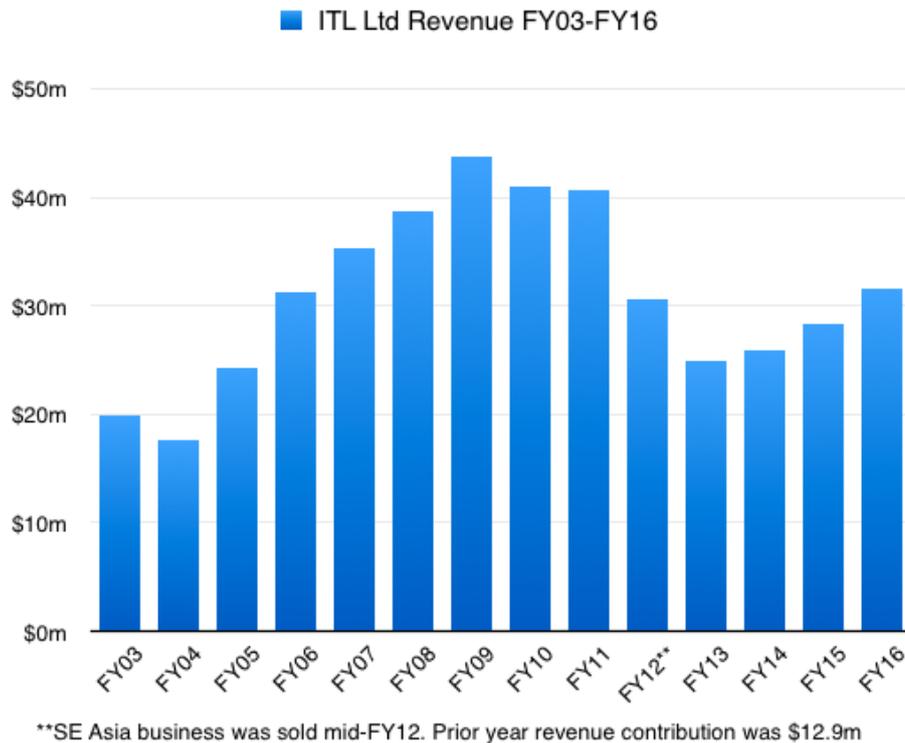
In 1998 ITL won foundation contracts in the US and Europe to supply large volumes of DonorCare which helped kickstart the business and in 1999 a manufacturing facility was established in Ipoh, Malaysia. The plan from the beginning was to build a broad portfolio of patent protected intellectual property which over the years has lent itself to sustainably high margins and customer longevity for this business, which today is known as ITL BioMedical.

In 2002, in preparation for a public listing, ITL established a custom procedure kit division, which provides customised packs of all the consumables used in operating procedures. This division was bolstered in 2003 when at the time of listing (ITL raised \$21m at 50c) the company acquired SurgiCare, an established custom procedure kit business. SurgiCare brought with it a 20 year operating history, long term customers and a Melbourne manufacturing facility. This subsidiary is today known as ITL Healthcare, or Healthcare Australia.

After a weak first year as a public company amidst contract delays, ITL began to turn the corner with a number of large contract wins for the BioMedical business and the release of new products further diversifying the sales mix. Revenue rebounded in 2005 before posting record levels in 2006 and again in 2007, though growing pains restricted profit growth as the company invested heavily into a new production facility (which is the current Chelsea Heights plant used for manufacturing custom procedure packs with 3x the capacity of the previous facility). The company also made the decision to bring the sterilisation process in-house as the reliance on outsourcing proved a constraint on growth (the value of this will be explored in a moment). A recurring theme for the company right through to the present day was that the custom procedure pack business, which operates in a market dominated by multinationals, was incredibly intensive and cyclical which tended to overshadow the very high margin, higher quality BioMedical and medical device businesses.

In 2008 the founder Bill Mobbs left the board but remained a large shareholder. The ensuing years amidst the GFC were difficult ones, though ITL remained profitable and grew revenue every year from 2004 through to 2009. Nevertheless the company struggled with a growing cost base, rising debt and large write downs required in FY10. That led to a push by Mobbs to be reinstated to the board, which he was successful in doing in 2010 being appointed Executive Chairman. Bill began a complete restructuring by appointing new directors and senior management (including reducing director remuneration), divesting excess assets, improving inventory management, cutting excessive costs and refinancing the company's debt facilities.

This restructuring occurred at the same time that the industry, particularly the blood bank market, was undergoing consolidation. Terumo acquired CaridianBCT from Gambro in 2011, which itself was acquired by Baxter the following year for US\$2.8b, and Cobe had been acquired by Gambro many years prior. Then Haemenetics acquired Pall's Transfusion Medicine for US\$550m, leaving Terumo as the only real competitor to ITL BioMedical. A market of what was once six large players turned to just two in a relatively short period while in the custom procedure pack business suppliers were lifting their prices and the large Australian hospital operators weren't willing to pay a premium for custom products, resulting in a margin crunch at both ends.



#### ITD Revenue FY03-FY16

FY11/12 marked the turnaround point for ITL as the restructuring began to show benefits, driven by Bill Mobbs who had taken control once again, resigning from his position as Chairman of UK listed Seeing Machines to focus on turning ITL around (note: a number of ex-Seeing Machines employees now work for ITL).

The South East Asian distribution business, which was generating ~\$12m in revenue but negligible profit, was sold (explaining the drop in total revenues from FY12 onwards). Margins in the custom procedure pack business were improved by going direct for consumables like drapes and gowns (previously outsourced to suppliers before being sterilised and packed by ITL) which along with numerous other initiatives saw the procedure pack business return to profitability while the Biomedical business remained a consistent performer.

The result for shareholders was a significant appreciation in the share price from the lows of 2010 over the next couple of years accompanied with approximately \$5m in dividends and \$12m of share buybacks from 2012 through to today.



### ITD Share Price 2010-2013

And with the turnaround largely complete the company began to focus on growth. In 2014 ITL acquired a state of the art Malaysian (Bemban) manufacturing plant and invested heavily in capacity expansion and automation. As favourable market trends emerged there was a renewed focus on the global potential of products like the Samplok Sampling Kit (SSK) and DonorGuard. This has resulted in a number of new contracts and expanded distribution agreements being secured, the most significant of which were announced in the latter part of 2016 and will be detailed later in this report.

ITL Healthcare was right-sized and roughly 40% of sales by revenue has been transitioned from the Melbourne manufacturing facility to the new plant in Malaysia. That saw margins reverse their decline and the business improve its profitability. The procedure kit business (a little over half of the ~\$20m of ITL Healthcare revenue) remained under pressure but was significantly improved, while the invasive blood pressure monitoring and IV Starter Kit businesses (the balance of the \$20m revenue and the products that are now entirely manufactured in Malaysia) remained positive contributors to ITL Healthcare.

With the core business returned to growing profitability ITL acquired MyHealthTest (MHT), a direct to consumer provider of pathology testing. While a start up, MHT is operating in a market that in the US has grown from around US\$10m in 2010 to US\$130m in 2015 and provides some optionality to shareholders should the business reach scale.

## Strong Q1 2016/17

### First Quarter Performance

Unaudited Management Accounts	Qtr ended 30/9/2016	Qtr ended 30/6/2016	Qtr ended 30/9/2015
Revenue	\$8.9m	\$8.1m	\$7.6m
EBITDA	\$1.5m	\$(0.3m)	\$1.0m
Profit Before Tax	\$1.0m	\$(0.7m)	\$0.7m

- Strong start to the year highlighted by increased revenue (17% over previous year) and profitability (EBITDA up 50%) driven by business improvement programs
- Current year includes MHT start up costs of \$(0.4m) not incurred in the prior year<sup>14</sup> so gains in underlying businesses even greater

#### ITL 1Q 2017 Results

#### ITL PROFIT DOUBLES IN HALF YEAR 2016/17 RESULTS

ITL Limited ("ITL"), an innovative diversified healthcare company, is pleased to announce excellent results for the half year ended 31 December 2016 compared with the previous corresponding period.

##### Highlights

- Profit after tax of \$2.12m (Dec 2015: \$1.04m; **up 104%**);
- Earnings per share of 2.2 cents (Dec 2015: 1.2 cents; **up 83%**);
- Revenue of \$17.5m (Dec 2015: \$15.7m; **up 11%**);
- Profit before tax of \$2.12m (Dec 2015: \$1.01m; **up 110%**);
- EBITDA was \$2.7m (Dec 2015: \$1.6m; **up 69%**);
- Net Debt \$5.0m (Jun 2016: \$5.5m; **down 9%**);

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**Unit 1, 63 Wells Road**  
**Chelsea Heights, Victoria, 3196**

ITL is an innovative diversified medical technology company that creates and manufactures leading edge medical devices for Operating Theatres, Bloodbanks and laboratories.

ITL's patented medical devices are sold in over 50 countries and protect healthcare workers in millions of procedures annually.

ITL's wholly owned subsidiary MyHealthTest creates and markets highly innovative direct to consumer pathology testing for major chronic diseases.

#### ITL 1H17 Results Snapshot

A hint at the extent of momentum in the business was provided at the FY16 AGM where the first quarter results were released reflecting strong revenue growth and a jump in profitability. That performance continued into 2Q and saw a very strong 1H result released in February. The contracts and distribution agreements announced recently, most notably the global distribution agreement with French giant bioMerieux for ITL's most profitable product, are significant and underpin the potential for incremental growth over a number of years. Combined with the positive outlook provided by management in recent presentations and interviews this suggests that the momentum in the business is likely to continue. If that's the case then the earnings growth that should follow will make ITL look cheap on an absolute basis, and exceedingly so when compared to its ASX-listed medical device manufacturing peers, making the company worthy of a detailed look.

## ITL Healthcare

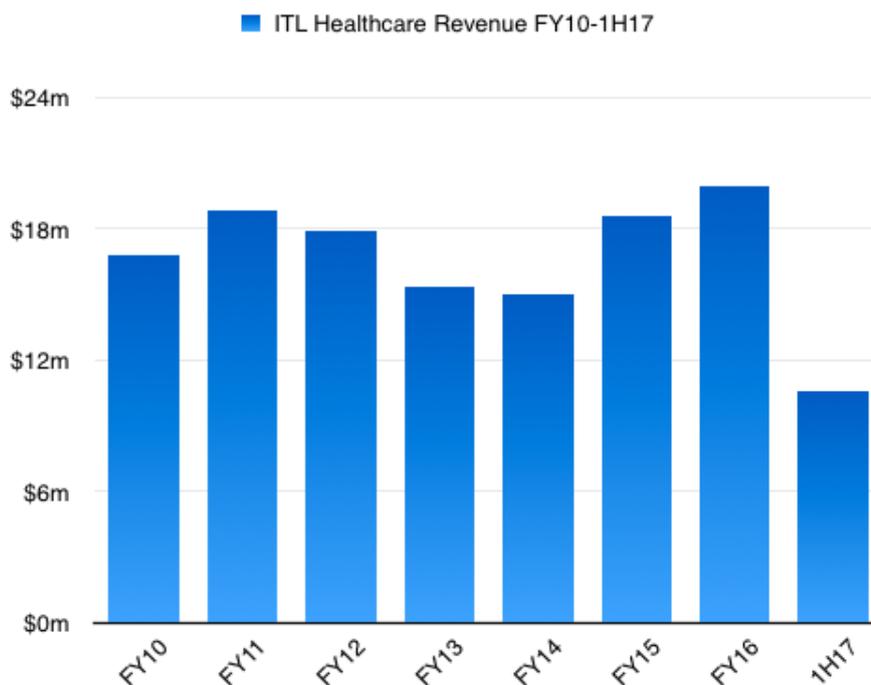


ITL Healthcare, or Healthcare Australia, was formed when ITL acquired Surgicare with the IPO in 2003. The business develops and manufactures custom procedure packs (CPP), invasive blood pressure monitoring systems and IV starter kits. ITL Healthcare generated ~\$20m in revenue in FY16 and typically accounts for 1/3 of ITL's profits.

### ITL Healthcare

The custom procedure pack business comprises ~\$11m of ITL Healthcare's revenue but minimal profit and is probably the lowest quality yet most intensive business for ITL. Procedure packs are, in simple terms, kits containing all of the consumables used in an operating procedure, with the major customers being the large Australian hospital operators. These packs are customised for the client but that is not necessarily able to be reflected in a premium selling price and since the market is dominated by multinationals margins have come under pressure since the GFC.

The remaining ~\$8m of revenue generated by ITL Healthcare is from invasive blood pressure monitoring devices and IV starter kits, which are a much higher quality line of business. Classified as Class 3 medical devices these products have a greater level of IP which is reflected in higher margins and profitability. The manufacturing of these products has been transferred to ITL's Malaysian plant, while the vast majority of the custom procedure packs continue to be made in the Chelsea Heights facility.



### ITL Healthcare Revenue FY10-1H17

The custom procedure pack market, while highly competitive, is an enormous industry assessed to be worth US\$20b globally and hence dominated by multinationals, though ITL focuses on the Australian market. As mentioned earlier this business has been through a rough period whereby suppliers crunched them on price while customers were unwilling to pay a premium. Various initiatives such as going direct for drapes and gowns, upgrading and investing in manufacturing facilities and rightsizing the cost base have driven a marked improvement to margins.

One of the attractive aspects of this business is that it is now the only Australian producer of procedure packs with in-house sterilisation capabilities. This is more of an advantage than it may seem. The sterilisation process is typically a 4-5 day process for ITL but is often extended to 2-3 weeks if outsourced. That of course results in reduced flexibility and a need for ITL's competitors to hold additional inventory.

Further, since the acquisition of Surgicare in 2003 ITL purchased and invested in a manufacturing facility in Chelsea Heights with 3x the capacity of the previous plant. That, in conjunction with in-house sterilisation capabilities, gives the procedure pack business significant strategic value should ITL look to divest the business (more on that later).

ITL management still have the option of transitioning all of the manufacturing from Chelsea Heights in Victoria to ITL's Malaysian plant, which would drive an increase in margins. Only a small fraction of the manufacturing for procedure packs is currently being done in Malaysia with the majority still in Victoria. If the company pursues this route then profitability is likely to improve. Further, some of the initiatives put in place in 1H17 are yet to be fully reflected in the bottom line, including improved purchasing, which should continue to flow through in 2H.

ITL Healthcare announced a string of new and renewal contracts throughout the latter part of 2016 including a one year contract extension with Austin Health for procedure packs (\$1.5m), a new 3 year contract with Metro South Health for IV Starter Kits (>\$1m p.a), a new one year contract with Barwon Health for a range of medical consumables (\$0.9m) and a 5 year contract with Macquarie University Hospital for invasive BP monitoring systems (\$0.5m). These contracts should ensure that FY17 is a decent one for ITL Healthcare.

## ITL BioMedical

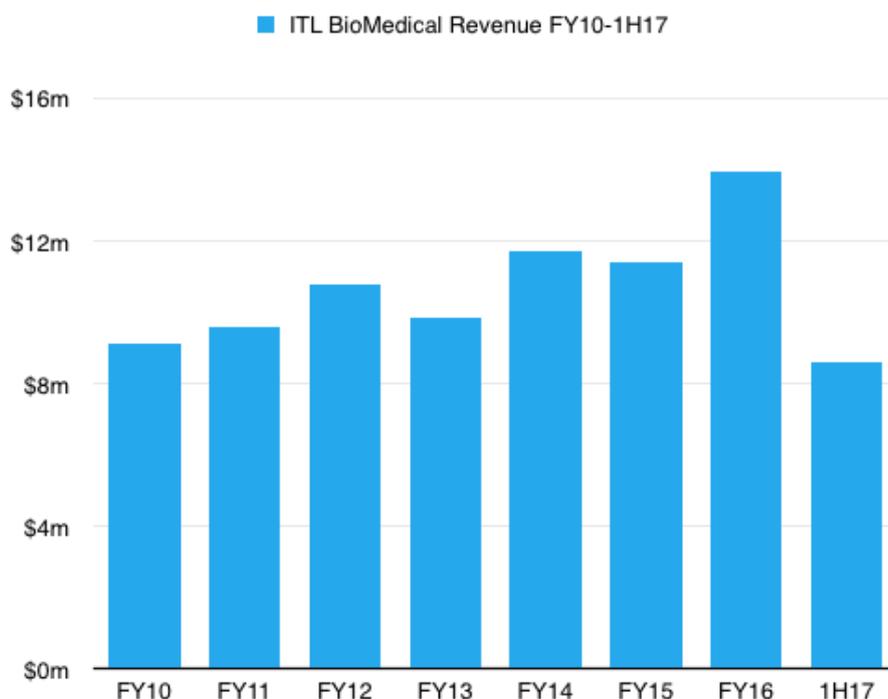


HUMAN INSPIRED. SCIENTIFICALLY ENGINEERED.

This is the jewel in the crown of ITL. Previously named the Innovations Division, this business was the founding focus of the company with the intention to build a high margin, medical technology licensing business. As it grew it became necessary to bring manufacturing in-house and so the business we see today was created. The significant amount of IP built up over the years, reflected by the company's 48 patents, is what has allowed ITL BioMedical to generate consistently high gross margins – upwards of 60% – over a long period of time.

### ITL Biomedical

ITL BioMedical develops a suite of products for biological sampling in the human and animal healthcare markets. Products like DonorCare Needle Guard used for the safe extraction of blood from donors at blood banks and was the founding product of ITL BioMedical having sold over 200 million units since 1998. The second version of the product, DonorCare Needle Guard 2, was released in mid October 2016 and by early November had already sold over a million units just in the US and Canadian markets.



### ITL BioMedical Revenue FY10 to 1H17

One of the most profitable products for ITL, and with the greatest runway for growth, is the Samplok Sampling Kit (SSK). To explain how this product works and the opportunity in front of it requires a broader overview of the market and the trends at play (for more info it is worth reading ITL's presentation on ITL BioMedical).

For patients with compromised immune systems requiring blood transfusions (typically cancer patients) there is a critical requirement for platelet testing to ensure the absence of bacteria. Over the last decade the industry has moved from taking whole blood and then manually separating the components to isolate the platelets, to an automated process whereby the donor's blood is extracted, a machine takes out the platelets and then gives back the other elements that aren't required. This allows a therapeutic dose of platelets to be gathered from one donor, rather than 4-5 as in the previous process, as less total blood needs to be extracted to collect a sufficient volume of platelets. These platelets extracted from one donor using an automated process are called apheresis platelets and in the US they make up 90% of all platelet samples.

From there the platelets need to be tested for bacteria. To do so the platelets are extracted from the donor bag to a testing bottle. Samplok Sampling Kit (SSK) is the product used to transfer the platelets from the bag to the testing bottle. SSK comes in 10ml and 16ml variations depending on whether aerobic or anaerobic testing (or both) is implemented.

### Samplok Sampling Kit (SSK)

These samples are then tested using culture-based microbial detection systems, one of the leading providers of which is bioMérieux – a key partner for ITL as a global distributor of SSK – through its bacT/ALERT system. bioMérieux is a major player in the US\$60b in vitro diagnostics market and looks set to become an important partner for ITL in the years to come.

The incubation process lasts a number of days (you can see the Australian Red Cross' explanation of this process here, who also use bioMérieux's bacT/ALERT detection system) and the majority of tests do of course prove negative for the presence of bacteria. In the event that a test comes back positive the next step is to identify the bacteria and to do so the sample needs to be extracted from the tube to a testing slide. Another of ITL's products – Safety SubCulture Unit (SCU) – is used to transfer the positive sample from the bacT/ALERT bottle to the testing slide for further analysis. SCU is also growing off the back of expanded distribution agreements with bioMérieux, most recently in Canada, but for the obvious reason that far more tests prove negative than positive the total addressable market for SSK is multiples that of SCU.



### ITL BioMedical Announces Distribution Agreement with bioMérieux Canada

[ITL BioMedical](#), a division of ITL (ASX: ITD) that sets industry standards for the innovative design and production of biological sampling systems for human and animal use, is pleased to announce it has signed a five year distribution agreement, with possible ongoing renewals, for its Safety SubCulture Unit (SCU) with [bioMérieux Canada Inc.](#) The total estimated number of subculture procedures performed in the Canadian market per year is between 700,000 to one million.

The interesting part is that not all countries currently test platelets for bacteria with a wide range of testing protocols across nations. Australia implemented 100% platelet bacterial testing in April 2008 and as a result there were no confirmed severe cases from 2008 until (at least) 2013. Scotland, Northern Ireland, the Netherlands and Wales test over 95% of samples while a surprisingly large number of countries across Europe implement no bacterial testing at all and the results are mixed in Latin America. This is despite it being broadly accepted that bacterial contamination of blood products poses the greatest risk in blood transfusions, with platelet concentrates most at risk. France for example, the third largest platelet market in Europe and ironically home to bioMerieux, does not enforce the testing of platelets and it is known that there are deaths occurring as a result. It is a primary focus of the French Blood Establishment to reduce this risk and it is largely expected that France will in time move to full bacterial testing of platelet concentrates. As a result, the French market is one of the key focuses for bioMerieux, and by extension ITL through the former's distribution of ITL's SSK product, in the recently announced global distribution agreement for SSK. France is just one example where this trend is likely to play out.


The Opportunity for the Blood Banking BCT Market

For personal use only

- The last 10-15 years have seen the transition from the sourcing of platelets through whole blood collection and separation to the use of automated methods, which produce apheresis platelets, used for transfusion to patients (typically cancer patients)
- The potential for bacterial contamination of platelet components is known to be one of the biggest risks for patients receiving transfused platelets, with the elderly and immuno-compromised most at risk
- Bacterial testing of platelet components is a rapidly growing market as more countries implement stricter regulations and/or mandatory testing. USA, Canada, and Australia enforce strict bacterial testing requirements and test the vast majority of all platelet components whereas France, the 3rd largest European market for platelet volumes<sup>(2)</sup>, performs little/no testing
- ITL's relationship with bioMerieux, a leader in the US\$60b in vitro diagnostics industry, is important to leverage growth in this market

(2) [http://ec.europa.eu/health/sites/health/files/blood\\_tissues\\_organ/docs/20150408\\_cc\\_report\\_en.pdf](http://ec.europa.eu/health/sites/health/files/blood_tissues_organ/docs/20150408_cc_report_en.pdf)

**ITL BioMedical Presentation Excerpt**

The enormous US market provides some insight as to the trends occurring in the industry. In 2004 the FDA required all accredited institutional members to “implement measures to detect and limit bacterial contamination in all platelet components.” Then the 2014 FDA guidelines for collection of platelets using automated methods stated that “bacterial contamination testing should be performed using a culture based methodology” (bioMerieux’s test is culture based). Further, the 2016 FDA draft legislation recommends, but does not make mandatory, secondary bacterial testing (using a non-culture based rapid test) by hospitals and transfusion centres that would allow the extension of platelet shelf life from 5 to 7 days.

There are now three FDA approved primary bacterial tests: bacT/ALERT by bioMerieux, eBDS owned by Haemenetics and Scan System by Hemosystem. The first two are culture based and are the dominant systems currently used in the US. Scan System is less widely adopted and uses the laser based scanning cytometry method which is not currently recommended by the FDA. In November 2009 the FDA approved the first rapid test (PGD by Verax) to be used for secondary testing which the Blood Advisory Committee in the US is strongly in favour of making mandatory.

In early 2016 The Centre for Medicare and Medicaid (CMS) made platelet components treated with pathogen reduction technology for hospital outpatients reimbursable. Then in November the CMS extended this definition to include platelet components that were tested using rapid bacterial testing methods. This is evident of the broad trend towards more comprehensive bacterial testing of platelet components. This trend is still in its early stages and the US market serves as an indicator of how other markets will likely play out. It goes a long way to explaining how ITL BioMedical has achieved 25% revenue growth in FY16, 27% growth in 1H17 and with momentum expected to continue from here.

*Brief Explanation: There are culture based tests like bacT/ALERT by bioMerieux and non-culture based tests such as PGD produced by Verax. Culture based tests are more comprehensive and have been cleared by the FDA for the quality control of apheresis platelets immediately following collection and before distribution. Non-culture based 'rapid' bacterial tests like Verax PGD have been approved by the FDA following testing by an FDA approved culture based device, and is now seen as an additional safety measure similar to pathogen reduction technology by the likes of Cerus. From January 2011 AASB prohibited the use of low sensitivity tests for the presence of bacteria (microscopy, PH, glucose) and regulatory standards for these tests are stringent. The trend moving forward is for more comprehensive testing to be employed at all levels.*

ITL have been successfully selling SSK in the US market for almost a decade. bioMerieux are currently investing US\$60m on a North Carolina based production facility focused on manufacturing bacT/ALERT bottles. The US market, and North America more broadly, is generating strong double digit revenue growth for BioMerieux while its competitor Haemenetics continues to struggle. BacT/ALERT was noted by bioMerieux as one of the highlights for the recent reporting period in their microbiology business (which does well over \$1b in sales) with unit sales expanding by 13%. All indications suggest bioMerieux are very keen to strengthen their position in the US market. This represents an exciting opportunity for ITL.

▶ **Salt Lake City (UT - U.S.): production of FilmArray®**

- ▶ Building construction finished, layout in progress
- ▶ Expected in-service date: Dec 2016
- ▶ ~\$95 million total investment



▶ **Durham (NC - U.S.): production of BacT/ALERT® bottles**

- ▶ Building to host the new line finished, manufacturing layout in progress
- ▶ Expected in-service date: first-half 2017
- ▶ ~\$60 million total investment

▶ **Marcy l'Etoile (France): site expansion and packaging of VIDAS®**

- ▶ In-service in H2 2016
- ▶ ~€62 million total investment



### bioMérieux US Production Plans

Other countries will likely move to full testing for the presence of bacteria in platelets prepared for transfusion, which will support the overall growth of the Blood Culture Testing market (assessed to be worth US\$3.3b currently and growing to US\$4.8b by 2021). And partnering with the leader in bioMérieux leaves ITL well positioned to take advantage of that opportunity.

The previous distribution agreement for SSK with bioMérieux was just for the UK but in the latter part of 2016 ITL announced the agreement had been made global, which opens up a much larger addressable market. The uplift in volumes, and hence revenue, as a result of this agreement are yet to be seen but the opportunity is large and given the high gross margins of SSK will be material to the bottom line.

### **Global Distribution Agreement with bioMérieux for SSK**

As a result of the bioMérieux global distribution agreement (announced October 2016) ITL are now partnered with the leading player to distribute one of their most profitable products in over 150 countries (where as the previous agreement with bioMérieux was solely for the UK). bioMérieux is investing heavily in growth and has given indications that it has confidence in ITL's products (e.g. see the NHSBT tender deal announcement in which SSK is used as part of the bioMérieux system). The market is yet to latch on to how important this deal is for ITL and that the strong FY16 and 1H17 results were delivered before this deal kicked in. It is likely that revenue and earnings growth for ITL BioMedical will experience growth off the back of this deal alone.

## ITL BioMedical Announces Global Distribution Agreement for SSK with bioMérieux

[ITL BioMedical](#), a division of ITL (ASX: ITD) that sets industry standards for the innovative design and production of biological sampling systems for human and animal use, is pleased to announce it has signed a global, multi-year distribution agreement for its SampLok® Sampling Kit (SSK) with [bioMérieux](#) (Euronext: BIM), a multinational biotechnology company and supplier of bacterial screening test systems and ancillaries.

ITL Announcement 17th October 2016

Then there is the prospect that the bioMérieux agreement is expanded to additional ITL products both released and in development, and this may not be limited solely to the current focus of platelet testing. For example, while bioMérieux are a global leader in platelet testing the number of tests they conduct each year in that part of the business is a fraction of their total testing volumes – things like food, veterinary, and cosmetics together comprise volumes that are multiples that of the platelet business. There is an opportunity for ITL to develop new products to leverage the existing relationship with bioMérieux and expand into these market segments, but for now the focus for growth is in platelet testing and specifically SSK, SCU and other ancillary products.



The slide features a blue header with the ITL logo and the text 'Innovative New Product Pipeline'. Below the header, there are two bullet points: 'Robust new innovative product pipeline' and 'Multiple ancillaries for the blood culture market are expected to be commercialised within the next 12 months'. At the bottom, three medical devices are displayed: a white plastic adaptor cap, a yellow-handled segment sampler, and a purple universal adaptor cap. Each device is labeled with its name: 'SampLok® Adaptor Cap 2', 'Segment Sampler', and 'Universal Adaptor Cap'. A small number '16' is visible in the bottom right corner of the slide.

- Robust new innovative product pipeline
- Multiple ancillaries for the blood culture market are expected to be commercialised within the next 12 months

SampLok® Adaptor Cap 2      Segment Sampler      Universal Adaptor Cap

16

### ITL BioMedical Product Pipeline

While the recently announced bioMérieux agreements are the most significant, ITL BioMedical has secured a number of other important agreements with the likes of OneBlood (US blood bank), Taiwan FDA approval for SSK and a contract extension with a large US community blood bank. And the multi-year tender win with the UK National Health Service Blood and Transplant for bioMérieux in which ITL will supply SSK as part of the tender is indicative of bioMérieux's confidence in the product.

## First Half Results Summary

- Significant growth in demand for ITL BioMedical's highly innovative SampLok® Sampling System ("SSK")
- Global Distribution Agreement for SSK signed with bioMérieux, a French multi national diagnostic solutions company
- Contract wins across Australia and overseas
- Contract renewals across all divisions
- Growing portfolio of innovative and client inspired products
- ITL BioMedical's EBITDA grew 54% to \$2.5m. The division is expected to see strong growth continue as sales of its innovative products increase within the large and fast growing existing and potential new markets

### ITL BioMedical First Half 2017

ITL BioMedical experienced 25% sales growth in FY16 and 27% sales growth in 1H17 (which resulted in a 54% EBITDA uplift to \$2.5m). That is before the global distribution agreement with BioMerieux kicked in meaning sales growth should sustain its strong performance into 2H and perhaps even accelerate from here. With gross margins typically north of 60% and with plenty of operating leverage should revenue continue to trend upwards the recent progress in sales growth should translate to attractive earnings growth for ITL BioMedical. It is the BioMedical business and its prospects moving forward that comprises the focus for the Capital H investment thesis in ITL Ltd.

### ITL BioMedical Outlook

#### ITL BioMedical – An Exciting Future

- Significant growth in first half 2016/17 with EBITDA up 54% to \$2.5m
- Diversified market and product portfolio spanning clinical, laboratory and blood banking markets
- Refocus on Blood Culture Testing (BCT) market has already produced a series of successes
- BCT market estimated to be worth \$3.3bn in 2016 and \$4.8bn by 2021
- Global Distribution Agreement with BioMerieux, a leader in the US\$60b in vitro diagnostics industry, gives ITL exposure to 155 countries
- Significant growth in SSK sales anticipated, already one of ITL's biggest profit generators

## MyHealthTest (MHT)



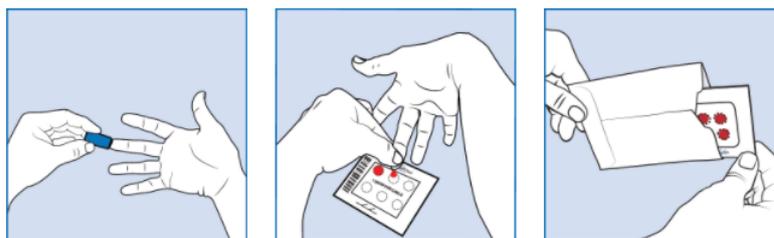
MyHealthTest is a developer of direct to consumer pathology tests for the assessment of chronic diseases and biomarkers. The company was co-founded by Bill Mobbs and vended into ITL in 2015. The direct to consumer pathology testing market is one that is new to Australia, but that has grown rapidly off a low base in the US, rising from US\$15m in 2010 to US\$131m in 2015.

At present the sole test that MHT has released to market is for the assessment and monitoring of diabetes. The MHT diabetes test measures Hba1c, which is a form of haemoglobin used to measure the average plasma glucose concentration over the preceding months. It was developed at The John Curtin School of Medical Research at the Australian National University (ANU) and since release has garnered strong support from Diabetes ACT, the Australian Diabetes Educator Association and a handful of ACT based pharmacies through which the test is being sold (in addition to the main channel of online). According to Diabetes Australia over a million Australians have been diagnosed with diabetes, 600k have undiagnosed diabetes and over 2 million suffer from pre-diabetes.

MHT uses Dried Blood Spot (DBS) tests that are sent to and analysed in MHT's own lab. DBS technology is not new having been around for many years and the credibility and accuracy of DBS testing has been validated in studies published in clinical journals, the most relevant of which can be read here.

Before exploring the business in more detail its worth understanding the process involved. Having actually done the test personally, the commentary below comes with some firsthand experience:

1. The test is purchased online for \$35 (or through a pharmacy). You provide some basic information about yourself as well as decide whether to have the results shared with your healthcare professional.
2. If you purchased the test online it is then mailed to you (it arrived within a couple of days). It comes packaged with clear instructions on how to perform the test yourself.
3. A safety lancet is used to prick your finger and drop a small amount of blood on the MyHealthTest card provided. You then place the card in the envelope provided and return it to the MHT lab (postage paid). This part of the process might be a little tricky for those with a phobia for blood or needles and hence may be difficult for some, but it is much less invasive than having the tests done at a standard lab. The safety lancet provided is quite easy to use and is not particularly painful.
4. The results are emailed to you in a secure, password protected PDF and shared with your healthcare professional if you chose that option. MHT will move to providing the results over a secure online portal rather than PDF when the platform is fully developed.



### MyHealthTest Process

The above process was quick and seamless. For those not too concerned with blood and needles there really shouldn't be any issue with doing the test themselves. Over time MHT plan to release further tests for thyroid, PSA, cardiac biomarkers and others that can be bundled together and sold as panels of tests.

There is enormous operating leverage in this business if it can achieve scale though it is quite a while off doing so and remains in start up mode. It is yet to be pushed hard but marketing will likely ramp up in FY18 following the release of additional tests.

Given how new this market is not only globally but particularly in Australia it is hard to precisely assess the opportunity in front of MHT. It is also probably difficult for someone who is broadly in good health and rarely requires medical attention or blood tests to see the value in direct to consumer testing. No one actively enjoys taking blood tests but for some it is a necessity in order to monitor chronic disease and MHT intends to offer an alternative to the current process of requiring doctor referred visits to pathology.

It's important to note that MHT is not trying to replace traditional pathologies nor are they trying to cut out the healthcare professional. In the US one of the strongest push backs to direct to consumer pathology testing has come from doctors who (rightly) believe that putting sensitive health information in the hands of patients without professional medical advice and left to their own devices (or with Dr Google) is risky. MHT's response to that is to actively involve the health care practitioner throughout the process. There is an option to have the test results sent to your doctor and the usual procedures of having results interpreted by a professional remain, particularly in the case of patients suffering chronic disease. For patients requiring regular monitoring the MHT tests may prove an attractive, less invasive and less time consuming option than visiting the doctor for a referral and then dropping by the nearest pathology. And there is of course the possibility that MHT pursue the option of engaging healthcare professionals directly which would open up the possibility of doctor-referred tests as well as Medicare rebates (a potentially big catalyst).

The other part of the addressable market are healthy individuals who have a desire to know more about the status of their health and find this additional information useful. The 'more data' trend in health and fitness circles has been occurring for many years now. The iPhone Health Platform (which can track virtually every health/fitness metric you can imagine), FitBit, MyFitnessPal, sleep monitoring devices, body composition scales – all massive markets built off the back of the consumers desire to know more about their health and wellbeing. MHT plays well into this market as it can potentially provide a cost effective means of monitoring key data points for the health or fitness 'enthusiast.'

Just how large this market in Australia will turn out to be is difficult to answer given it is still so new, but being the first mover in a small but rapidly growing market is a good place to be. The plan over the medium term for MHT is to build it into a viable business in the Australian market before pursuing international growth, which obviously multiplies the size of the addressable market. But this strategy is quite a while off yet with the focus over the next 12-24 months likely to be on the Australian market.

In the meantime this business is being ascribed no value in the current share price so provided that costs are kept under control the downside should be limited. If MHT were to be spun off as a separate entity, backdoor listed on to the ASX and promoted by brokers it would probably attract a valuation well into the double digit millions, but since it is hidden away as a subsidiary of a highly profitable medical device company its being given no value at all – such are the ways of the ASX.

As MHT progresses certain milestones could act as catalysts for the share price as the market gradually prices in some value for the business. The development and release of new tests, NATA accreditation for the lab (not currently required by law but will be by 30th June), sales growth, expansion of marketing initiatives and receipt of Medicare reimbursement approval are all potential catalysts to keep an eye out for.

In the US there is a business called Everly Well that runs a similar model to MHT and at its most recent raising in early 2016 was valued at US\$9m before it had even entered commercialisation (it has since done so). The main difference is that Everly Well currently outsources their lab services with the intention to bring the process internal at a later date. MHT on the other hand run their own lab and have done so from the very start. That has resulted in higher costs up front but will provide significant scale benefits as revenue grows. This video on Everly Well is worth watching to grasp the opportunity in direct to consumer pathology testing.

The base case expectation is for MHT to move closer to profitability throughout FY18 with the real earnings upside likely 18+ months away, though the market may price that in sooner. The Capital H thesis for ITL focuses on the highly profitable and fast growing core businesses with the current share price effectively throwing in MHT for free. Very large opportunity if they get it right but comes with start-up risks. Consider it optionality.

## **Strategic Value Of Custom Procedure Pack Business**

As part of the restructure of ITL Healthcare management considered all options to achieve value for shareholders, with the main focus being on what path to take for the custom procedure pack business. This is a business that generates ~\$11m revenue but relatively little profit compared to the BioMedical business and is competing against large multinationals. As we understand it when the restructure began management were deciding between two paths: 1) divesting the custom procedure pack business, or 2) transitioning manufacturing of these packs from the Chelsea Heights facility to the Malaysian facility where the BioMedical products are produced.

Now as the story has played out management have thus far moved ~40% of ITL Healthcare product manufacturing to Malaysia (IV starter kits and invasive BP monitoring devices) but the majority of procedure packs are still manufactured in Victoria. This move has been one of the primary drivers for the improved profitability of this business. But there is still the very real possibility that the custom procedure pack business (along with the Chelsea Heights facility and in-house sterilisation capabilities) will be sold since in the event all production is moved to Malaysia these assets would no longer be needed. As a result it's worth considering what impact this would have for shareholders.

These businesses typically transact on revenue multiples of around ~1x (implying ~\$11m). Further, and as outlined earlier, ITL's Chelsea Heights and sterilisation facilities have real value to potential acquirers and would be worth far more in the hands of a multinational acquirer than when owned by ITL. If ITL were to sell this division then the consideration received should be material and is likely to act as a catalyst. It would allow the market to focus on the fast growing BioMedical business which by itself warrants a higher earnings multiple owing simply to the fact that it is a higher quality business with far more attractive growth prospects. And since around \$3m of ITL's debt is associated with the CPP business a divestment would see the company quickly move to a net cash position. This is of course far from certain to occur and should be considered speculative but the potential upside is large and at the very least it underpins the valuation for ITL.

Alternatively, if things continue as they are and ITL transition the rest of its product manufacturing to Malaysia we should see another increase in the profits generated by ITL Healthcare in FY18. The divestment of the CPP business would be highly value accretive and lucrative for shareholders however given there is no guarantee of this occurring the Capital H thesis assumes the CPP business is retained with a resulting margin increase as procedure packs are moved to Malaysia.

## **Key Risks**

The risks of an investment in ITD include but are not limited to:

Competitive Pressures in CPP business: As noted earlier the custom procedure pack business is tough. Management have spent a great deal of time and effort in turning this business around and for FY17 it looks like the business will perform well. But it is a competitive market dominated by multinationals and so there is a risk that performance is volatile in the medium term. While it is a decent chunk of revenue (\$11m) its profit contribution is minimal so the reliance on this business performing well is quite low. Management need just keep it profitable in order to let the value in ITL BioMedical show through for ITL.

There are a couple factors offsetting this risk. The first is better purchasing by ITL Healthcare this year which has partly been the driver of the improved performance in 1Q. Some of that benefit is still yet to flow through. Second, ITL still have the option to move production of packs to Malaysia which would result in improved earnings that would flow through in FY18. This may help ensure the rest of FY17 and/or the start of FY18 see a bump up in profit. And of course if it were divested this risk turns into a catalyst.

MHT in Start up Mode: The key risk in the short term for MHT is that costs need to stay under control. That probably isn't an issue in FY17 but in FY18 it will be something to watch as the business is pushed harder. Management are very aware of the need to focus on profitability though and if the core business grows as expected this risk should be well contained, particularly given the margin of safety in the share price.

Regulatory Change: Both the Healthcare, Biomedical and MHT businesses operate in highly regulated markets and so this is a risk to be aware of.

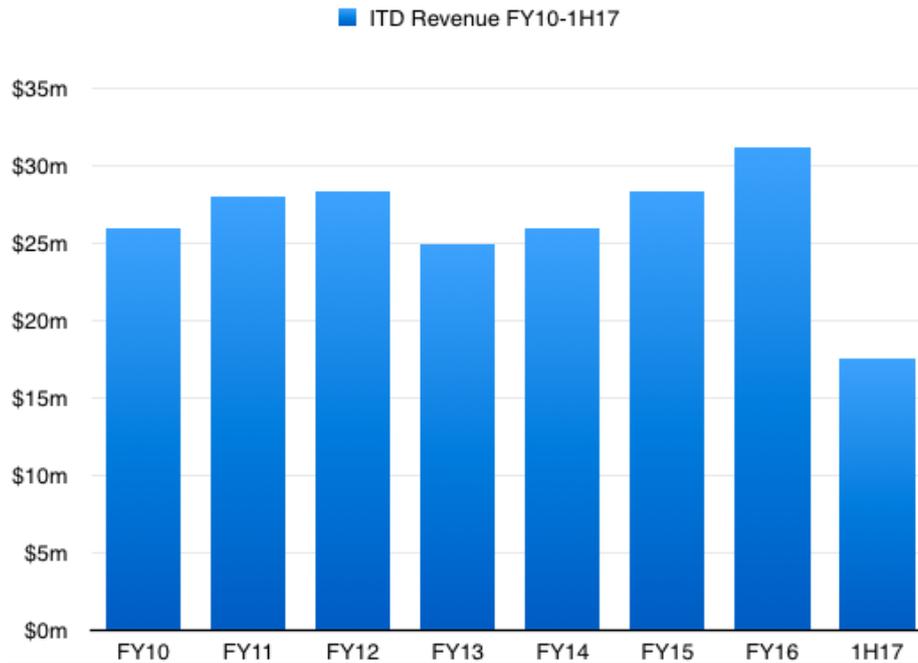
New Technologies: The blood culture testing market is experiencing strong growth as recognition of the need for comprehensive testing increases. As a result companies are investing heavily into new technologies to reduce the risks associated with contaminated samples and the introduction of new technologies could pose a risk to ITL BioMedical. However, the business is not standing still and continues to invest heavily into new product development as well as working closely alongside key partners like bioMerieux, which would presumably keep the business ahead of market trends.

Currency Fluctuations: The BioMedical business is the primary driver of growth moving forward and being an exporter the business is exposed to the fluctuation of currencies, primarily the USD. A decent portion of costs are in MYR given the Bemban manufacturing facility.

## **Financials**

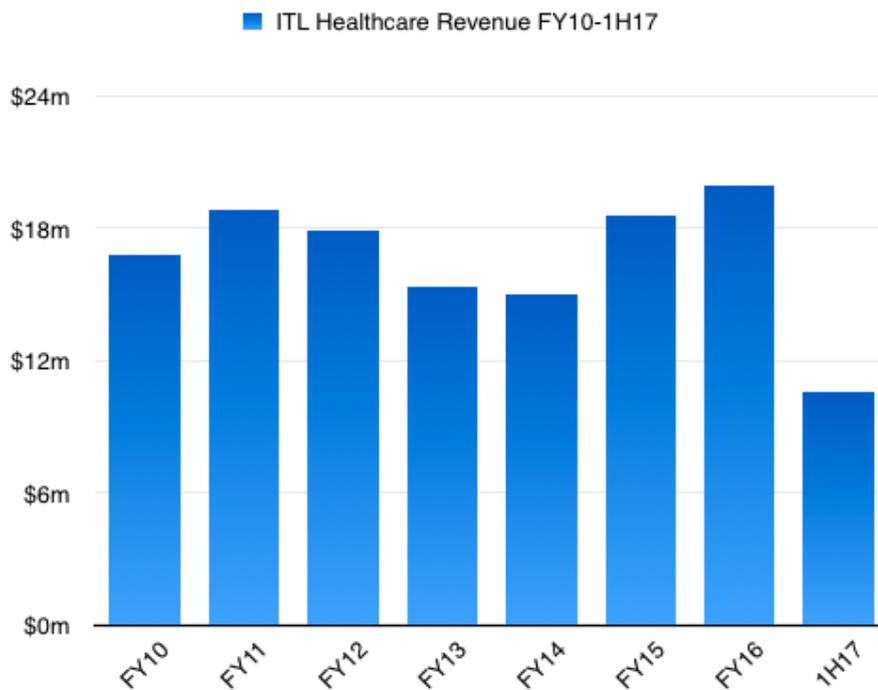
ITL BioMedical, the core of the investment thesis, grew sales by 25% in FY16 and that momentum has continued into FY17 with 1H17 sales up 27%. EBITDA jumped 54% to \$2.5m for 1H17 and management have given a very optimistic outlook to the market suggesting that 2H should continue to show strength.

The following charts provide some context as to ITD's revenue and earnings over the years. The first chart of ITD revenue shows that since Bill Mobbs regained control the company has managed to grow group revenue from FY10 to FY16 with that growth becoming more consistent from FY13 onwards post divestment of the SE Asian Healthcare business and the steadying of the blood bank market after a couple of years of consolidation.

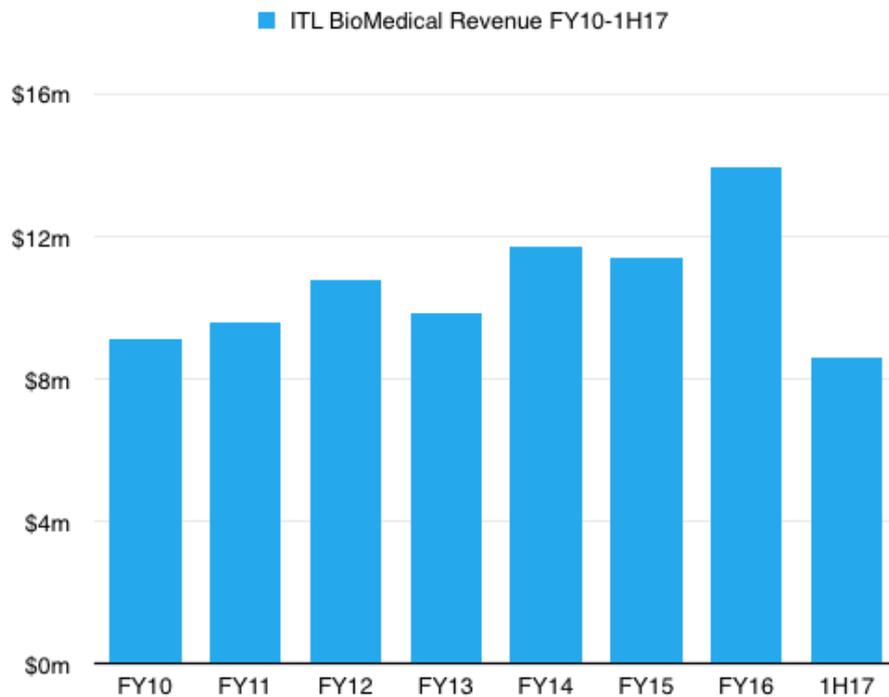


**ITD Revenue FY10-1H17**

The following two charts break down that revenue between ITL Healthcare and ITL BioMedical. What you'll see is that while ITL Healthcare revenues experienced a steady decline in the earlier years before resuming growth more recently, ITL BioMedical has experienced far more steady sales growth over the period with that growth strengthening over the last couple of years with the renewed global push for the BioMedical products, and accelerating further in the last 12 months (see strong 1H17 result).

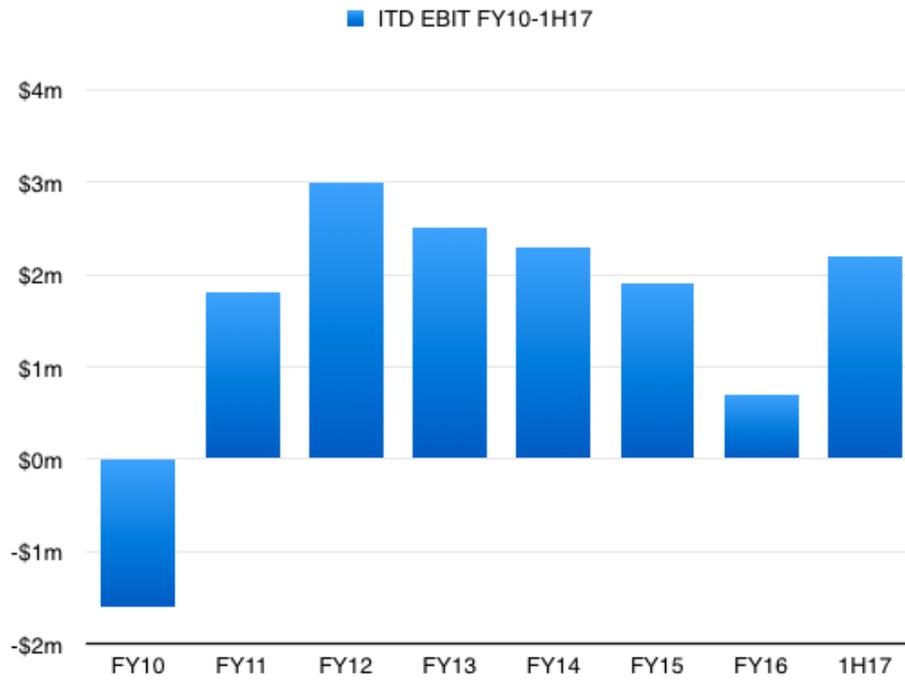


**ITL Healthcare Revenue FY10-1H17**



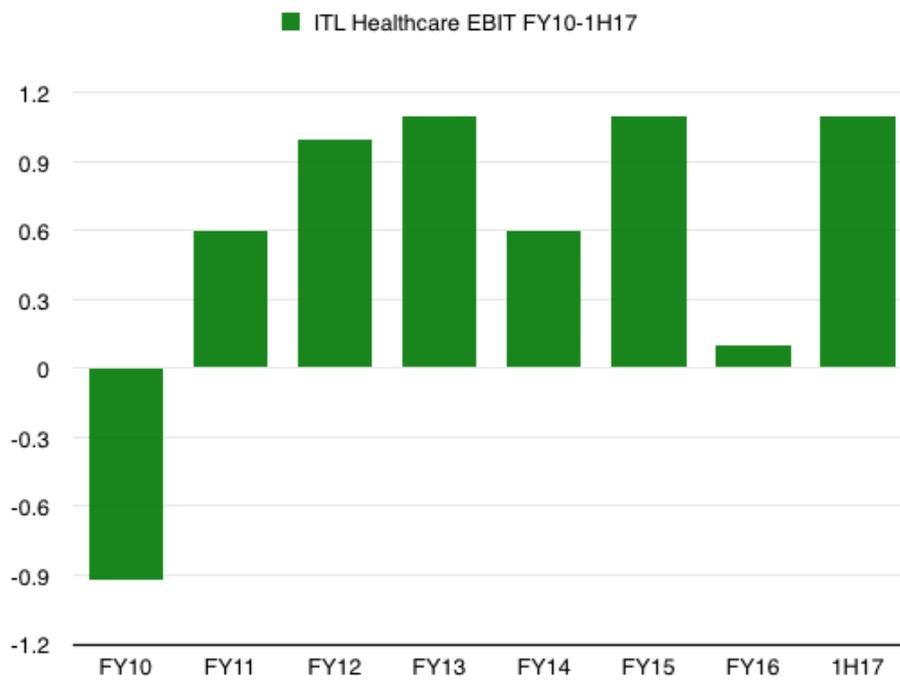
#### ITL BioMedical Revenue FY10 to 1H17

Next, take a look at ITD EBIT from FY10-FY16, shown below. A few things to note. Firstly, there is a sharp turnaround in the years following Bill's return. Then earnings stagnate from FY14-FY16 despite the steady revenue growth outlined in the charts shown above. There are a few important reasons for this. Firstly, and as shown further below, ITL Healthcare EBIT has been very volatile ranging from >\$1m EBIT to barely break even last year, while ITL BioMedical has remained far more consistent. As this report has outlined ITL Healthcare is the tougher of the two (due to the CPP business) that has only recently been turned around. Second, from FY14-15 there was an increased investment in growth including spend associated with the purchase and investment in the new Malaysian manufacturing facility, expanding production capacity and the acquisition/related costs of MHT. Third, and more recently, FY16 saw a breakdown of equipment in the Malaysian plant which held back ITL BioMedical's earnings growth, that has since been rectified. Finally, and most importantly, take a look at the 1H17 result for ITD. This strong performance is a reflection of 1) the restructuring of ITL Healthcare to return that business to profit and 2) the ongoing strong sales growth of ITL Biomedical starting to flow through to the bottom line. Management have signalled that momentum is expected to continue into 2H17.



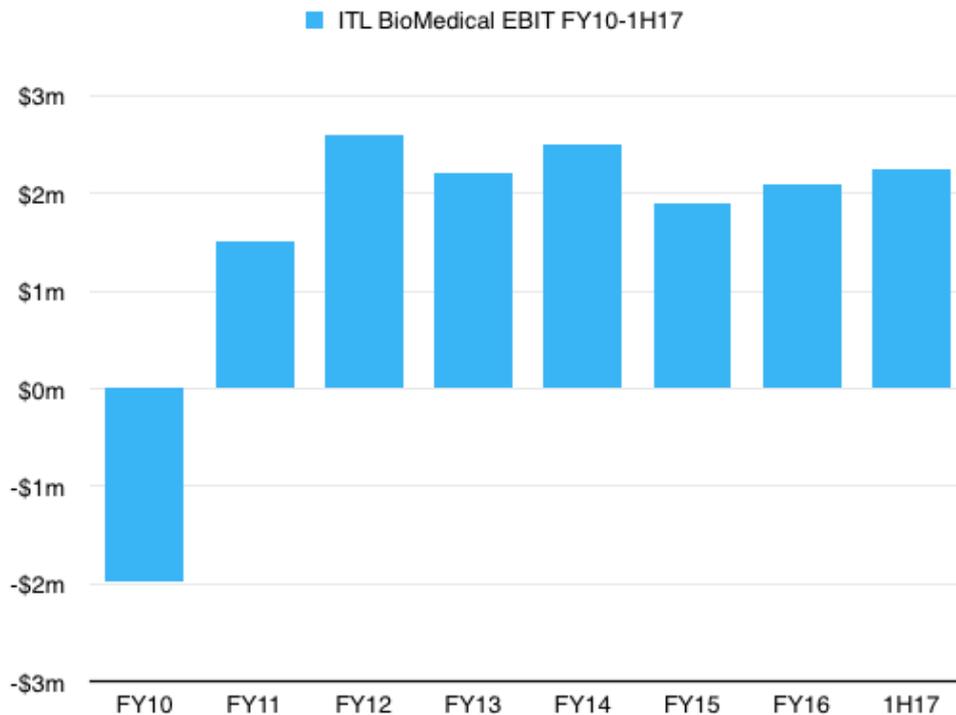
**ITD EBIT FY10-1H17**

ITL Healthcare returned to profitability:



**ITL Healthcare EBIT FY10-1H17**

ITL BioMedical experiencing strong growth that has started to be reflected in 1H17, already surpassing last year's result:



ITL BioMedical EBIT FY10-1H17

So as it stands today we have a business that has spent the last 2-3 years investing heavily in growth and capacity expansion, with that investment now flowing through nicely to the bottom line. ITL BioMedical is driving the company's growth with sales growing >25% and gross margins north of 60%, an equation that will result in some very attractive earnings growth in FY18 should it be sustained. As this report has outlined there is a case to argue that sales growth actually accelerates from here.

The company has ample tax assets to ensure the tax rate for FY17 remains below 10% (if not 0) with FY18 likely to move higher as they are utilised. Net debt is ~\$5m, which is comfortable but not ideal (ideal being zero). Roughly half of this is associated with the procedure pack business so there should be some improvements yet to come as inventory management is improved. The business is generating good free cash flow so debt levels will continue to come down over time.

The Healthcare business is primarily AUD revenue as it is domestically focused while the BioMedical business is largely USD. While ITL BioMedical sells into well over 50 countries (soon to expand to 150+ with the BioMerieux agreement) they do so through distributors and most of the purchases are made in USD. For example with the bioMerieux agreement ITL sell to them in USD with product sent to the French warehouse and then dispatched to the various end customers all over the world.

A significant portion of costs are in Malaysian currency as production is increasingly sourced from ITL's Malaysian plant. As a result the key currencies to watch are the USD and MYR. Looking at seasonality over the last seven financial years (FY10-FY16) the average revenue splits between 1H/2H for each business are shown below:

ITL Healthcare: 1H = 52%, 2H = 48%

ITL BioMedical: 1H = 48.6%, 2H = 51.4%

What the above suggests is that the Healthcare business has a stronger weighting to the 1H (this makes logical sense, there is a rush to complete surgeries before the December holidays and in January surgeons are away on vacation making it a slow month). Because Healthcare revenues comprise a larger chunk of total revenue it means that at a group level revenue may be slightly weighted towards 1H, but since BioMedical makes up a much larger portion of earnings the split is likely to be far more even at the profit level. The BioMedical business has typically had a slight leaning towards 2H strength though this is likely due to the growth being experienced by the business.

It is the momentum in the BioMedical business that underpins management's outlook for a strong full year result despite some historical seasonality in the Healthcare business.

These figures line up with our expectation that 2H17 may see Healthcare revenue slightly weaker than 1H but that BioMedical should continue to be strong. At a group level this gets us to a conservative estimate of a 55/45 earnings split though 50/50 is certainly achievable. This would see EBITDA come in at \$4.9-\$5.5m for FY17. Ongoing growth is expected in FY18.

### **Capital H Thesis**

The focus of the Capital H investment thesis for ITL is the BioMedical business. This is a high quality medical device business that is being overlooked by the market. It has generated consistently high gross margins for many years and is in a new growth phase as the global potential of its products are being recognised with tailwinds from favourable industry trends. The relationship with bioMerieux is significant and likely not yet fully understood by the market. It has the potential to provide a source of growth over a number of years while in the short term the pick up in SSK volumes should begin in 2H17 resulting in FY17 being a strong one for the BioMedical business. Investors should take note that the very impressive 1H17 result was achieved before any volume increases associated with the SSK global distribution agreement meaning the benefits of this deal, which management has stated is significant, are still to come and should build on the momentum in the BioMedical business.

*"Significant growth in SSK sales anticipated, already one of ITL's biggest profit generators."  
– ITL Presentation 20th February 2017*

The Healthcare business, in particular CPP, is tough but management are to be credited for the work done in turning it around. Recent new and renewal contracts should ensure FY17 is a decent one for ITL Healthcare. A potential divestment of the CPP business would act as a large catalyst and if it occurred would likely push the share price to levels well above where it stands today. And if business as usual continues then we should see some improvements in 2H from better purchasing and a margin uplift from moving production of procedure packs to Malaysia in FY18. This is the base case assumption for the ITL thesis while a divestment should be considered (very large but potential) upside.

MHT is an opportunity that is difficult to assess in quantum but given costs are likely to remain under control and the share price isn't factoring in any value for the business, the downside appears rather limited. It could potentially provide some of the optionality that helps drive the share price higher as key milestones are achieved. The core business can quite easily fund MHT and any progress in this start up can only be beneficial to the share price. And indeed if the direct to consumer pathology market in Australia follows anything like the growth path that the US market has set then MHT, as the first mover domestically, will have tailwinds at its back.

The management team, led by Bill Mobbs who owns 36%, are well incentivised and many in key positions have been there for the long term. The company recently announced a transaction that brought on a specialist small cap fund manager to whom Bill sold some of his stock. Fellow director Mark Peatey also picked up about \$200k worth of stock in this transaction which is a decent vote of confidence. Well known small cap fund manager TBF Investment Management recently announced they had gone substantial in ITL (though this is a different fund to the one that purchased stock off Bill Mobbs earlier). There is no broker coverage but it is likely that will change as the story becomes more well known.

Management have told the market that the full year result is expected to be strong even with some seasonality. A conservative assumption would be a 55/45 earnings split for 1H/2H given some seasonality in ITL Healthcare, but ITL BioMedical may post a more impressive performance (say 50/50 split or a bit better). That would have the stock trading on 11-12x earnings for FY17 based on current prices.

Given the very positive outlook from management one would assume the sales growth in ITL BioMedical will continue into FY18 and if it does we will see some very nice operating leverage at play. Consider that ITL BioMedical is growing sales at 25%+ with gross margins ranging from 60-85% depending on the product and the fact that medical device companies trade on well above market multiples. It is not difficult to envision fair value for ITL being materially above the current share price.

In this thesis we aren't attributing any value to MHT but it's worth considering that this business does provide some nice optionality (and is unlikely to actually be worth zero). At the moment the stock price is undervaluing the core business in its own right and assigning no value to MHT. There is the possibility that firstly the stock continues to revalue to reflect a more appropriate valuation for ITL's core business and secondly that the market starts to wake up to the opportunity within MHT. Investors may recall Compumedics (ASX: CMP) followed a similar path from undervalued but highly profitable core business driving a re-rate that was extended as the market factored in the optionality in their loss making but high potential e-Health business, helped along by increasing broker coverage. ITD is now in a similar position.

ASX-listed medical device companies trade on a wide range of multiples, but so long as they can demonstrate a clear forward path for revenue growth, are operating in markets with tailwinds and can clearly communicate their story then multiples in the high teens and well above are the norm. Based on broker estimates CMP trades on 19x, ELX on 50x and CGS on 20x FY18 earnings. That is too broad of a range to use as an accurate guide but certainly ITD, which is likely on just a single digit PE for FY18, stands out as attractive value and worth a close look from investors.

The stock has performed well of late but with a recent pullback there is a compelling case to argue that ITL is worth significantly more than the current share price. It remains under the radar for most investors but that will change so long as ITL BioMedical can continue its strong performance. And as sales pick up off the back of the bioMerieux global distribution agreement the market should increasingly take a liking to the ITL growth story. Based on the above research Capital H has taken a large position in ITL Ltd.



Voted Australia's 16<sup>th</sup> most  
Innovative Company by the  
Financial Review

