

PORTFOLIO UPDATE

22Jun16

### IDT AUSTRALIA LTD (ASX.IDT)

#### INVESTMENT PROPOSITION

#### The Business:

- US FDA approved generic drug portfolio
- Two in-house products, one FDA approved
- Growing contract drug development revenues
- Growing contract drug manufacturing revenues
- Growing clinical trial revenues (CMAX, Adelaide)

Approaching major revenue inflection point with impending product launches

Further pipeline expansion planned

High tech 12,000m<sup>2</sup> facility in Melbourne, replacement value ~\$75m

Specialization in high potent and difficult to manufacture drugs



Aggregate Addressable Market over US\$750m

www.idtaus.com.au

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### 35 YEAR HISTORY A PLATFORM FOR RAPID GROWTH

**IDT Service Business:** 

**Provides revenues and capabilities** 

Drug development services revenues













Contract drug manufacture revenues















Transformative M&A

2014 and onwards

**IDT Specialty Generics:** 

Leverages facilities and multiplies margins

Revenue Step Change via Proprietary IDT Generic Drug Portfolio

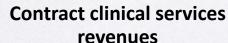




























## IDT GENERIC PORTFOLIO SNAPSHOT

- 25 products with multiple SKUs
- Aggregate US addressable markets C. USD750m
- Variety of clinical indications
- Most are solid oral dose (tablets or capsules)
- Good facility fit to IDT Boronia manufacturing
- Established distribution arrangements for US (ANI & Mayne)
- Discussions in train for EU and Japan
- CMO (Wellspring) appointed for certain products to speed path to market



# IDT PORTFOLIO OVERVIEW

Aminophylline	Leucovorin
Carbi/Levodopa	Methoxsalen
Ciprofloxacin	Mexiletine
Clarithromycin	Nefazodone
Dexamethasone	Nortriptyline
Dextroamphetamine	Pindolol
Diflunisal	Prazosin
Dipyridamole	Procainamide
Doxazosin	Procainamide ER
Etodolac	Temozolomide
Etodolac ER	Tetracycline
Flecainide	Thiotepa
Fluconazole	



# IDT PORTFOLIO PROGRESS and POTENTIAL

Product	Priority	Manufacturer	<b>US Distributor</b>	Addressable Market (USD millions, 2015)
Carbi/Levodopa	1	Wellspring	ANI	\$65
Diflunisal	1	Wellspring	ANI	\$9
Doxazosin	1	IDT	ANI	\$84
Flecainide	1	IDT/Wellspring	TBA	\$39
Leucovorin	1	IDT	ANI	\$2
Mexiletine	1	Wellspring	ANI	\$12
Nefazodone	1	TBA	ANI	\$14
Pindolol	1	Wellspring	ANI	\$10
Prazosin	1	Wellspring	ANI	\$42
Temozolomide	1	IDT	Mayne Pharma	\$200
Thiotepa	1	TBA	TBA	\$80
			Total Cat. 1	\$557
Ciprofloxacin	2	IDT	ANI	\$45
Clarithromycin	2	Wellspring	ANI	\$16
Fluconazole	2	Wellspring	ANI	\$98
Nortriptyline	2	IDT/Wellspring	ANI	\$25
			Total Cat. 2	\$184
			Total Cat. 1 & 2	\$741

EU and Japanese opportunities exist for some of these products



# IDT LOWER PRIORITY MOLECULES

Product	Priority	Manufacturer	US Distributor
Aminophylline	3		ANI
Dexamethasone	3		ANI
Dextroamphetamine	3		ANI
Dipyridamole	3		ANI
Etodolac	3		
Etodolac ER	3		
Methoxsalen	3		ANI
Procainamide	3		
Procainamide ER	3		
Tetracycline	3		ANI

These dossiers will be assessed for divestment or JV with third parties



## COMPLETED PORTFOLIO MILESTONES as at 02Jun16





## PRODUCT TEMOZOLOMIDE

- Addressable US market USD200m (Dec15)
- Treatment for a variety of malignant brain cancers
- ANDA filed Dec2013
- ANDA approved by FDA March 2016
- Mayne Pharma appointed as distributor
- IDT manufacture
- Likely launch window Q2 FY2016/17



## PRODUCT DOXAZOSIN

- Addressable US market USD84m (Dec15)
- Treatment for benign prostatic hyperplasia
- Development and stability studies complete
- Likely Prior Approval Supplement pathway
- ANI Pharma appointed as distributor
- IDT manufacture



## PRODUCT LEUCOVORIN

- Addressable US market USD2m (Mar16)
- Treatment to improve chemotherapy effectiveness
- Development complete
- Likely CBE30 pathway
- IDT manufacture
- ANI Pharma appointed as distributor



## PRODUCT PINDOLOL

- Addressable US market USD10m (Dec15)
- Treatment for hypertension
- Development complete
- Likely CBE30 pathway
- ANI Pharma appointed as distributor
- Wellspring manufacture



## PRODUCT PRAZOSIN

- Addressable US market USD42m (Dec15)
- Treatment for high blood pressure, PTSD and panic disorder
- Development commenced
- Likely CBE30 pathway
- ANI Pharma appointed as distributor
- Wellspring manufacture



## PRODUCT MEXILETINE

- Addressable US market USD12m (Dec15)
- Treatment for cardiac arrhythmias
- Development commenced
- Prior Approval Supplement pathway
- ANI Pharma appointed as distributor
- Wellspring manufacture



## PRODUCT THIOTEPA

- C. USD12m API product for IDT over the next 4 years
- Addressable global finished good (injectable) market USD80m (estimate)
- Treatment for stem cell transplant preparedness and relapsing hormone dependant cancers
- Development prototyping complete
- ANDA pathway in US or equivalent in other markets
- Strong interest from distribution partners
- Working to identify suitable manufacturing partner
- Launch window to be advised once manufacturing location determined



## IDT US DISTRIBUTOR SNAPSHOT (15Jun16)

#### **ANI Pharma (NASDAQ:ANIP)**

- Market cap. USD \$630m
- Located Minnesota, USA
- US wide distribution capability
- Focus on specialty generics sales
- Aggressive market shares for their own products to date

#### Mayne Pharma (ASX.

- Market cap. USD \$1.3b
- Located Salisbury, Australia and North Carolina, USA
- US wide distribution capability
- Focus on specialty generics sales
- Good sales into specific channels such as HMOs



## PRODUCT CONTRACT MANUFACTURING

- Revenue growth continues, with reactivation of most of the Melbourne site
- Some headcount expansion has been needed to service this reactivation
- Higher than anticipated CAPEX: repairs, facility remodelling and capacity expansion
- Reliable base of routine contract manufacture has been created, supplemented by new contract development work



## PLANT AND SITE UPGRADES AND EXPANSIONS

- Building of new cytotoxic capsuling and packing lines
  - Expanded capacity for temozolomide
  - Better segregation of potent and non-potent molecules
- New, larger tableter and blender:
  - Tripling of tableting capacity
  - Reduction in doxazosin CoGS
  - Better segregation of potent and non-potent molecules
- Sterile capacity upgrades:
  - Renewal of much of the sterile infrastructure
  - Resumption of sterile capacity after many years of non-use
- CMAX build completion
  - On-time and on-budget
  - Very promising early evidence of -> increased flexibility, and hence capacity and throughput



## PRODUCT CLINICAL SERVICES

- Oldest, largest and most experienced clinical unit in Australia
- New, state-of-the-art facility recently opened in Adelaide
- Consistent double digit year on year growth
- Reliable, predictable profits and free cash generation
- Strong forward work order book



#### TARGET

### 2016 MILESTONES

- INCREASED ORGANIC SALES TOWARDS PROFITABILITY
- CONTINUE TO PROGRESS TEMOZOLOMIDE THROUGH FDA
- MOVEMENT OF AN ADDITIONAL INTERNAL PRODUCT TOWARDS MARKET
- PROGRESS WITH RE-COMMERCIALISATION OF US GENERIC PORTFOLIO
- MOVE FROM SERVICE PROVIDER, TOWARDS SPECIALTY GENERIC PHARMACEUTICAL COMPANY, GROWTH & PROFITS



#### FINANCIALLY

### POSITIONED TO DELIVER

#### **FINANCIALS (ASX: IDT)**

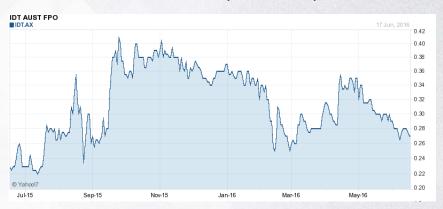
	FY2014	FY2015	1H FY2016
REVENUE	\$13.4m	\$15.7m	\$6.5m
EARNINGS AFTER TAX	(\$6.6m)	(\$3.0m)	(\$3.5m)
NET ASSETS	\$25.5m	\$39.2m	\$43.7m
CASH	\$2.40	\$0.13	\$4.90
DEBT*	\$0.1m	\$0.0m	\$0.0m

<sup>\* \$4.25</sup>m currently unused debt facility available

#### FY guidance:

Improvement 2015 to 2016
Improvement from H1 2016 to H2

#### MARKET CAP \$58.9m (20Jun16)



#### **CAPITAL STRUCTURE**

(1)	SHARES ON ISSUE	219.4M
0	UNLISTED OPTIONS	500,000
0	STOCK PRICE (20Jun16)	A\$0.27
0	AV. TRADING VOL./DAY	117,000
<b>(D)</b>	TOP 20 SHAREHOLDERS	61.8%



### SUMMARY 2016/17 YEAR OUTLOOK

- Modest growth of base business revenues expected to continue
- Cost containment while supporting growth and new business remains a key focus
- First proprietary generic product launches expected
- More generics to move into recommercialization in line with priorities flagged

