



Oct16

# IDT AUSTRALIA LTD (ASX.IDT) INVESTMENT PROPOSITION

## The Business:

- ① US FDA approved 23 generic drug portfolio
  - ① Two in-house products, one FDA approved
  - ① Growing contract drug development revenues
  - ① Growing contract drug manufacturing revenues
  - ① Growing clinical trial revenues (CMAX, Adelaide)
- Aggregate Addressable Market over US\$750m

Approaching major revenue inflection point with impending product launches

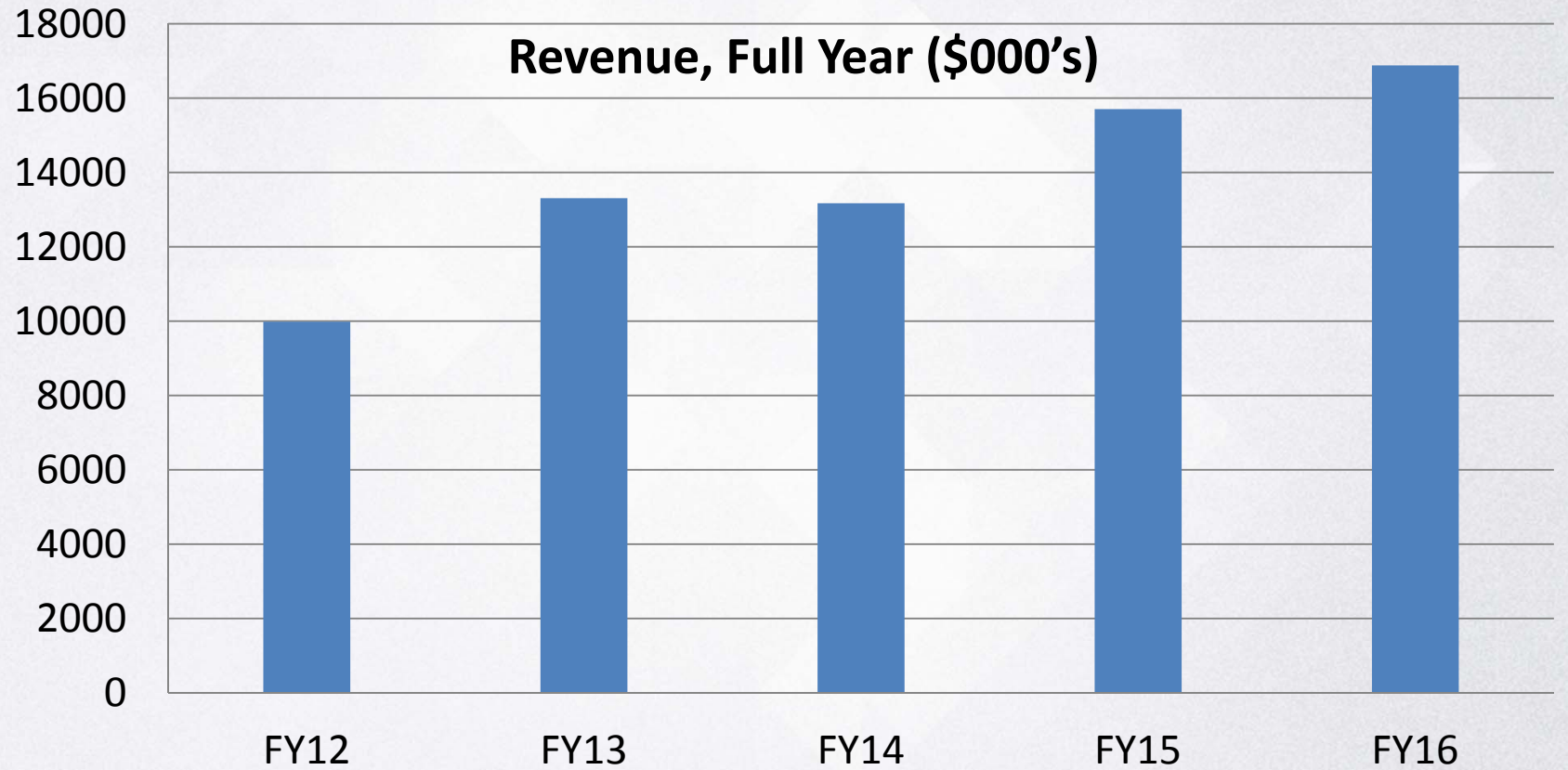
Further pipeline expansion planned

High tech 12,000m<sup>2</sup> facility in Melbourne, insured value ~\$90m

Specialization in high potent and difficult to manufacture drugs

2015/16

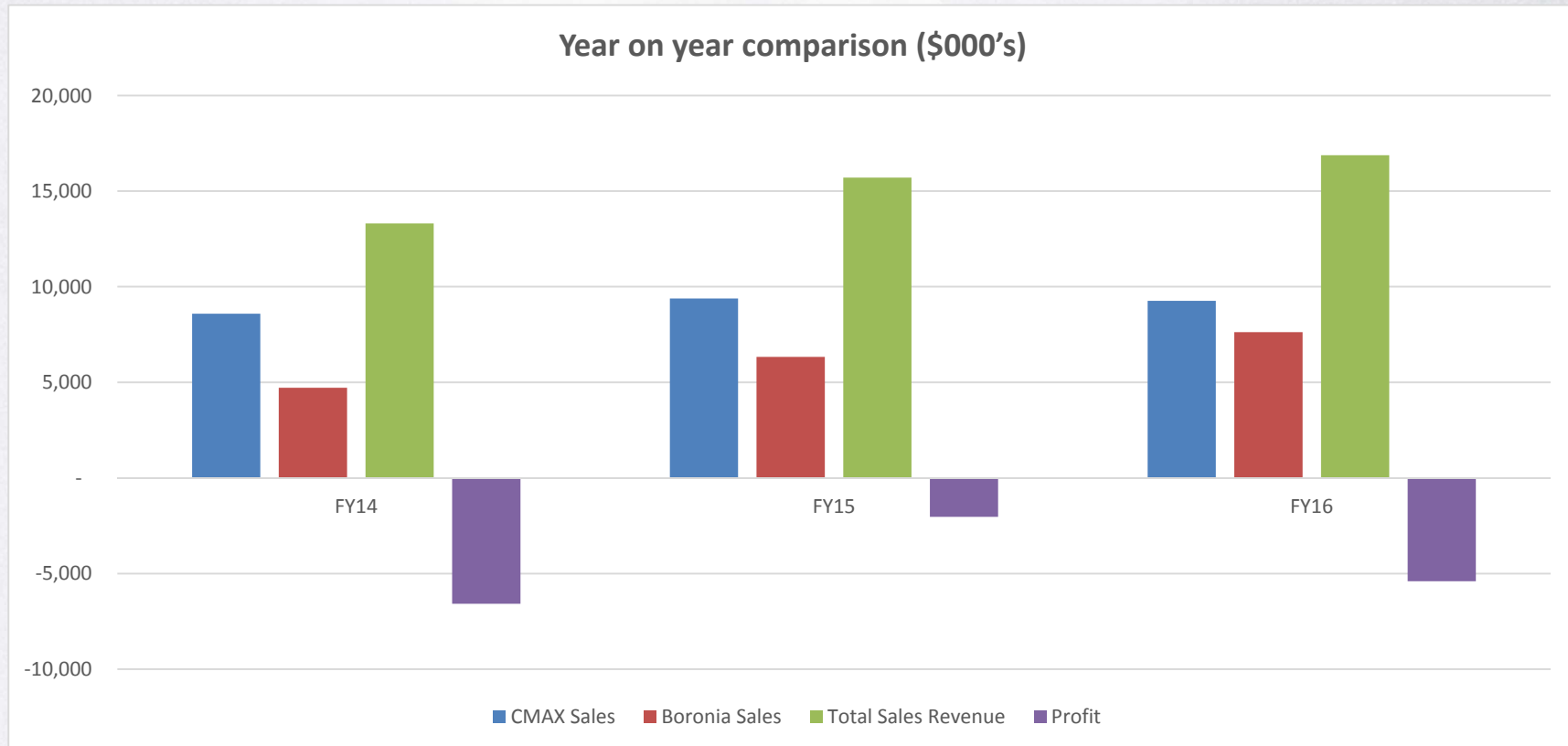
# YEAR ON YEAR GROWTH



CAGR 14%

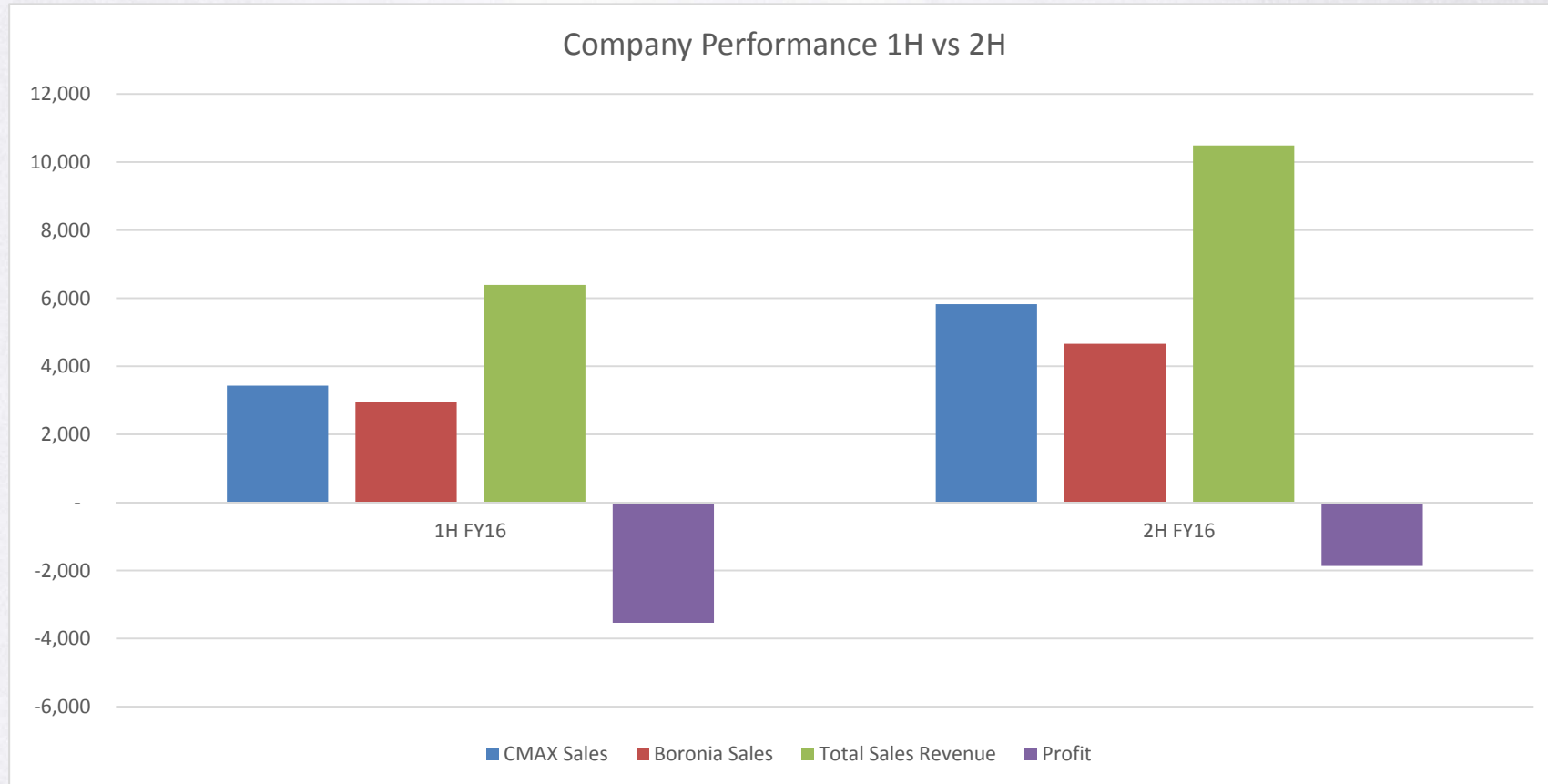
# 2015/16

## COMPARATIVE RESULTS



2016 results impacted by investment in Capacity, and generics development

# 2015/16 HALF YEAR RESULTS



IDT results improved in the second half against the long term trend

# IDT GENERIC PORTFOLIO SNAPSHOT

- 24 product portfolio with multiple SKUs
- Aggregate US addressable markets US\$750m+
- Further product in development
- 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 PROGRESS and POTENTIAL

Product	Priority	Manufacturer	US Distributor	Addressable Market (US\$ millions, 2015)
Carbi/Levodopa	1	Wellspring	ANI	\$65
Diflunisal	1	Wellspring	ANI	\$9
Doxazosin	1	IDT	ANI	\$84
Flecainide	1	TBA	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
			<b>Total Cat. 1</b>	<b>\$557</b>
Ciprofloxacin	2	TBA	ANI	\$45
Clarithromycin	2	Wellspring	ANI	\$16
Fluconazole	2	Wellspring	ANI	\$98
Nortriptyline	2	IDT/Wellspring	ANI	\$25
			<b>Total Cat. 2</b>	<b>\$184</b>
			<b>Total Cat. 1 &amp; 2</b>	<b>\$741</b>

EU and Japanese opportunities exist for some of these products

# COMPLETED PORTFOLIO MILESTONES as at Oct16





# PRODUCT TEMOZOLOMIDE

- Addressable US market US\$200m (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 US\$84m (Dec15)
- Treatment for benign prostatic hyperplasia
- Development and stability studies complete
- Likely Prior Approval Supplement pathway
- ANI Pharma appointed as distributor
- IDT manufacture
- Likely launch window H2 FY2016/17

# PRODUCT PINDOLOL

- Addressable US market US\$10m (Dec15)
- Treatment for hypertension
- Development complete
- Likely CBE30 pathway
- ANI Pharma appointed as distributor
- Wellspring manufacture
- Likely launch window Q2/3 FY2016/17

# PRODUCT THIOTEPA

- C. US\$12m API product for IDT over the next four years
- Addressable global finished good (injectable) market US\$80m (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. US\$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. US\$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, price increases

# 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 ACHIEVED



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)

\$m	Total 2015	1 <sup>st</sup> Half 2016	2 <sup>nd</sup> Half 2016	Total 2016	Year on Year %
Revenue	15.7	6.4	10.5	16.9	7.6%
Operating Loss After Tax	3.0	3.5	0.5	4.0	33.9%

\* \$4.25m currently unused debt facility available

## CAPITAL STRUCTURE

🌐 SHARES ON ISSUE	248.2M
🌐 UNLISTED OPTIONS	500,000
🌐 STOCK PRICE (17Oct16)	A\$0.21
🌐 AV. TRADING VOL./DAY	172,100
🌐 TOP 20 SHAREHOLDERS	61.8%

## MARKET CAP \$52.1m (17Oct16)



# 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 this year, with steady rollout to follow
- More generics to move into re-commercialization in line with priorities flagged