

AFT Pharmaceuticals

Updates on several products

AFT Pharma recently made announcements affecting several of its marketed products. Importantly, the Australian Therapeutic Goods Administration (TGA) has made an interim decision that all products containing codeine (a key competitor to AFT's Maxigesic) are to be rescheduled to prescription-only as of 1 February 2018. Also, AFT has licensed its cold/flu product Maxiclear to Angelini in 16 European countries. Additionally, due to continued Metoprolol shortages, the New Zealand government pharmaceutical buying agency, PHARMAC, has requested proposals from alternative providers, potentially affecting AFT's sales of the product.

Year end	Revenue (NZ\$m)	PBT* (NZ\$m)	EPS* (NZ\$)	DPS (NZ\$)	P/E (x)	Yield (%)
03/15	56.2	(11.4)	(9.46)	0.0	N/A	N/A
03/16	64.0	(10.8)	(0.11)	0.0	N/A	N/A
03/17e	70.4	(14.3)	(0.15)	0.0	N/A	N/A
03/18e	99.1	0.3	0.00	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Codeine to require a prescription in Australia

With the TGA decision, all codeine-containing products, which are mostly combination painkillers and cough medicines, will require a prescription and will no longer be available over the counter (OTC) after 1 February 2018. With a key OTC competitor now re-scheduled, Maxigesic may increase its market share (currently <1%) in the Australian market for OTC ibuprofen and paracetamol/acetaminophen containing products, which is estimated by IMS Health to be ~NZ\$400m.

Maxiclear licensed in 16 European countries

AFT has licensed the combination cold/flu product Maxiclear (500mg paracetamol/acetaminophen and 5mg phenylephrine hydrochloride) to Angelini in 16 mostly southern and eastern European countries for undisclosed upfronts, milestones and royalties. The total addressable market in estimated to be approximately NZ\$420m in the licensed areas by IMS Health.

Further Metoprolol downside possible

Due to an ongoing global shortage of Metoprolol, PHARMAC has requested proposals for either a dual listing or sole supply of the beta blocker. As AFT is currently the sole provider of Metoprolol, it is possible it may lose the entire contract for the product, which accounts for ~4% of sales. Timing of a PHARMAC decision is unclear but proposals are due by 27 January 2017.

Valuation: NZ\$461m or NZ\$4.76 per share

We are maintaining our valuation of NZ\$461m or NZ\$4.76 per share as we await further clarity on the financial impact of the recent announcements. We expect to update our valuation following clinical results from the NasoSURF and Maxigesic IV clinical studies.

Product update

Pharma & biotech

20 January 2017

Price	NZ\$2.75
Market cap	NZ\$266m
	NZ\$0.68/US\$
Net debt (NZ\$m) at September 201	16 5.99
Shares in issue	96.8m
Free float	10%
Code	AFT
Primary exchange	NZX
Secondary exchange	ASX

Share price performance



Business description

AFT Pharmaceuticals is a specialty pharmaceutical company that operates primarily in Australasia but has product distribution agreements across the globe. The company's product portfolio includes prescription and over-the-counter drugs to treat a range of conditions and a proprietary nebuliser.

Next events

IV Maxigesic Phase III data	2017
Analysts	

-	
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Edison profile page

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Product updates

AFT has recently announced updates that affect several products, most notably Maxigesic, Maxiclear and Metoprolol. With regards to Maxigesic, the TGA has confirmed an interim decision that all products containing codeine will require a prescription from 1 February 2018. These products were up-scheduled due to the risk of dependence and adverse events associated with their use. In total, market research conducted by the company suggests that 40-47% of current consumers who buy 750 million OTC codeine analgesics each year in Australia would switch to another OTC analgesic rather than get a doctor's prescription. Maxigesic currently has less than 1% of the Australian market for OTC ibuprofen and paracetamol/acetaminophen containing products, which is estimated by IMS Health to be ~NZ\$400m, and with this decision could start increasing its share. Maxigesic reaching the 6.5% market share in Australia, which it has attained in the New Zealand market, would equate to NZ\$26m in sales for the product compared to less than 1% currently.

AFT has also announced that it has been able to develop a new Maxigesic oral formulation, which would enable greater clinical benefits and improve the intellectual property position. It is also working on a formulation that can be taken without water, which would be suitable for countries where clean water is not readily available. The IV version is on track with a pivotal Phase III underway in the United States.

Maxiclear licensed by Angelini in Europe

AFT has licensed the combination cold/flu product Maxiclear (500mg paracetamol/acetaminophen and 5mg phenylephrine hydrochloride) to Angelini in 16 mostly southern and eastern European countries (Italy, Spain, Portugal, Russia, Turkey, Czech Republic, Slovakia, Romania, Poland, Hungary, Austria, San Marino, Vatican City, Greece, Bulgaria and Croatia). The total addressable market is estimated by IMS Health to be approximately NZ\$420m in the licensed areas. Angelini is a private Italy-based healthcare company with over €1.5bn in annual sales and is currently partnered with AFT on Maxigesic in Italy, Turkey, San Marino and Vatican City. Per the agreement, AFT will receive undisclosed upfront, commercial and regulatory milestones and royalties.

Metoprolol at risk

Metoprolol is a beta blocker used to treat angina, high blood pressure and heart failure. Since November 2015, there has been an ongoing global shortage of the active ingredient, metoprolol succinate, due to a manufacturing issue. In an effort to alleviate the shortage, PHARMAC has requested proposals for either a dual or sole supplier of the product. AFT is currently the sole supplier and will be submitting a proposal to PHARMAC but clearly its contract is at risk. The company announced at its H1 FY17 results that Metoprolol issues hurt sales by NZ\$0.6m and estimates it currently accounts for 4% of sales (putting the total at risk between NZ\$2m and NZ\$3m). Proposals are due by 27 January 2017 but it is unclear when the new supplier would take over. Also, PHARMAC will only consider proposals from companies with existing registrations for metoprolol, which limits the pool of candidates to AFT, AstraZeneca (the originator) and Mylan. On the positive side, AFT announced the company has NZ\$7m in PHARMAC tenders outstanding and it recently won hospital prescription contracts totalling A\$3.5m per year. So any downside coming from a loss in the Metoprolol contract will likely be replaced by other areas.

NasoSURF and Pascomer

NasoSURF is a proprietary nebuliser for the intranasal delivery of medication with an initial application in conscious sedation, which the company estimates to be a \$1.2bn opportunity in the



US. An IND is expected this year with pharmacokinetic and efficacy studies likely to be concluded in the next 12-15 months. Licensing discussions are expected to commence around that time as well.

Pascomer (aka Pascaderm in certain markets) is a topical dermatology drug to treat a hereditary skin condition that is being developed as part of a 50/50 joint venture with Medicas Group. The IND is expected in 2017, which will enable a pivotal study to begin. The company estimates potential peak sales for the initial indication to be \$600-800m in the US and EU.

Valuation

We are maintaining our valuation of NZ\$461m or NZ\$4.76 per share as we await further clarity on the financial impact of the recent announcements. We expect to update our valuation following clinical results from the NasoSURF and Maxigesic IV clinical studies.

Exhibit 1: DCF sensitivity table (NZ\$)

	Terminal EBIT margin						
Terminal revenue growth	15%	25%	34%	38%	42%		
-2%	2.28	3.00	3.65	3.93	4.22		
-1%	2.36	3.15	3.85	4.16	4.48		
0%	2.46	3.32	4.09	4.44	4.78		
1%	2.57	3.53	4.39	4.78	5.16		
2%	2.72	3.80	4.76	5.20	5.63		
3%	2.91	4.14	5.24	5.73	6.23		
4%	3.16	4.59	5.88	6.45	7.03		
5%	3.51	5.22	6.77	7.46	8.14		

Source: Edison Investment Research

Financials

We are maintaining our forecasts for the time being. We currently forecast NZ\$70.4m in FY17 sales and with a March 2017 fiscal year end do not expect the recent announcements to have much of an impact. We forecast FY18 sales of NZ\$99.1m and believe the growth attributable to overseas Maxigesic sales will far outpace any recent issues.



Exhibit 2: Financial summary

	NZ\$000	2014	2015	2016	2017e	2018e	2019e	2020e
March		NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP
PROFIT & LOSS								
Revenue		48,939	56,241	64,014	70,415	99,113	126,219	151,885
Cost of Sales		(28,609)	(35,083)	(40,435)	(41,926)	(50,261)	(58,052)	(65,367)
Gross Profit		20,330	21,158	23,579	28,490	48,852	68,168	86,518
EBITDA		(341)	(9,659)	(7,821)	(11,588)	2,134	17,241	30,372
Operating Profit (before amort. and except.)		(201)	(9,530)	(7,667)	(11,434)	2,288	17,395	30,526
Intangible Amortisation		82	99	114	114	114	114	114
Exceptionals		0	0	0	0	0	0	0
Other		1,594	(546)	(618)	834	2,199	2,310	2,427
Operating Profit		1,475	(9,977)	(8,171)	(10,487)	4,601	19,820	33,067
Net Interest		(963)	(1,908)	(3,145)	(2,829)	(2,000)	(2,000)	00,007
Profit Before Tax (norm)		(1,164)	(11,438)	(10,812)	(14,263)	288	15,395	30,526
Profit Before Tax (reported)		512	(11,885)	(11,316)	(13,316)	2,601	17,820	33,067
Tax		59	282	42	(10,010)	(112)	(4,343)	(8,579)
Profit After Tax (norm)		(1,105)	(11,156)	(10,770)	(14,362)	177	11,056	21,951
Profit After Tax (reported)		571	(11,603)	(11,274)	(14,302)	2,488	13,477	21,951
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Average Number of Shares Outstanding (m)		1.2	1.2	96.8	96.8	96.8	96.8	96.8
EPS - normalised (NZ\$)		(0.94)	(9.46)	(0.11)	(0.15)	0.00	0.11	0.23
EPS - normalised fully diluted (NZ\$)		(0.94)	(9.46)	(0.11)	(0.15)	0.00	0.11	0.23
EPS - (reported) (NZ\$)		0.48	(9.84)	(0.12)	(0.14)	0.03	0.14	0.25
Dividend per share (NZ\$)		0.00	0.00	0.00	0.00	0.00	0.00	0.00
Gross Margin (%)		41.5	37.6	36.8	40.5	49.3	54.0	57.0
EBITDA Margin (%)		N/A	N/A	N/A	N/A	2.2	13.7	20.0
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A	2.2	13.8	20.0
1 0 0 (1)()		N/A	11/7	IN/A	IN/A	2.5	13.0	20.1
BALANCE SHEET								
Fixed Assets		1,824	2,488	3,249	3,681	4,167	4,708	5,299
Intangible Assets		1,419	1,669	2,111	2,399	2,687	2,975	3,263
Tangible Assets		405	411	407	551	749	1,002	1,305
Investments		0	408	731	731	731	731	731
Current Assets		23,569	30,725	62,055	46,445	48,387	61,013	72,779
Stocks		12,654	14,686	17,686	18,248	21,876	25,267	28,451
Debtors		9,558	11,251	16,288	16,806	20,147	23,270	26,202
Cash		1,248	4,700	28,055	11,366	6,338	12,450	18,100
Other		109	88	26	26	26	26	26
Current Liabilities		(9,208)	(10,148)	(13,511)	(13,842)	(15,981)	(17,981)	(19,858)
Creditors		(9,208)	(10,148)	(13,511)	(13,842)	(15,981)	(17,981)	(19,858)
Short term borrowings		0	0	0	0	0	0	0
Long Term Liabilities		(13,137)	(20,739)	(23,161)	(23,161)	(23,161)	(23,161)	(11,581)
Long term borrowings		(13,137)	(20,739)	(23,161)	(23,161)	(23,161)	(23,161)	(11,581)
Other long term liabilities		0	0	0	0	0	0	0
Net Assets		3,048	2,326	28,632	13,123	13,412	24,579	46,640
CASH FLOW								
Operating Cash Flow		614	(11,479)	(11,326)	(13,060)	(2,160)	13,263	26,670
Net Interest		(963)	(11,479) (1,908)	(11,326) (3,145)	(13,060) (2,829)	(2,180)	(2,000)	20,070
Tax		(903)	282	(3,143)				
					(100)	(112)	(4,343)	(8,579)
Capex		(502)	(483)	(694)	(700)	(754)	(808)	(860)
Acquisitions/disposals		0	12.050	20.257	0	0	0	0
Financing		(8)	12,859	38,357	0	0	0	0
Dividends		0	(763)	(1,652)	0	0	0	0
Net Cash Flow		(800)	(1,492)	21,582	(16,689)	(5,027)	6,112	17,231
Opening net debt/(cash)		11,426	11,889	16,039	(4,894)	11,795	16,823	10,711
HP finance leases initiated		0	0	0	0	0	0	0
Other		337	(2,658)	(649)	0	0	0	0
Closing net debt/(cash)		11,889	16,039	(4,894)	11,795	16,823	10,711	(6,520)
Source: Edison Investment Research, c	ompany repo	orts						

Source: Edison Investment Research, company reports



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