EDISON

AFT Pharmaceuticals

Development update

A licensing deal for Pascomer

Pharma & biotech

AFT Pharmaceuticals has reported a North American licensing deal for Pascomer, a topical formulation of rapamycin being developed for facial angiofibromas in tuberous sclerosis complex (TSC), to private US-based Timber Pharmaceuticals. Timber will fund clinical development and provide AFT with over US$10m in upfront, development and regulatory milestones, as well as over US$10m in sales milestone payments and royalties. An Investigational New Drug Application has been approved by the FDA. The first of two 120-patient clinical studies is expected to start shortly, with results in 2020.

Year end	Revenue (NZ$m)	PBT* (NZ$m)	EPS* (NZ$)	DPS (NZ$)	P/E (x)	Yield (%)
03/18	81.2	(12.9)	(0.13)	0.0	N/A	N/A
03/19	85.1	(2.5)	(0.03)	0.0	N/A	N/A
03/20e	99.9	6.4	0.07	0.0	45.6	N/A
03/21e	119.5	17.6	0.18	0.0	17.7	N/A

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

An attractive orphan market

According to the US National Institute of Neurological Disorders and Stroke, TSC affects between 25,000 and 40,000 Americans and one to two million people worldwide. Angiofibromas, which can be highly disfiguring, affect around 80% of patients with TSC. Current therapies are typically surgical, such as chemical peeling, excision and laser surgery.

Evidence of rapamycin efficacy

Oral rapamycin was first approved in 1999 for immunosuppressant use. Initial evidence of its potential efficacy in angiofibromas occurred in a patient who initiated oral rapamycin because of renal transplantation and her facial angiofibromas improve markedly. A review of recent studies indicates that compounded topical formulations of rapamycin have improved lesions in 94% of subjects although there is no topical formulation available commercially.

A low-risk development plan for AFT

The licensing agreement with Timber allows AFT to retain some of the upside potential of Pascomer but without having to yield near- to medium-term profitability to fund its development. Timber will have full responsibility for R&D investment, while AFT will collect high-margin royalties if Pascomer is successfully developed.

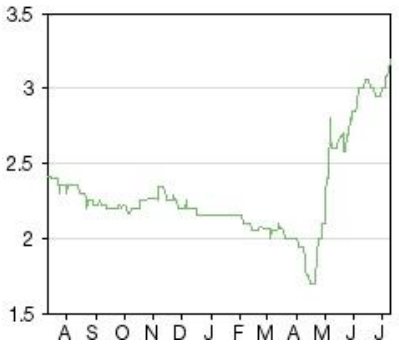
Valuation: NZ$495m or NZ$5.09 per share

We are maintaining our valuation of NZ$495m or NZ$5.09 per share. To be conservative, we are not including Pascomer development in our estimates due to its early stage but we will revisit this as the programme progresses. Also, the company reiterated its operating profit target is between NZ$9m and NZ$12m for FY20.

10 July 2019

Price	**NZ$3.19**
Market cap	**NZ$310m**
	NZ$0.65/US$
Net debt (NZ$m) at 31 March 2019	34.8
Shares in issue	97.3m
Free float	21.6%
Code	AFT
Primary exchange	NZX
Secondary exchange	ASX

Share price performance



%	1m	3m	12m
Abs	6.3	64.4	32.4
Rel (local)	1.6	53.5	17.8

52-week high/low NZ$3.19 NZ$1.70

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

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Edison profile page

Pascomer for facial angiofibromas in TSC

AFT has announced it has licensed Pascomer, which is being developed for facial angiofibromas in TSC patients, to Timber Pharmaceuticals for over US$10m in upfront, development and regulatory milestones, as well as over US$10m in sales milestone payments and royalties.

TSC is a multisystem, autosomal dominant genetic disorder resulting from a mutation in one of two tumour suppressor genes, TSC1 (encoding hamartin) or TSC2 (tuberin). TSC is characterised by benign tumours, known as hamartomas, in various organs, most commonly the skin, brain, kidneys, heart and lungs. A hamartoma is composed of an overgrowth of mature cells and tissues, which normally occurs in the affected tissue. TSC affects both sexes and all ethnic groups, affecting as many as 25,000–40,000 individuals in the US and one to two million individuals worldwide, with an estimated prevalence of one in 6,000 newborns according to the US National Institute of Neurological Disorders and Stroke. Angiofibromas, which can be highly disfiguring, affect around 80% of patients with TSC.

Pascomer is a topical version of rapamycin (marketed as Rapamune by Pfizer), an immunosuppressant used for prophylaxis of organ rejection in patients receiving kidney transplants. It is also approved for the treatment of lymphangioleiomyomatosis, a progressive disease often associated with TSC that results in lung destruction. Rapamycin is an inhibitor of mammalian target of rapamycin (mTOR), which has many functions in protein synthesis and cell growth and is aberrantly activated in patients with TSC, making it a logical target for development in the treatment of this disease.

Initial evidence of rapamycin's potential efficacy in angiofibromas occurred in a patient who initiated oral rapamycin because of renal transplantation and her facial angiofibromas improve markedly.[1] As rapamycin is a potent immunosuppressive, systemic exposure for the sake of improving facial angiofibromas is not ideal and there have been several small studies of topical rapamycin in this indication.

According to one review, 94% of the 84 patients treated with a topical rapamycin in various studies showed improvement in their lesions.[2] In the one randomised, double-blind, placebo-controlled study (with 23 subjects) in the review, 73% of the subjects who received treatment reported a subjective improvement in their angiofibromas compared to 38% in placebo although the p value was not significant (p=0.18), likely because of the size of the study.[3] Importantly, although a variety of different topical formulations were used, rapamycin was detected in only three patients out of the 74 tested for serum rapamycin levels, indicating a lack of systemic exposure. However, one of the issues with the various topical formulations used in these studies is that stability is limited. AFT believes it has developed a formulation using a proprietary dermal delivery technology that would be stable and hence commercially viable.

For intellectual property, there are no unexpired patents related to Rapamune in the FDA Orange Book so AFT appears to be free to operate. We do not know the extent of the patent estate for Pascomer but at the very least it will be eligible for orphan drug exclusivity, which is seven years in

1 Hofbauer et al. The mTOR inhibitor rapamycin significantly improves facial angiofibroma lesions in a patient with tuberous sclerosis. *British Journal of Dermatology* 2008 159, pp. 473–475

2 Balestri et al., Analysis of current data on the use of topical rapamycin in the treatment of facial angiofibroma in Tuberous Sclerosis Complex. *Journal of the European Academy of Dermatology and Venereology.* 2015, 29, 14–20

3 Koenig et al. Topical rapamycin therapy to alleviate the cutaneous manifestations of tuberous sclerosis complex. *Drugs in R&D* 2012 Sep: 12(3): 121–126

the United States and 10 years' worth of data exclusivity in the EU (although we would expect patent coverage to go well beyond that due to the proprietary nature of the formulation).

As part of the agreement, Timber will cover the clinical trial costs associated with clinical development. An Investigational New Drug Application has already been approved by the FDA with the first of two 120-patient clinical studies expected to start shortly in eight centres in the US (the Mayo Clinic), Australia, New Zealand, Spain and the UK. Results are expected in 2020.

Valuation

We are maintaining our valuation of NZ$495m or NZ$5.09 per share as Pascomer development is too early stage to include in our estimates. We will revisit this as the programme progresses.

Exhibit 1: DCF sensitivity table (NZ$/share)

	Terminal EBIT margin				
Terminal revenue growth	**30.00%**	**34.00%**	**36.0%**	**40.0%**	**45.0%**
-2%	3.42	3.71	3.85	4.14	4.50
-1%	3.60	3.92	4.08	4.39	4.79
0%	3.83	4.17	4.35	4.69	5.13
1%	4.10	4.48	4.68	5.06	5.54
2%	4.44	4.87	**5.09**	5.52	6.06
3%	4.87	5.37	5.62	6.11	6.73
4%	5.45	6.03	6.32	6.90	7.62
5%	6.27	6.96	7.30	8.00	8.86

Source: Edison Investment Research

Financials

We are maintaining our financial estimates as the precise size of the upfront payment is undisclosed. Also, the company has reiterated its operating profit target of between NZ$9m and NZ$12m for FY20.

Exhibit 2: Financial summary

NZ$000	2018	2019	2020e	2021e
March	NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP
PROFIT & LOSS				
Revenue	81,176	85,127	99,947	119,505
Cost of Sales	(45,880)	(44,397)	(51,547)	(56,407)
Gross Profit	35,296	40,730	48,400	63,098
EBITDA	(10,479)	5,797	10,288	21,447
Operating Profit (before amort. and except.)	(10,353)	5,912	10,403	21,562
Intangible Amortisation	214	204	204	204
Exceptionals	0	0	0	0
Other	(364)	1,716	1,802	1,892
Operating Profit	(10,503)	7,832	12,409	23,658
Net Interest	(2,527)	(8,375)	(4,000)	(4,000)
Profit Before Tax (norm)	(12,880)	(2,463)	6,403	17,562
Profit Before Tax (reported)	(12,666)	(2,259)	8,409	19,658
Tax	(58)	(168)	0	0
Profit After Tax (norm)	(12,938)	(2,631)	6,403	17,562
Profit After Tax (reported)	(12,724)	(2,427)	8,409	19,658
Average Number of Shares Outstanding (m)	97.2	97.3	97.3	97.3
EPS - normalised (NZ$)	(0.13)	(0.03)	0.07	0.18
EPS - (reported) (NZ$)	(0.14)	(0.03)	0.09	0.20
Dividend per share (c)	0.00	0.00	0.00	0.00
Gross Margin (%)	43.5	47.8	48.4	52.8
EBITDA Margin (%)	N/A	6.8	10.3	17.9
Operating Margin (before GW and except.) (%)	N/A	6.9	10.4	18.0
BALANCE SHEET				
Fixed Assets	8,291	12,334	15,540	18,785
Intangible Assets	5,118	8,239	11,245	14,366
Tangible Assets	330	357	557	681
Investments	2,843	3,738	3,738	3,738
Current Assets	48,312	51,261	53,543	69,382
Stocks	24,412	25,158	27,958	30,594
Debtors	16,954	19,187	17,474	19,121
Cash	6,946	6,916	8,112	19,667
Other	0	0	0	0
Current Liabilities	(18,607)	(58,504)	(15,249)	(16,567)
Creditors	(18,489)	(16,368)	(15,249)	(16,567)
Short term borrowings	0	(41,750)	0	0
Long Term Liabilities	(30,654)	0	(41,750)	(41,750)
Long term borrowings	(30,654)	0	(41,750)	(41,750)
Other long term liabilities	0	0	0	0
Net Assets	7,342	5,091	12,084	29,850
CASH FLOW				
Operating Cash Flow	(6,582)	9,610	8,721	19,120
Net Interest	(4,264)	(8,375)	(4,000)	(4,000)
Tax	(58)	(168)	0	0
Capex	(2,853)	(3,465)	(3,525)	(3,564)
Acquisitions/disposals	(3,002)	(1,419)	0	0
Financing	877	0	0	0
Dividends	(412)	(134)	0	0
Net Cash Flow	(16,294)	(3,951)	1,196	11,556
Opening net debt/(cash)	7,446	23,708	34,834	33,638
HP finance leases initiated	0	0	0	0
Other	32	(7,175)	(0)	0
Closing net debt/(cash)	23,708	34,834	33,638	22,083

Source: Edison Investment Research, company accounts

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