

One-product companies currently on a knife edge



The dramatic declines in the share prices of Arpida and Targanta Therapeutics last week, down 84% and 86% respectively following a negative FDA advisory committee review of their antibiotic drugs, highlights the high level of risk associated with investing in companies who have put all their resources behind the development of one product.

Whilst constraints over cash and resources often ultimately dictates a one-product strategy for many small biotech and specialty companies, in today's financial climate this approach has become even riskier. An analysis of NPV data from EvaluatePharma reveals that for 72 companies, just one clinical stage product accounts for at least 95% of their total NPV and highlights those companies currently on a knife edge with just one filed or phase III drug and precious little cash to fall back on if trial results or regulatory reviews go awry (see table below).

At the mercy of regulators

For the following companies, just one filed product accounts for 100% of the total NPV currently being assigned to the company's products by analysts, according to EvaluatePharma's NPV Analyzer.

The problem for companies such as Dyax, Introgen Therapeutics and Advanced Life Sciences is that current cash reserves are almost empty, therefore a positive review of their drugs is absolutely vital to the companies' very survival.

Companies with a single product NPV = 100% of total NPV (filtered on filed products, ranked on years of cash)						
	Company	Product	Today's NPV (\$m)	Latest Cash (\$m)	Years of Cash	Market Cap. (\$m)
1	Dyax	DX-88	770	64	0.1	172
2	Introgen Therapeutics	Advexin	450	11	0.1	11
3	Advanced Life Sciences	Cethromycin (ABT-773)	495	9	0.1	10
4	Targanta Therapeutics	Oritavancin	446	59	0.4	23
5	NeurogesX	NGX-4010	584	53	0.5	21
6	Arpida	Iclaprim	630	59	0.7	15
7	Somaxon Pharmaceuticals	Silenor	303	33	1.0	22
8	TiGenix	ChondroCelect	305	46	1.1	88
9	Cypress Bioscience	Milnacipran	470	153	4	196
10	Pain Therapeutics	Remoxy	404	177	5	357
11	Intercell	Ixiaro	1,415	370	>7	1,306

The 35% slump in Somaxon Pharmaceuticals' shares on Monday with news that the FDA has delayed its review

of Somaxon's insomnia drug, Silenor, by three months is clear evidence of the potential volatility.

Whilst companies with significantly healthier cash reserves, such as Cypress Bioscience, Pain Therapeutics and Intercell are better placed to cope with a regulatory rejection as their immediate future is more secure, the impact of a negative decision is still likely to be significant.

Conversely, given the obvious difference between the potential NPV of the drugs and the respective companies' current market capitalisation, the upside should approval be granted is significant.

Definition of pivotal data

Focusing on companies currently with just one phase III product accounting for all of their current NPV, a similar analysis highlights the following 24 companies in particularly precarious position.

The problem for many companies still seeking a commercial partner for their products the desperate need for cash suggests their bargaining power is considerably weaker and with most share prices suffering heavy losses this year, some could be prime takeover candidates.

Companies with a single product NPV = 100% of total NPV (filtered on phase III products, ranked on years of cash)

	Company	Product	Today's NPV (\$m)	Latest Cash (\$m)	Years of Cash	Market Cap. (\$m)
1	Osiris Therapeutics	Prochymal	536	11	(0.1)	606
2	MannKind	Technosphere Insulin System	2,307	180	0.0	335
3	Aastrom Biosciences	Bone Repair Cells	200	22	0.1	55
4	ARIAD Pharmaceuticals	Deforolimus (MK-8669)	953	60	0.2	95
5	La Jolla Pharmaceutical	Riquent	367	41	0.3	38
6	Repros Therapeutics	Proellex	483	14	0.4	133
7	Theratechnologies	TH9507	314	32	0.7	73
8	OXIGENE	Zybrestat	431	18	0.8	27
9	Isotechnika	Trans-ISA247	686	29	0.8	13
10	Vanda Pharmaceuticals	Tasimelteon (VEC-162)	293	63	0.9	17
11	Cougar Biotechnology	CB7630	715	115	0.9	487
12	Dendreon	Provenge	786	114	1.0	439
13	Amsterdam Molecular Therapeutics	Glybera	346	62	1.0	83
14	Bioniche Life Sciences	Urocidin	1,967	4	1	25
15	NicOx	HCT 3012	862	196	1.1	644
16	Poniard Pharmaceuticals	Picoplatin	560	75	1.5	99
17	MolMed	TK	178	63	1.5	195
18	Affymax	Hematide	671	141	1.5	183
19	Protalix BioTherapeutics	prGCD	557	53	1.6	91
20	Vertex Pharmaceuticals	VX-950	4,121	822	1.6	3,712
21	Newron Pharmaceuticals	Safinamide	257	91	1.6	119
22	Dynavax Technologies	Heplisav	636	64	1.7	10
23	Biodel	VIAject	1,086	71	1.9	59
24	Infinity Pharmaceuticals	Retaspimycin (IV)	348	94	2.2	131