Evaluate Vantage

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Back to the drawing board for Sumitomo’s deal-making

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Yet another project brought in through business development fails, exposing Sumitomo’s limited pipeline.

When generics are causing your sales to flatline and profitability to come under pressure it is good to have planned ahead with deal-making. But matters are not helped when the deals you have done keep firing blanks.

This is the situation in which Sumitomo Dainippon Pharma finds itself, and of which it was reminded this week when the Boston Biomedical-derived napabucasin flunked a pivotal trial in pancreatic cancer. A rather limited late-stage pipeline puts pressure on the Japanese group to do more business development, but to do it more smartly than before.

That said, with limited firepower and a share price that has fallen 40% since January, Sumitomo looks unlikely to be able to finance any transformational deals. For the fiscal year ended March the group reported a cash balance of around $1.3bn.

Among the few bright spots is the imeglimin project it licensed from Poxel. After a long and tortuous development path this diabetes asset scored a surprise clinical trial success in April, which was followed by a second phase III hit in June (*Poxel tastes sweet success at last, April 9, 2019*).

Sumitomo only has Japan and Asia rights to imeglimin, and should now seriously be considering taking full ownership. Poxel, meanwhile, is capitalised at an undemanding $200m, and is likely to be seeking financing or business development opportunities.

Selected Sumitomo Dainippon projects, phase II or above			
Project	**Mechanism, use**	**Source**	**Note**
Filed			
Apomorphine Sublingual Film	D2 agonist, Parkinson's disease	Cynapsus Therapeutics, bought for $624m	CRL Jan 2019
Phase III			
SEP-225289	SNRI, ADHD	Sepracor, bought for $2.6bn	CRL Aug 2018
Napabucasin (BBI608)	NANOG, STAT3, Wnt inhibitor, cancer	Boston Biomedical, bought for $200m	Failed phase III pancreatic cancer study, Jul 2019
Imeglimin	OXPHOS inhibitor, diabetes	Licensed from Poxel for Asia	Phase III success, Apr & May 2019
Qinprezo	Topoisomerase II inhibitor, cancer	In-house, licensed to Sunesis	Failed phase III Valor study in 2015, making filing impossible
EPI-743	NQO1 regulator, mitochondrial diseases	Licensed from Bioelectron Technology	Studies in Friedreich's ataxia, Rett & Parkinson's "completed"
Phase II			
Alvocidib	CDK9 inhibitor, cancer	Tolero, bought for $200m	Targets competitive space dominated by Pfizer's Ibrance
SB623	Mesenchymal cell therapy, stroke	Licensed from Sanbio	Failed phase II stroke trial, Jan 2019
Amcasertib (BBI503)	Cell stemness kinase inhibitor, cancer	Boston Biomedical, bought for $200m	Development ongoing in liver cancer; other studies withdrawn or terminated
SEP-363856	5-HT1A & TAAR1 agonist, schizophrenia	Sepracor, bought for $2.6bn	Promising phase II data, Dec 2018
EPI-589	Unknown, ALS	Licensed from Bioelectron Technology	Promising phase II data, Sep 2018
DSP-7888	WT1 stimulant, cancer	In-house	Phase II data Apr 2020
TP-0903	AXL inhibitor, cancer	Tolero, bought for $200m	BergenBio yet to prove this mechanism's value
SEP-4199	Unknown, bipolar depression	In-house	Phase II data Mar 2020
Source: EvaluatePharma & clinicaltrials.gov.			

Apart from this Sumitomo has few significant pipeline assets worth watching; a phase II trial of SEP-4199 in depression will read out early next year, while SEP-363856 last year showed promise in schizophrenia and the company hopes it could become the first drug for the disease that does not target dopamine D2 receptors. Sumitomo got both assets through the $2.6bn acquisition of Sepracor in 2009.

But that move now looks ill-judged: Sepracor’s main asset was the insomnia drug Lunesta, which within five years saw its patent expire, causing sales to fall off the proverbial cliff.

To add insult to injury, another Sepracor-derived asset, the non-stimulant ADHD project SEP-225289, got a US complete response letter last August. Another complete response letter was dished out in January to a sublingual formulation of apomorphine that Sumitomo had acquired through the $624m takeover of Cynapsus Therapeutics.

Taken together with January's failure of SB623 in stroke, this week's discontinuation of napabucasin's phase III study in pancreatic ductal adenocarcinoma after a futility analysis completed a triple whammy of 2019 disappointments for Sumitomo. Napabucasin remains in phase III in colorectal cancer, but a pivotal lung cancer trial was earlier terminated.

The project had been originated by Boston Biomedical, and it is some solace that Sumitomo picked this company up for only $200m up front; the only other asset that came from Boston, amcasertib, looks to have been deprioritised, and it seems unlikely that many of the takeover's $540m development milestones have been triggered.

The acquisitions of Boston, along with Sepracor, Cynapsus and Tolero, were driven by realisation that the patents on Sumitomo's schizophrenia blockbuster, Latuda, would soon expire. At present the Japanese group seems to have delayed this threat until 2023 by striking authorised generic deals.

But this has only kicked the can down the road. With so few serious growth drivers in the pipeline Sumitomo cannot afford to take its eyes off business development opportunities.