EpiCept Corporation

Merger with Immune Pharmaceuticals

Edison investment research

Deal to form Immune Pharma

Pharma & biotech

EpiCept's search for a strategic transaction has resulted in a planned reverse-merger with Immune Pharmaceuticals, a private Israel-based biopharma company focused on antibodies for inflammatory disease and cancer. The resulting company – to be called Immune Pharmaceuticals Inc – will have bertilimumab, which is ready to enter Phase II trials for ulcerative colitis, as its lead product, together with three other clinical-stage programmes. EpiCept shareholders will end up with 22.5% of the new entity. EpiCept believes the deal offers its shareholders the best option to participate in economic value created by a potential future development/commercial partnership for AmiKet, its topical product for chemotherapy-induced peripheral neuropathy.

Year end	Revenue ($m)	PBT* ($m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/10	1.0	(15.4)	(32.1)	0.0	N/A	N/A
12/11	1.0	(15.3)	(22.9)	0.0	N/A	N/A
12/12e	7.7	(7.2)	(6.3)	0.0	N/A	N/A
12/13e	N/A	N/A	N/A	N/A	N/A	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation and exceptional items.

Merger to form Immune Pharmaceuticals Inc

The proposed transaction would effectively reverse-merge Epicept and Immune Pharmaceuticals. EpiCept will issue ordinary shares to acquire all of Immune's outstanding shares, which would leave EpiCept's shareholders with approximately 22.5% ownership of the resulting company (fully diluted). Registration statements have not yet been filed, so the exact financial terms are not known. However, the transaction will likely require in excess of 300m new shares to be issued. The deal is expected to close during Q113, following shareholder approval.

Immune develops next-generation antibodies

Immune is a privately held Israeli biopharmaceutical company focused on the development of antibody therapeutics for treating inflammatory diseases and cancer. Its lead product, bertilimumab (previously CAT-213), is licensed for non-ophthalmic indications from the Canadian biotech iCo Therapeutics (and originated at Cambridge Antibody Technology in the UK). Immune also has a technology, NanomAbs, for generating antibody drug conjugates, in preclinical studies.

Financials: Funded to Q113

EpiCept ended Q3 with $1.1m in cash and $1.1m in restricted cash. A pro forma cash figure for the new company is not yet known. However, it is likely that the new company would have to raise additional funds in the short term.

Valuation: EV of $9m

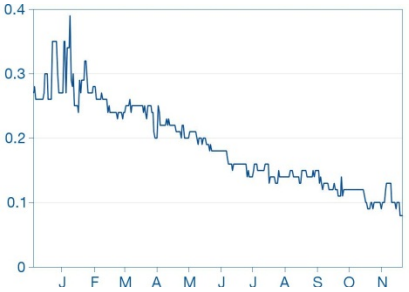
EpiCept has an EV of $9m, based on its market cap of $7m, a senior secured loan of $4.1m and Q3 cash/restricted cash of $2.2m. Our previously published rNPV for EpiCept alone, which principally reflected AmiKet, was $29m.

22 November 2012

Price	US$0.08
Market cap	US$7m

Shares in issue	92.2m
Free float	99%
Code	EPCT
Primary exchange	NASDAQ OMX Stockholm
Other exchanges	OTCQX

Share price performance



%	1m	3m	12m
Abs	(11.1)	(46.7)	(74.2)
Rel (local)	(8.4)	(45.8)	(77.9)
52-week high/low	US$0.40		US$0.03

Business description

EpiCept is a US specialty pharmaceutical company focused on the development and commercialisation of pharmaceutical products for cancer treatment and pain management.

Next events

AmiKet licensing deal	TBA
Crolibulin trial progress to Phase II	Q412
Q4 results	Q113

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Immune Pharmaceuticals datasheet

Immune Pharmaceuticals Inc R&D pipeline

Product	Indication	Development notes
Bertilimumab (CAT-213)	Ulcerative colitis	42-pt Phase IIa study in active moderate to severe UC planned. Non-ophthalmic indications licensed from **iCo Therapeutics** (which itself licensed the product from **AstraZeneca's MedImmune).**
AmiKet (NP-1)	Peripheral neuropathy	Amitriptyline/ketamine fixed dose combination in topical formulation. Three Phase II trials completed (see below).
Ceplene (histamine dihydrochloride)	Maintenance of CR in AML	Rights held outside EU (where marketed) and Pacific rim. US development on hold, as a result of issues with FDA's proposed design.
Crolibulin (EPC2407)	Anaplastic thyroid cancer	70-pt Phase I/IIa study of crolibulin/cisplatin in ATC. The Phase I stage consists of dose-escalation cohorts of 3-6 pts, dosed with crolibulin/cisplatin in 21-day treatment cycles. Primary endpoint of the first stage: S/T and MTD. The Phase II stage consists of pts randomised to crolibulin/cisplatin or cisplatin monotherapy. Primary endpoint of second stage is PFS. Results expected: Q413.
Azixa (verubulin)	Glioblastoma multiforme	Part completed Phase II trial in 30 pts in combination with carboplatin after failure on temozolomide showed 6 SD and 2 PRs (7.8 and 16 months duration), for ORR of 42%.

Competing biological agents for moderate to severe ulcerative colitis (Phase II/III)

Product	Mechanism	Studies
Simponi (golimumab)/ **J&J/Merck & Co/ Mitsubisihi Tanabe**	Anti-TNF-alpha MAb	Regulatory submissions filed in Jul 2012 for use in pts with an inadequate response to conventional therapy, based on positive results in Phase III (PURSUIT) study in moderately to severely active UC.
Vedolizumab/**Takeda (Millennium)**	a4b7 integrin MAb	Regulatory filings expected on basis of positive 895-pt Phase III study (GEMINI I), which showed statistically significant difference vs pbo (45% vs 14%) in corticosteroid-free clinical remissions. 2,200-pt open label Phase III study in UC and Crohn's (GEMINI LTS). Also positive result in 1,115-pt Phase III study (GEMINI II) in Crohn's.
Catridecacog/**Novo Nordisk**	rDNA Factor XIII	80-pt Phase II study (results: Jan 2013).
AMG181/**Amgen/ AstraZeneca**	alpha4/beta7 MAb	315-pt Phase II study (results: April 2014).
Tralokinumab/**AstraZeneca**	Anti-IL13 MAb	110-pt Phase II study (results: Jun 2013).
etrolizumab (RG7413)/**Roche**	beta7 MAb	120-pt Phase II study (results: Jan 2015).
PF-00547659/**Pfizer**	MadCAM MAb	300-pt Phase study (TURANDOT; results: Jan 2017).
Vatelizumab/SAR339658/ **Sanofi Aventis**	Alpha 2 MAb	84-pt Phase II study (FUSIA; results: Sept 2013).
BMS-936557/**Bristol-Myers Squibb**	Anti-IP-10 MAb	289-pt Phase II study (results: Dec 2012).

AmiKet datasheet

Indication	Trial results
Chemotherapy induced peripheral neuropathy	460-pt, six-week Phase II study meets primary endpoint of showing significant reduction in CIPN intensity, using average daily neuropathy intensity scores vs placebo (p<0.001). The subgroup (>50% of the ITT) with taxane-induced CIPN shows a significant reduction in average daily neuropathy intensity scores (p=0.034). Secondary endpoints confirm superiority vs placebo, while safety profile was comparable to placebo.
Diabetic neuropathy	215-pt, four-week Phase II study shows trend in primary endpoint, change in pain intensity (p=0.0715), and secondary endpoints including proportion of pts achieving a >30% reduction of pain scores (60% vs 48%, p=0.076) and >50% reduction in pain scores (33% vs 21%, p=0.078). Data indicate analgesic effect builds over time hence a longer study should reach statistical significance.
Post-herpetic neuralgia	360-pt four-week Phase II non-inferiority trial shows significant pain relief based on change in pain intensity (p=0.024) and equivalence in pain relief to gabapentin. AmiKet shows favourable safety profile vs gabapentin. 63% of treated pts achieve a >30% reduction in pain score (p=0.033).

Competing products in Phase III trials for CIPN

Product	Company	Notes
Baclofen, amitriptyline and ketamine gel	NCI	148-pt Phase III study for CIPN. Results due: 2011.
Glutathione	NCI	186-pt Phase III study for prevention of paclitaxel/carboplatin-induced PN (results: Q414).
Glutamine	Sanofi	200-pt Phase III study of oral glutamine and calcium-magnesium with calcium-magnesium alone in the prevention of oxaliplatin-induced neurotoxicity in colorectal cancer (results: Q412).
Ca gluconate/ Mg sulphate	NCI	354-pt Phase III study of oral glutamine and calcium-magnesium with calcium-magnesium alone in the prevention of oxaliplatin-induced neurotoxicity in CRC (results: Jul 2014).
Acetyl-l-carnitine	NCI GOG	322-pt Phase III trial for preventing PN in ovarian cancer (results: May 2015).
Lyrica (pregabalin)	Pfizer	200-pt Phase III trial for prevention/reduction of oxaliplatin-induced PN (results due: Aug 2012).

Source: Edison Investment Research

Update: Merger with Immune Pharmaceuticals

EpiCept is to merge with the private Israel-based company, Immune Pharmaceuticals Ltd, to form a new quoted US-Israeli biotech to be called Immune Pharmaceuticals Inc. Immune is developing antibodies for treating inflammatory diseases and cancer and will provide what will be the lead product for the new company, bertilimumab (previously CAT-213), which is ready to enter Phase II studies for ulcerative colitis. Immune Pharmaceuticals will inherit three programmes from EpiCept: AmiKet (Phase III ready for chemotherapy-induced peripheral neuropathy), Azixa (which has been in Phase II trials for glioblastoma multiforme) and Crolibulin (in an NCI-sponsored Phase I/II trial for anaplastic thyroid cancer).

Merger terms

EpiCept has entered into a definitive merger agreement with Immune Pharmaceuticals, under which EpiCept will issue ordinary shares in exchange for all of Immune's outstanding shares. EpiCept's shareholders will have an approximately 22.5% ownership of the combined company (fully diluted) and Immune's shareholders will hold 77.5%. The proportionate ownership of the combined is subject to adjustment based on the size of EpiCept's liabilities at the time of the merger and does not initially include the exercise or conversion of EpiCept's options and warrants whose current exercise/conversion prices are significantly higher than the current trading price of EpiCept's shares.

Registration statements have not yet been filed, so the exact financial terms are not known. However, the transaction will likely require over 300m new shares to be issued. The deal is subject to customary closing conditions, including shareholder approval, and is expected to close during Q113.

Immune's current chairman/CEO, Dr Daniel Teper, will become the chairman and CEO of the new company, which will have a dual headquarters in Herzliya-Pituach, Israel, and in the New York City area, with research laboratories in Rehovot, Israel. Immune's board director Dr David Sidransky will become vice-chairman. The board of directors will comprise up to six current Immune directors and at least one current EpiCept director. Immune's management team will include Robert Cook, EpiCept's interim CEO, who will become the CFO, and Dr Stephane Allard, EpiCept's CMO, who will become the CMO. Serge Goldner, Immune's CFO will become the new executive vice-president and COO.

Immune develops next generation mAbs for inflammation and cancer

Immune licensed worldwide rights for systemic indications of bertilimumab in June 2011 from the Canadian biotech, iCo Therapeutics, which is developing the product (as iCo-008) for ophthalmic applications[1]. Bertilimumab is a monoclonal antibody targeting eotaxin-1 that originated at Cambridge Antibody Technology (CAT) and later licensed by iCo from AstraZeneca's MedImmune.

Immune's licensing deal with iCo included an upfront payment of $500k and $32m of milestone payments, net sales royalties and a 6.14% equity stake in Immune. iCo had earlier licensed exclusive worldwide rights to bertilimumab in 2006 from AstraZeneca's MedImmune unit (the successor to CAT) for an upfront payment of $400k and $7m of milestone payments. Immune has also licensed from Yissum, the technology transfer unit of the Hebrew University of Jerusalem, the injectable applications of the antibody nanoparticle conjugate technology (NanomAbs) developed by Professor Shimon Benita.

Bertilimumab is a full human monoclonal antibody to eotaxin-1, a chemokine involved in eosinophilic inflammation, angiogenesis and neurogenesis. Immune is initiating a 42-patient Phase II trial with bertilimumab for the treatment of active moderate to severe ulcerative colitis. The primary endpoint is a

[1] iCo plans a Phase II trial in vernal keratoconjunctivitis.

decrease in Mayo score from baseline of at least three points and at least 30%, and either a decrease in the rectal bleeding sub-score of at least one point, or a rectal bleeding sub-score of 0 or one.

Bertilimumab would seem to be one of a relatively small number of biological therapies[2] in development specifically for ulcerative colitis; there are two agents in registration or expected to be filed soon, and seven competing agents in Phase II studies (shown on page 2). There are a similar number of biological therapies in development for Crohn's disease, a related form of inflammatory bowel disease.

Immune is also developing NanomAbs antibody drug conjugates that aim to increase drug specificity to improve treatment efficacy and safety. A proprietary synthetic linker is used to couple a controlled number of mAbs to polymeric nanoparticles incorporating a chemotherapeutic drug. NanomAbs may improve delivery of the chemotherapy to inaccessible cancer cells by reducing premature elimination by organs and also by specific delivery to the tumour cells.

Valuation

We cannot revise our valuation until the terms of the merger are known. EpiCept's EV is currently $9m, based on a market cap of $7m, an outstanding senior secured loan of $4.1m and end-September cash of $1.1 and restricted cash of $1.1m. Our previously-published risk-adjusted net present value for pre-merger EpiCept was $29m using a 12.5% discount rate. This valuation was principally based on the potential economic value of AmiKet, assuming that it can be licensed.

Financials

EpiCept had cash of $1.1m in cash and an additional $1.1m that is restricted by EpiCept's lender at 30 September 2012. Current cash is anticipated to be sufficient to run operations into Q113. It also has an $8.6m 11.5% senior secured term loan facility with MidCap Financial (a healthcare commercial finance firm) with a final maturity of 27 May 2014. EpiCept currently has $4.1m of the facility outstanding. MidCap was granted five-year warrants for 1.1m ordinary shares at $0.63/share. The loan is secured against all EpiCept's IP. The signing of the definitive merger agreement with Immune met the 15 November 2012 deadline imposed on EpiCept by MidCap. The loan is expected to be restructured and assumed by the combined company at the closing of the merger.

As a result of various fundraisings, EpiCept has 26.0m warrants and 4.4m share options outstanding, with an exercise price ranging from $0.21 to $8.79 and expiry ranging from 2012 to 2017. If all the outstanding Series A and B preferred shares are converted at the new conversion price of $0.08 per share, an additional 16.3m shares would be issued. Therefore, the total shares issuable are 46.7m. We estimate that the merger will require the issue of significant number (>300m) of additional new shares. We cannot forecast accounts post-FY12 until Immune's historic and pro forma accounts have been published and registration documents filed. Our 2013 forecasts for EpiCept have been withdrawn.

[2] There are a number of small molecules in development for UC, including six in Phase II studies. The only compound in Phase III studies for UC is Pfizer's Xeljanz (tofacitinib, recently approved in rheumatoid arthritis).

Exhibit 1: Financial summary

$'000s	2010	2011	2012e
Year end 31 December	FASB	FASB	FASB
PROFIT & LOSS			
Revenue	**994**	**994**	**7,714**
Cost of Sales	(997)	(692)	(396)
Gross Profit	(3)	302	7,318
EBITDA	**(15,374)**	**(14,053)**	**(6,236)**
Operating Profit (before GW and except.)	**(15,374)**	**(14,053)**	**(6,236)**
Intangible Amortisation	(159)	0	0
Exceptionals	0	0	0
Other	0	(340)	0
Operating Profit	**(15,533)**	**(14,393)**	**(6,236)**
Net Interest	0	(1,259)	(997)
Profit Before Tax (norm)	**(15,374)**	**(15,312)**	**(7,233)**
Profit Before Tax (FRS 3)	**(15,533)**	**(15,652)**	**(7,233)**
Tax	(4)	(4)	0
Profit After Tax (norm)	**(15,378)**	**(15,656)**	**(7,233)**
Profit After Tax (FRS 3)	**(15,537)**	**(15,656)**	**(7,233)**
Average Number of Shares Outstanding (m)	47.9	68.3	115.5
EPS - normalised (c)	(32.1)	(22.9)	(6.3)
EPS - FRS 3 (c)	(32.5)	(22.9)	(6.3)
Dividend per share (c)	0.0	0.0	0.0
BALANCE SHEET			
Fixed Assets	**1,553**	**1,578**	**1,603**
Intangible Assets	506	506	506
Tangible Assets	1,047	1,072	1,097
Investments	0	0	0
Current Assets	**2,947**	**6,738**	**1,253**
Stocks	179	360	6
Debtors	0	0	0
Cash	2,435	6,378	1,247
Current Liabilities	**(4,834)**	**(5,756)**	**(10,172)**
Creditors	(4,310)	(5,756)	(10,172)
Short term borrowings	(524)	0	0
Long Term Liabilities	**(13,990)**	**(21,564)**	**(11,995)**
Long term borrowings	(448)	(8,022)	(3,417)
Other long term liabilities	(13,542)	(13,542)	(8,578)
Net Assets	**(14,324)**	**(19,004)**	**(19,311)**
CASH FLOW			
Operating Cash Flow	**(10,400)**	**(12,455)**	**(1,466)**
Net Interest	0	(1,259)	(997)
Tax	0	0	0
Capex	25	(25)	(25)
Acquisitions/disposals	0	0	(2,600)
Financing	8,556	10,900	4,562
Dividends	0	0	0
Net Cash Flow	(1,819)	(2,839)	(526)
Opening net debt/(cash)	**(3,190)**	**(1,463)**	**1,644**

Source: Edison Investment Research. Note: Edison FY12 estimates relate to EpiCept on existing, pre-merger basis.

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