EDISON

Opexa Therapeutics

Q4 update

Restructuring sharpens focus on Tcelna data

Pharma & biotech

On 2 March Opexa announced it has embarked on a restructuring initiative to prioritize its spending towards completing the ongoing 190-patient Abili-T Phase II study of lead candidate Tcelna in secondary progressive multiple sclerosis (SPMS). The company has reduced its overall headcount by about 30%, but this does not affect the Abili-T study timelines, for which data are expected in early Q416. The restructuring lengthens the company's financial runway into Q117 (vs prior guidance of Q416), providing added flexibility around the timing of Tcelna data. Our rNPV is $35.1m, which after including $12.4m Q415 net cash equates to an equity valuation of $6.81 per share.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/14	1.3	(15.1)	(4.33)	0.0	N/A	N/A
12/15	2.6	(12.1)	(2.06)	0.0	N/A	N/A
12/16e	26.6	14.2	2.03	0.0	1.1	N/A
12/17e	0.0	(14.3)	(1.90)	0.0	N/A	N/A

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

Abili-T final dose in February, data planned in Q416

The final patient dose of Tcelna in the Abili-T study was administered in February 2016, and approximately 97% of expected patient visits have been completed to date. Patients receive two annual courses of Tcelna treatment consisting of five subcutaneous injections per year at weeks zero, four, eight, 12 and 24. The primary endpoint is the percentage of brain volume change (whole brain atrophy) at 24 months. The firm has guided that it plans to release top-line data in early Q416; if data are positive, we anticipate Merck KGaA will exercise its option to license into the program, potentially triggering a $25m milestone payment to Opexa.

OPX-212 hits snag, its outlook is uncertain

Opexa has encountered technical difficulties with OPX-212 development, particularly with regard to its manufacturing given the hydrophobic nature of some of the peptides associated with the protein fragments targeted by the treatment. Management is continuing to develop the product but has withdrawn guidance of when an IND will be filed, and has also raised the possibility that the product may not proceed to human studies.

Valuation: rNPV of $35.1m

Given the technical challenges reported for OPX-212, we are lowering our OPX-212 probability of success to 3% (from 5%) and pushing back potential launch to 2022. We have lowered our SG&A and corporate cost assumptions, given the restructuring, and rolled our forecasts forward. The change to our OPX-212 projections are netted out by the cost savings now forecast, and our rNPV is thus unchanged at $35.1m. Given the restructuring and lower cost overhead, we now also forecast 2016 cash burn of $12.3m (vs $16.1m previously). Given Q415 net cash of $12.4m, our equity valuation is now $47.6m or $6.81 per share.

1 April 2016

Price	**US$2.32**
Market cap	**US$16m**
	$1.43/£
Net cash ($m) at Q415	12.4
Shares in issue	7.0m
Free float	97%
Code	OXPA
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(2.9)	(16.2)	(47.2)
Rel (local)	(8.9)	(16.9)	(47.0)
52-week high/low		US$5.0	US$1.7

Business description

Opexa is developing a personalized T-cell immunotherapy to treat multiple sclerosis (MS) and other autoimmune diseases such as neuromyelitis optica (NMO). Lead candidate Tcelna is in Phase IIb studies for secondary progressive MS (SPMS), with data expected in Q416.

Next events

Tcelna results	Q416
NMO IND	H216

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Rationalising cost structure to firm Tcelna runway

Opexa has announced that it has embarked on a restructuring initiative to prioritize its spending towards completing the ongoing 190-patient Abili-T Phase II study of lead candidate Tcelna in secondary progressive multiple sclerosis (SPMS) and extending financial flexibility. The firm has reduced its overall headcount (35 to 40 people before the restructuring) by about 30% (approximately eight to 10 people) across all business areas (such as product manufacturing, quality control, administration, etc.), except those directly associated with the operations of ongoing Abili-T study. The reduction in some of the operational and manufacturing roles coincides with the nearing completion of the Abilit-T study, as the final patient dose was administered in late February. The employee reduction also included the firm's CFO, Karthik Radhakrishnan. The current CEO (Neil K. Warma, CEO since 2008) will assume CFO responsibilities, as he did for several years before Mr. Radhakrishnan joined the firm in H113. Opexa estimates it will record a one-time severance-related charge of approximately $325,000 in Q116.

Cash runway extended into Q117

Opexa reported Q415 and 2015 results on 15 March 2016, with a net Q415 loss of $2.4m ($0.34 per share) and 2015 loss of $12.0m ($2.05 per share FD; $2.06 adjusted). The company's 2015 operating cash flow was negative $10.5m, and 2015 R&D expense was $10.0m, down from $12.1m in 2014 due to a decreased need for clinical trial product manufacturing and investigator costs, associated with a decreasing number of patients requiring doses and monitoring, following their completion of study protocols. Opexa finished 2015 with a gross cash position of $12.58m and after netting out a $0.15m note payable, we measure the net cash position at $12.4m.

Following the announced restructuring and associated headcount reductions, Opexa extended its anticipated cash runway guidance into Q117, whereas its prior guidance was for its cash and liquid resources to meet its projected cash needs into Q416. The lengthened runway gives the company added flexibility to engage with Merck KGaA (which has an option to license Tcelna in MS until a pre-defined time on the release of Abili-T top-line data) or if required (ie if Merck does not exercise the option) with other parties, on the completion of the Abili-T study. Opexa has also refined the projected timeline for the completion of the Abili-T study into early Q416 (from H216, previously).

Restructuring not expected to impact timing Tcelna programme

Opexa initiated the placebo-controlled (1:1 randomization) Abili-T study in fall 2012, completed recruitment in June 2014 and approximately 97% of expected patient visits have been completed to date. Patients receive two annual courses of Tcelna treatment consisting of five subcutaneous injections per year at weeks zero, four, eight, 12 and 24. The primary endpoint is the percentage of brain volume change (whole brain atrophy) at 24 months, and Expanded Disability Status Scale (EDSS) score changes and annual relapse rates (ARR) are included as secondary endpoints. Given that patient dosing has been completed, the headcount reductions and restructuring are not expected to negatively impact the Tcelna Abili-T study or the Tcelna program in any way. If study data are positive, Opexa management is confident it will be able to re-engage the related positions that were rationalized as part of the restructuring quickly enough not to negatively impact future development steps or add delays.

OPX-212 hits snag; development outlook uncertain

Following successful preclinical data reported in November 2015 for OPX-212 in a mouse model, Opexa had anticipated it could file an IND for this immunoregulatory candidate for neuromyelitis optica (NMO) in H116, and potentially start a Phase I/II human study in Q216. However, the firm recently indicated that it has encountered technical difficulties with OPX-212 development,

particularly with regard to its manufacturing. The hydrophobic nature of some of the peptides associated with the protein fragments associated with NMO (intended to be targeted by the OPX-212 product) have created manufacturing difficulties. Management indicates that OPX-212 in NMO remains an active preclinical program for the company, and further OPX-212 development is planned and included within its revised financial outlook/runway guidance to Q117. However, the firm cannot confirm when or whether it expects the technical difficulties with OPX-212 manufacturing to be definitively resolved, and according to its 15 March press release, it "does not expect to provide guidance in the foreseeable future on any timetable with respect to its development of OPX-212 in NMO, but instead to report substantive milestones only when and if they occur."

The challenges faced by Opexa in advancing its Immpath immunotherapy platform (the underlying basis for the Tcelna cell therapy program and OPX-212) towards Aquaporin 4 (AQP4) proteins implicated in NMO suggest the company could also face similar difficulties in adapting Immpath towards other autoimmune indications. One of Opexa's longer-term goals is to seek opportunities for Immpath in other autoimmune or related diseases, and/or to out-license the platform for such areas. In our valuation, we have not included any consideration for the Immpath immunotherapy platform in other potential areas.

Financials and valuation

Our model assumes that if Abili-T results meet the primary endpoint (whole brain atrophy vs placebo), Merck KGaA will exercise its option to in-license Tcelna and will then fund all remaining development and commercialization activities in MS. Under a best-case scenario, a Phase III pivotal SPMS study could start in 2017, with potential approval and launch in SPMS in 2021.

For OPX-212, given the technical challenges reported with this program and the increased uncertainty as to whether it will reach human trials, we are pushing back our timeline assumptions by one year, and have lowered our probability of success estimate from 5.0% to 3.0%. We now assume a pivotal study in 2019 (vs 2018 previously) and launch in 2022 (vs 2021 previously). If Phase I/II study results are exceptional, there is the possibility for a breakthrough therapy and quicker approval timeline. Our peak sales forecasts are unchanged. Please refer to the 30 November 2015 initiation note for more detailed information on our Tcelna forecasts.

Given the restructuring, we reduced our corporate costs & expenses assumptions and near term R&D costs (as we expect a lower expenditure on OPX-212 in 2016 than previously). Whereas we previously forecast a 2016 cash burn rate of $16.1m (excluding the potential $25m upfront fee from Merck KGaA in the event of positive Abili-T data), we now expect an operating burn rate of $12.3m. Hence, given Q415 net cash of $12.4m, we are also modelling that the firm's cash on hand will be sufficient to fund operations into Q117.

In addition, our model previously forecast that Opexa would raise $2.5m in equity in 2016 and $2.0m in 2017 as part of the $5m five-tranche milestone-based stock purchase agreement entered with a private investor in September 2015 ($0.5m was already raised; $4.5m remains outstanding). Given the OPX-212 difficulties cited above, we pushed back our forecasts for the timing of the proceeds from this line by one year ($2.5m in 2017 and $2.0m in 2018). We have also rolled our forecasts forward.

Exhibit 1: Opexa Therapeutics rNPV assumptions

Product contributions (net of R&D costs)	Indication	rNPV ($m)	rNPV/share ($)	Probability of success	Launch year	Peak US market share	Peak WW sales (US$m)
Tcelna*	SPMS	77.4	11.07	15.0%	2021	30%	$2.6bn in 2026
OPX-212	NMO	12.7	1.82	3.0%	2022	40%	$0.38bn in 2027
Corporate costs & expenses							
SG&A expenses		(30.1)	(4.30)				
Net capex, NWC & taxes		(24.9)	(3.56)				
Total rNPV		35.1	5.03				
Net cash (debt) (Q415a)		12.4	1.78				
Total equity value		47.6	6.81				
FD shares outstanding (000) (Q415a)		6,987					

Source: Edison Investment Research. Note: *Our Tcelna valuation applies a 15% probability of success for all forthcoming Tcelna-related event and milestone payments from Merck KGaA, including the $25m upfront fee.

Given the above changes (positive effect of rolling forward forecasts and lowering SG&A costs, offset by reduced forecasts and probability for OPX-212), our rNPV is unchanged at $35.1m. After including $12.4m Q415 net cash, our equity valuation of $47.6m equates to $6.81 per share fully diluted.

Exhibit 2: Financial summary

US$(000)	2013	2014	2015	2016e	2017e	2018e
31-December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	1,267	1,272	2,556	26,600*	0	0
Cost of Sales	0	0	0	0	0	0
General & Administrative	(3,671)	(3,833)	(4,258)	(4,025)	(4,200)	(4,483)
Research & Development	(9,181)	(12,119)	(10,039)	(8,200)	(10,100)	(9,200)
EBITDA	(11,585)	(14,680)	(11,741)	14,375	(14,300)	(13,683)
Depreciation	(336)	(388)	(351)	(318)	(287)	(276)
Amortization	0	0	0	0	0	0
Operating Profit (before exceptionals)	(11,921)	(15,068)	(12,093)	14,057	(14,587)	(13,958)
Exceptionals	(2,483)	2	68	0	0	0
Other	0	0	0	0	0	0
Operating Profit	(14,404)	(15,066)	(12,025)	14,057	(14,587)	(13,958)
Net Interest	(2,252)	13	6	114	321	126
Profit Before Tax (norm)	(14,173)	(15,054)	(12,087)	14,171	(14,266)	(13,832)
Profit Before Tax (FRS 3)	(16,656)	(15,052)	(12,019)	14,171	(14,266)	(13,832)
Tax	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(14,173)	(15,054)	(12,087)	14,171	(14,266)	(13,832)
Profit After Tax and minority interests (FRS 3)	(16,656)	(15,052)	(12,019)	14,171	(14,266)	(13,832)
Average Number of Shares Outstanding (m)	1.7	3.5	5.9	7.0	7.5	8.0
EPS - normalised ($)	(8.50)	(4.33)	(2.06)	2.03	(1.90)	(1.73)
EPS - normalised and fully diluted ($)	(8.50)	(4.33)	(2.06)	2.03	(1.90)	(1.73)
EPS - (IFRS) ($)	(9.99)	(4.33)	(2.05)	2.03	(1.90)	(1.73)
Dividend per share (C$)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets	1,473	1,137	838	739	694	692
Intangible Assets	0	0	0	0	0	0
Tangible Assets	1,473	1,137	838	739	694	692
Current Assets	24,767	10,665	13,579	26,249	14,029	21,958
Short-term investments	0	0	0	0	0	0
Cash	23,645	9,906	12,584	25,254	13,034	20,963
Other	1,123	759	995	995	995	995
Current Liabilities	(3,324)	(3,132)	(4,801)	(3,201)	(3,201)	(2,462)
Creditors	(3,324)	(3,132)	(4,653)	(3,053)	(3,053)	(2,313)
Short term borrowings	0	0	(148)	(148)	(148)	(148)
Long Term Liabilities	(2,338)	(1,231)	0	0	0	(20,000)
Long term borrowings	0	0	0	0	0	(20,000)
Other long term liabilities	(2,338)	(1,231)	0	0	0	0
Net Assets	20,577	7,439	9,615	23,787	11,521	189
CASH FLOW						
Operating Cash Flow	(3,873)	(14,209)	(10,518)	12,775	(14,300)	(14,422)
Net Interest	(2,252)	13	6	114	321	126
Tax	0	0	0	0	0	0
Capex	(259)	(191)	(92)	(219)	(241)	(274)
Acquisitions/disposals	0	0	0	0	0	0
Financing**	28,337	648	13,281	0	2,000	2,500
Net Cash Flow	21,953	(13,738)	2,677	12,670	(12,220)	(12,071)
Opening net debt/(cash)	(215)	(23,645)	(9,906)	(12,435)	(25,105)	(12,886)
HP finance leases initiated	0	0	0	0	0	0
Other	1,477	0	(148)	0	0	0
Closing net debt/(cash)	(23,645)	(9,906)	(12,435)	(25,105)	(12,886)	(815)

Source: Company documents, Edison Investment Research. Note: *While this forecast includes $25m upfront from Merck KGaA (not risk-adjusted), if the company decides not to exercise this option, the amount is reduced to zero; our rNPV valuation applies a 15% probability of success to this upfront payment and future milestones from Merck KGaA. **Our financing forecast includes the full draw-down of the $5m equity facility directed towards OPX-212 by 2018 ($2.0m in 2017 and $2.5m in 2018).

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