EDISON

Pluristem Therapeutics

Earnings update

New avenues of study

Pharma & biotech

Pluristem continues to advance its PLX technology platform. In a recent paper it investigated the application of these cells for their ability to inhibit tumor growth; it was found that the cells inhibit growth of a mouse xenograft of a triple-negative breast cancer cell line and induced complete remissions in three out of 10 mice. Additionally, PLX-PAD received approval for an expanded access program from the FDA, allowing it to be used to treat critical limb ischemia (CLI) outside the ongoing Phase III clinical study.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
06/16	2.8	(20.2)	(0.25)	0.0	N/A	N/A
06/17	0.0	(24.2)	(0.28)	0.0	N/A	N/A
06/18e	0.0	(28.5)	(0.27)	0.0	N/A	N/A
06/19e	0.0	(45.0)	(0.39)	0.0	N/A	N/A

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

It's a great time to be a mouse

The recent paper examined the anti-cancer activity of PLX cells induced with tumor necrosis factor alpha (TNF-α) and interferon-gamma (IFN-γ) and found they inhibit growth in 26 of 59 cancer cell lines. When a cell line for triple-negative cancer was examined in xenografts, it was found that the cells inhibited growth in vivo and induced complete remission in 3 out of 10 mice. This activity is potentially driven by a reduction in cytokines that promote tumor growth and vascularization.

Expanded access PLX-PAD for CLI

In January 2018, the company announced that the FDA had approved PLX-PAD for its expanded access program, also known as compassionate use. This will allow the treatment to be available to CLI patients with no other options who are not eligible for the ongoing Phase III. We believe that the benign safety record of the treatment contributed to this decision, and the company may be able to use data from these patients to further support its safety and drive future clinical studies.

Q218 results: Expansion of costs

The company reported an operating loss of $8.5m for Q218 ending 30 December 2017. This is a slight increase over the previous period ($7.4m), which we assume is associated with the expansion of the Phase III CLI program. The company guided to completion of the Phase II intermittent claudication (IC) trial in fiscal Q418, which has delayed some expected expenses from the follow-up trial into FY19.

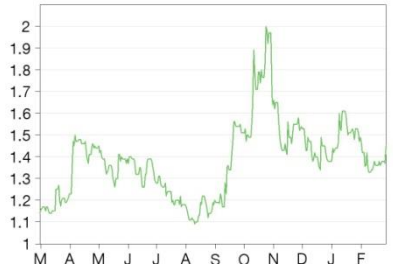
Valuation: Increased to $208m or $1.89/basic share

We have slightly increased our valuation to $208m (from $202m) or $1.89 per basic share. This is largely driven by advancing our NPVs and a delay in the cost of the IC program, offset by an increase in our expected SG&A run rate. We expect to update our valuation with the completion of the Phase II IC trial in fiscal Q418. We forecast that the company will require $50m in additional financing before profitability in 2020.

28 February 2018

Price*	**US$1.45 NIS4.81**
Market cap	**US$160m NIS530m**
*Priced at 27 February 2018	
	NIS3.51/$
Net cash ($m) at end Q218	35.86
Shares in issue	110.1m
Free float	93%
Code	PSTI
Primary exchange	NASDAQ
Secondary exchange	TASE

Share price performance



%	1m	3m	12m
Abs	(5.2)	(8.2)	28.3
Rel (local)	(0.8)	(13.0)	10.8
52-week high/low	US$2.0	US$1.1	

Business description

Pluristem Therapeutics is a biotech company, headquartered in Israel, focused on the development of cell-based therapeutics derived from placenta. The company is advancing PLX-PAD for critical limb ischemia (CLI) in Phase III and has a Phase III study planned for hip fracture. PLX-R18 is being advanced for acute radiation syndrome and hematopoietic cell transplant.

Next events

FNF IND submission	Coming months
IC Phase II top-line results	Fiscal Q418

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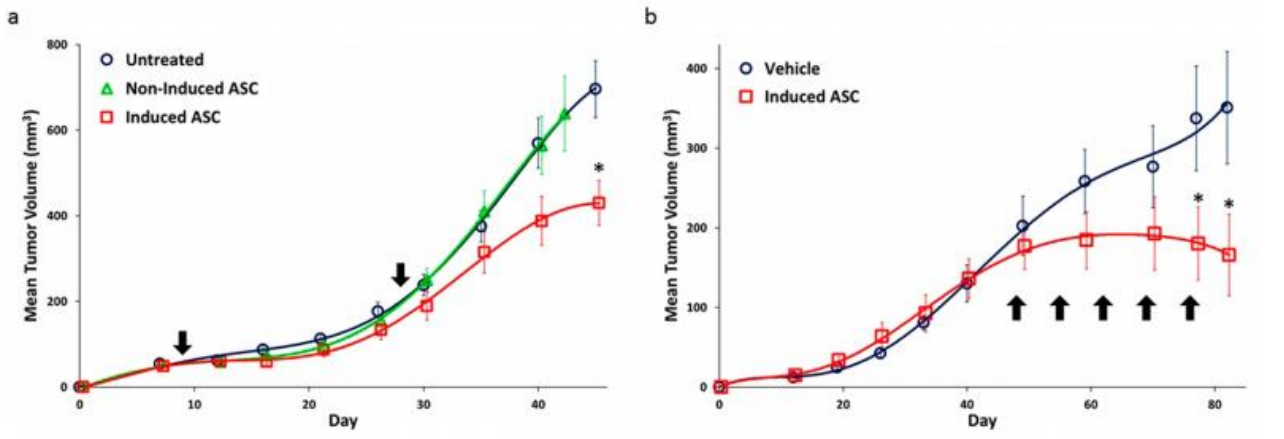
Edison profile page

Preclinical data suggest application in cancer

The company recently published data from a preclinical study on the application for its PLX cell technology outside its current clinical indications for the treatment of cancer. The study found that cells conditioned with tumor necrosis factor alpha (TNF-α) and interferon-gamma (IFN-γ) inhibited tumor growth in 26 of 59 cancer cell lines.[1] Additionally, the study went on to investigate one human cell line for triple-negative breast cancer via mouse xenograft (Exhibit 1). Cells from the MDA-MB-231 cell line were injected either subcutaneously or in the mammary fat pad. In both cases there was a significant difference in tumor mass at day 84 (although the treatment schedules were different in each case). The paper further investigated the histology of these tumors, which suggests that the induced PLX cells inhibit proliferation and vascularization. There was a 48% reduction in proliferating cells (p=0.0029) and a 58% reduction in vascularization (as shown by anCD34 staining, p=0.0032). The tumors showed a reduction in the cytokines associated with these processes, although it failed to reach statistical significance compared to untreated tumors.

Exhibit 1: Inhibition of mouse xenografts by induced PLX cells



Source: Allen et al. Note: Arrows are PLX cell injections – a) subcutaneous tumor, b) mammary fat pad tumor. *p<0.05.

The results from this study are very interesting and may provide additional avenues for research in the future. However, the study was limited by its exploratory nature. The fact that less than half of the test cell lines responded to the treatment suggests that it may be only narrowly applicable. Moreover, reductions in tumor volume in the xenograft study were modest. This being said, triple-negative breast cancer is notoriously hard to treat, and these results are worth further investigation.

FDA approves expanded access program for PLX-PAD

In January 2018, the FDA accepted the company's application to allow PLX-PAD to be available to patients through the so-called expanded access program, also known as compassionate use, for the treatment of patients with "no option" critical limb ischemia. The program will allow patients who do not qualify for the ongoing Phase III clinical trial to receive treatment using the cells, and the company may be entitled to remuneration for the cost to produce (although this determination is forthcoming).

We believe the key takeaway from this designation is that the FDA recognizes the innocuous safety profile of the treatment. The criteria for expanded access are that there is evidence of safety and

[1] Allen H, et al. (2017) Human Placental-Derived Adherent Stromal Cells Co-Induced with TNF-α and IFN-γ Inhibit Triple-Negative Breast Cancer in Nude Mouse Xenograft Models. *Sci. Rep.* 8, 670.

effectiveness and a lack of other treatments. Although these patients cannot be used to support evidence of efficacy for approval (as they are outside clinical trials), they may potentially be used as part of the safety database, as well as to provide insight into particular patient groups worthy of future study.

Valuation

We have slightly increased our valuation to $208m or $1.89 per basic share from $202m or $1.87. This increase is largely driven by advancing our NPVs to the most recent period and a slight delay in the expected costs associated with the IC pivotal trial initiation (based on guidance to Phase II data in Q418). These effects are offset by an increase in unallocated costs associated with an increase in our expected SG&A run rate. We expect to update our valuation with the results from the Phase II IC study, which we believe will also provide insight into the CLI program. We may also add the cancer program to our valuation at a later date if it continues to show promise and is tested in a clinical setting, although we do not expect this in the near term.

Exhibit 2: Valuation of Pluristem

Development program	Prior data	Clinical stage	Prob. of success	Launch year	Launch Pricing ($)	Peak sales ($m)	Patent/Exclusivity Protection	Royalty/ margin	rNPV ($m)
CLI, US	2x Phase I	Phase III	10%	2021	22,500	235	2036	63%	44.57
CLI, Europe	2x Phase I	Phase III	10%	2021	13,500	247	2036	59%	42.30
CLI, Japan	2x Phase I	Phase I/II	20%	2021	22,500	76	2036	27%	9.83
CLI, development costs									(18.94)
FNF (US and Europe)	Phase I for THR	Phase III ready	15%	2021	22,100	171	2036	55%	17.76
ARS	Primate Studies	Pivotal Primate Study	10-20%	2020	N/A	155/ contract	2036	77%	36.86
IC, US	N/A	Phase II	7.5%	2022	11,500	443	2036	57%	38.27
IC, Europe	N/A	Phase II	7.5%	2022	6,900	466	2036	50%	33.94
IC, Japan	N/A	Phase II	15%	2022	11,500	144	2036	20%	7.22
IC, development costs									(31.35)
HCT (US and Europe)	Mouse Studies	Phase I	5%	2023	29,300	239	2036	61%	8.37
Unallocated costs									(16.22)
Total									**172.60**
Net cash and equivalents (Q218) ($m)									35.86
Total firm value ($m)									**208.46**
Total basic shares (m, Q218)									110.1
Value per basic share ($)									**1.89**
Dilutive warrants									7.62
Diluted firm value ($m)									219.12
Value per diluted share ($)									$1.86

Source: Edison Investment Research, Pluristem company reports

Financials

Pluristem recently reported an operating loss of $8.5m for Q218 ending 31 December 2017. R&D spending for the period was $5.6m, compared to $4.7 in Q1. We assume this increase is associated with the advancement of the Phase III CLI trial and preparations for the Phase III FNF trial. The company guided to results from the Phase II IC study in Q418, which has shifted our spending estimates for this study to later periods. This has resulted in a reduction of our expected FY18 R&D spending estimated to $22.8m from $33.8m, although these costs will be made up in later years. We have increased our expected SG&A spending in 2018 to $10.2m from $7.2m to align with current trends. We expect the company to require $50m in additional capital ($20m in FY18, $30m in FY19, recorded as illustrative debt) to reach profitability in 2020.

Exhibit 3: Financial summary

$000s	2015	2016	2017	2018e	2019e
Year end 30 June	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS					
Revenue	379	2,847	0	50	0
Cost of Sales	(13)	(100)	0	(2)	0
Gross Profit	366	2,747	0	48	0
Research and development	(19,173)	(19,580)	(21,092)	(22,754)	(36,267)
Selling, general & administrative	(6,460)	(6,486)	(6,927)	(10,215)	(10,726)
EBITDA	(27,341)	(25,469)	(30,196)	(34,896)	(48,163)
Operating Profit (before amort. and except.)	(25,267)	(23,319)	(28,019)	(32,878)	(46,993)
Intangible Amortisation	0	0	0	0	0
Exceptionals/Other	0	0	0	0	0
Operating Profit	(25,267)	(23,319)	(28,019)	(32,878)	(46,993)
Net Interest	590	73	205	(1,075)	(3,475)
Other (change in fair value of warrants)	0	0	0	0	0
Profit Before Tax (norm)	(20,625)	(20,173)	(24,152)	(28,460)	(44,975)
Profit Before Tax (IFRS)	(24,677)	(23,246)	(27,814)	(33,953)	(50,468)
Tax	0	0	0	0	0
Deferred tax	0	0	0	0	0
Profit After Tax (norm)	(20,625)	(20,173)	(24,152)	(28,460)	(44,975)
Profit After Tax (IFRS)	(24,677)	(23,246)	(27,814)	(33,953)	(50,468)
Average Number of Shares Outstanding (m)	70.3	79.5	87.4	106.5	115.7
EPS - normalised (c)	(29.35)	(25.36)	(27.63)	(26.72)	(38.88)
EPS - IFRS ($)	(0.35)	(0.29)	(0.32)	(0.32)	(0.44)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	11,287	10,345	8,518	6,829	10,862
Intangible Assets	0	0	0	0	0
Tangible Assets	10,173	9,216	7,277	5,537	9,570
Other	1,114	1,129	1,241	1,292	1,292
Current Assets	56,868	35,596	29,016	42,918	26,235
Stocks	0	0	0	0	0
Debtors	1,691	2,228	1,036	172	172
Cash	53,119	32,750	26,665	41,702	25,019
Other	2,058	618	1,315	1,044	1,044
Current Liabilities	(6,183)	(5,775)	(5,414)	(6,766)	(9,090)
Creditors	(6,183)	(5,775)	(5,414)	(6,766)	(9,090)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(3,829)	(2,010)	(1,869)	(21,975)	(51,975)
Long term borrowings	0	0	0	(20,000)	(50,000)
Other long term liabilities	(3,829)	(2,010)	(1,869)	(1,975)	(1,975)
Net Assets	58,143	38,156	30,251	21,007	(23,968)
CASH FLOW					
Operating Cash Flow	(20,605)	(18,522)	(21,611)	(24,008)	(41,480)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(831)	(1,750)	(378)	(350)	(5,203)
Acquisitions/disposals	0	0	0	0	0
Financing	17,201	807	15,728	15,837	0
Dividends	0	0	0	0	0
Other	0	0	0	0	0
Net Cash Flow	(4,235)	(19,465)	(6,261)	(8,522)	(46,684)
Opening net debt/(cash)	(58,819)	(53,119)	(32,750)	(26,665)	(21,702)
HP finance leases initiated	5	0	0	0	0
Exchange rate movements	0	0	0	0	0
Other	(1,470)	(904)	176	3,559	0
Closing net debt/(cash)	(53,119)	(32,750)	(26,665)	(21,702)	24,981

Source: Company accounts, Edison Investment Research

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