EDISON

Pluristem Therapeutics

Earnings update

FDA gives two programs the green light with IND

Pharma & biotech

In April 2018, Pluristem announced that the FDA had given two pipeline programs IND clearance: PLX-PAD for femoral neck fracture (FNF) healing and PLX-R18 for acute radiation syndrome (ARS). The company plans to initiate the Phase III trial investigating PLX-PAD for FNF healing later this year. IND approval of the PLX-R18 program allows for potential use of the product in the event of radiological emergencies for investigational purposes, which could provide in-human data.

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	(19.7)	(0.19)	0.0	N/A	N/A
06/19e	0.0	(43.9)	(0.38)	0.0	N/A	N/A

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

Plans to initiate PLX-PAD FNF trial in 2018

The company recently announced that the FDA has granted IND approval for the Phase III clinical trial investigating the use of PLX-PAD cell therapy for the treatment of FNF healing. The randomized, double-blind, placebo-controlled trial will enrol 240 patients undergoing hip arthroplasty across the US and Europe. Pluristem remains in discussions with the EU regarding clinical trial approval; however, the company anticipates enrolling patients in both regions later this year.

PLX-R18 IND approval for investigational purposes

IND approval for the PLX-R18 cell therapy program for ARS allows for the treatment of victims who may have been exposed to acute high-dose radiation due to radiological emergencies such as either industrial accidents or nuclear weapons devices. However, given the limited occurrence of these events, we do not expect this to alter the clinical development path or need for non-human primate studies.

Indiana University collaboration agreement

In April 2018, the company announced that the NIH had awarded $2.5m to Indiana University to study survival efficacy in geriatric and pediatric populations treated with the PLX-R18 cell therapy. As per this five-year agreement, Pluristem will be reimbursed for supplying the PLX-R18 cells for use in these studies. The company plans to use the first year of data to support its BLA filing for marketing approval.

Valuation: $212m or $1.92 per basic share

We have slightly increased our valuation to $212m or $1.92 per basic share from $208m or $1.89 per share. This increase is driven by advancing our NPVs to the most recent period, which is partially offset by cash expenditure. We expect Pluristem to need $50m in financing to reach profitability in 2020.

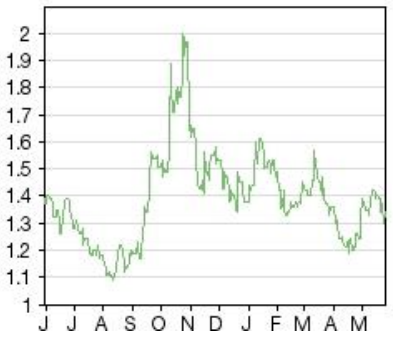
29 May 2018

Price*	**US$1.34**
	NIS4.83
Market cap	**US$148m**
	NIS532

*Priced as at 25 May 2018

	NIS3.57/$
Net cash ($m) at end Q318	34.07
Shares in issue	110.1m
Free float	93%
Code	PSTI
Primary exchange	NASDAQ
Secondary exchange	TASE

Share price performance



%	1m	3m	12m
Abs	8.1	(6.3)	(3.6)
Rel (local)	3.1	(2.0)	(15.1)

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 (ARS) and hematopoietic cell transplant.

Next events

IC Phase II top-line results	June 2018
Initiate ARS Phase III study	Year-end 2018

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Edison profile page

PLX-PAD for FNF Phase III study is a "go" in the US

The company recently announced that the FDA has approved the IND for a Phase III study of PLX-PAD cell therapy for the treatment of muscle injury following hip arthroplasty due to femoral neck fracture (FNF). The Phase III trial will enrol 240 patients across the US and Europe who will receive an intramuscular (IM) injection of 150m PLX-PAD cells (or placebo treatment, allocated at a ratio of 1:1) during an arthroplasty procedure. The study will be randomized, double-blind and placebo-controlled. The primary endpoint will be change in the Short Physical Performance Battery (SPPB) at 6.5 months following treatment. The SPPB is a series of physical tests of the lower extremities that mimic the physical requirements of daily activity that is typically used to assess geriatric patients. The battery is semi-quantitative and composed of three sections measuring different aspects of function: balance, gait speed, and getting into and out of a chair (Exhibit 1). Each test is scored objectively on a scale ranging from zero to four, where a score of zero indicates the subject is unable to perform the task. The company plans to begin enrolment some time in 2018 in both regions.

Exhibit 1: SPPB assessment

Function	Test
Standing balance	Feet in a side-by-side position for 10 seconds
Gait speed	Timed 8-foot (2.4-meter) walk
Getting into and out of a chair	Five timed, repetitive chair stands

Source: Multiple sources.

FDA accepts PLX-R18 IND for the treatment of ARS

In April 2018, the FDA accepted the company's IND application for PLX-R18 for acute radiation syndrome (ARS) allowing for the treatment of victims who may have been exposed to acute high-dose radiation, potentially attributable to either industrial accidents or nuclear weapons devices, which could provide in-human data for investigational purposes. This radiation can cause DNA damage, which can have devastating effects on rapidly dividing cells such as those in the bone marrow. PLX-R18 is derived from placenta donated after delivery from a fraction of cells existing at the interface between the maternal and fetal tissue that secretes growth factors encouraging hematopoiesis. Therefore, the company hopes to use these properties of the treatment to encourage the recovery of bone marrow cells and the immune system after they are killed with radiation. Following this clearance, the company has stated that it will begin the necessary preparations for accumulating an emergency inventory of PLX-R18 in case of radiological emergencies. It is important to note that this product is being developed via the FDA animal rule, which allows for approval based on animal studies for conditions such as ARS that cannot be feasibly studied in human clinical trials. We therefore assume that the completion of the non-human primate trial and human/animal dose conversion study are both pivotal to its clinical advancement, and essential for obtaining emergency use authorization (EUA) and an eventual Strategic National Stockpile (SNS) contract.

Furthermore, the National Institute of Allergy and Infectious Disease (NIAID) department of the NIH recently granted $2.5m to Indiana University to study survival efficacy in geriatric and pediatric populations treated with the PLX-R18 cell therapy, as well as to compare effectiveness and analyze drug-drug interactions. According to this agreement, Pluristem will be reimbursed for supplying the PLX-R18 cells for these studies. The company plans to use the first year of this five-year research collaboration to support its BLA filing for marketing approval.

Valuation

We have slightly increased our valuation to $212m or $1.92 per basic share from $208m or $1.89 per share. This increase is driven by advancing our NPVs to the most recent period, which is partially offset by the lower cash position. Our assumptions remain unchanged. We expect to update our valuation with the results from the Phase II IC study, which we believe will have implications for this program and provide insight into the CLI program.

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 ($m)
CLI, US	2x Phase I	Phase III	10%	2021	22,500	235	2036	63%	45.90
CLI, Europe	2x Phase I	Phase III	10%	2021	13,500	247	2036	59%	43.56
CLI, Japan	2x Phase I	Phase I/II	20%	2021	22,500	76	2036	27%	10.13
CLI, development costs									(19.51)
FNF (US and Europe)	Phase I for THR	Phase III ready	15%	2021	22,100	171	2036	55%	18.29
ARS	Primate Studies	Pivotal Primate Study	10%-20%	2020	N/A	155/ contract	2036	77%	37.96
IC, US	N/A	Phase II	7.5%	2022	11,500	443	2036	57%	39.41
IC, Europe	N/A	Phase II	7.5%	2022	6,900	466	2036	50%	34.95
IC, Japan	N/A	Phase II	15%	2022	11,500	144	2036	20%	7.43
IC, development costs									(32.29)
HCT (US and Europe)	Mouse Studies	Phase I	5%	2023	29,300	239	2036	61%	8.62
Unallocated costs									(16.71)
Total									**177.76**
Net cash and equivalents (Q318) ($m)									34.07
Total firm value ($m)									**211.82**
Total basic shares (m, Q318)									110.1
Value per basic share ($)									**1.92**
Dilutive warrants									7.62
Diluted firm value ($m)									222.49
Value per diluted share ($)									$1.89

Source: Pluristem Therapeutics reports, Edison Investment Research

Financials

Pluristem ended its fiscal Q318 in 31 March 2018 with an operating loss of $9.0m. R&D spending was the company's major expense at $6.4m, which was slightly up from previous quarters (Q218: $5.6m, Q118: $4.6m). We assume this increase is associated with the advancement of the Phase III CLI and preparations for the Phase III FNF trial. Our FY18 R&D and SG&A estimates remain unchanged at $22.8m and $10.2m, respectively. 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

$'000s	2015	2016	2017	2018e	2019e
Year end 30 June	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS					
Revenue	379	2,847	0	50	0
Cost of Sales	(13)	(100)	0	(2)	0
Gross Profit	366	2,747	0	48	0
Research and development	(19,173)	(19,580)	(21,092)	(22,754)	(36,267)
Selling, general & administrative	(6,460)	(6,486)	(6,927)	(10,215)	(10,726)
EBITDA	(27,341)	(25,469)	(30,196)	(34,872)	(48,165)
Operating Profit (before amort. and except.)	(25,267)	(23,319)	(28,019)	(32,878)	(46,993)
Intangible Amortization	0	0	0	0	0
Exceptionals/Other	0	0	0	0	0
Operating Profit	(25,267)	(23,319)	(28,019)	(32,878)	(46,993)
Financing income	590	73	205	6,668	(3,475)
Other (change in fair value of warrants)	0	0	0	0	0
Profit Before Tax (norm)	(20,625)	(20,173)	(24,152)	(19,684)	(43,941)
Profit Before Tax (IFRS)	(24,677)	(23,246)	(27,814)	(26,211)	(50,468)
Tax	0	0	0	0	0
Deferred tax	0	0	0	0	0
Profit After Tax (norm)	(20,625)	(20,173)	(24,152)	(19,684)	(43,941)
Profit After Tax (IFRS)	(24,677)	(23,246)	(27,814)	(26,211)	(50,468)
Average Number of Shares Outstanding (m)	70.3	79.5	87.4	105.9	114.5
EPS - normalized (c)	(29.35)	(25.36)	(27.63)	(18.58)	(38.38)
EPS - IFRS ($)	(0.35)	(0.29)	(0.32)	(0.25)	(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	6,854	10,885
Intangible Assets	0	0	0	0	0
Tangible Assets	10,173	9,216	7,277	5,546	9,577
Other	1,114	1,129	1,241	1,308	1,308
Current Assets	56,868	35,596	29,016	47,145	31,993
Stocks	0	0	0	0	0
Debtors	1,691	2,228	1,036	596	596
Cash	53,119	32,750	26,665	45,503	30,351
Other	2,058	618	1,315	1,046	1,046
Current Liabilities	(6,183)	(5,775)	(5,414)	(6,269)	(9,090)
Creditors	(6,183)	(5,775)	(5,414)	(6,269)	(9,090)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(3,829)	(2,010)	(1,869)	(21,936)	(51,936)
Long term borrowings	0	0	0	(20,000)	(50,000)
Other long term liabilities	(3,829)	(2,010)	(1,869)	(1,936)	(1,936)
Net Assets	58,143	38,156	30,251	25,794	(18,147)
CASH FLOW					
Operating Cash Flow	(20,605)	(18,522)	(21,611)	(24,084)	(39,948)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(831)	(1,750)	(378)	(292)	(5,204)
Acquisitions/disposals	0	0	0	0	0
Financing	17,201	807	15,728	17,314	0
Dividends	0	0	0	0	0
Other	0	0	0	0	0
Net Cash Flow	(4,235)	(19,465)	(6,261)	(7,062)	(45,152)
Opening net debt/(cash)	(58,819)	(53,119)	(32,750)	(26,665)	(25,503)
HP finance leases initiated	5	0	0	0	0
Exchange rate movements	0	0	0	0	0
Other	(1,470)	(904)	176	5,900	0
Closing net debt/(cash)	(53,119)	(32,750)	(26,665)	(25,503)	19,649

Source: Company accounts, Edison Investment Research

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