EDISON

Pluristem Therapeutics

Grants and collaborations to support development

Earnings and valuation update

Pharma & biotech

Pluristem now has three ongoing clinical programs: critical limb ischemia (CLI, Phase III), intermittent claudication (IC, Phase II) and the acute radiation syndrome program (ARS, primates), which was recently expanded due to the participation of the US Department of Defense (DOD). Many of the costs of these programs have been offset, for instance due to NIH support of the ARS program as well as new grants of $16.6m to study PLX-PAD. The company recently received FDA and EMA sign-offs on a Phase III study in femoral neck fracture, which we expect to start shortly.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
06/15	0.4	(24.7)	(0.35)	0.0	N/A	N/A
06/16	2.8	(23.2)	(0.29)	0.0	N/A	N/A
06/17	0.0	(27.8)	(0.32)	0.0	N/A	N/A
06/18e	0.0	(43.3)	(0.44)	0.0	N/A	N/A

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

US DOD to research PLX-R18

Pluristem announced in August 2017 that the US DOD has begun work on the effect of PLX-R18 for the treatment and prevention of ARS. This study is different from the NIH-sponsored studies in that it will also test whether the cells can prevent the damage from ARS when given before exposure. The DOD program, if successful, could open the door to additional purchasing agreements from the military.

Grant money, FDA/EMA feedback on FNF Phase III

The company announced that it will be participating in two new programmes using PLX-PAD financed by EU Horizon 2020 for up to $8.7m and $7.9m, of which Pluristem will receive a portion. This brings the total from the programmes to study PLX-PAD to $24.6m.The company also announced a proposed protocol for the Phase III FNF clinical trial following “positive feedback” from the FDA and EMA. The primary endpoint will be the change of Short Physical Performance Battery six months after surgery. It is filing an IND in the coming months and we expect the trial to start shortly afterwards.

PLX-PAD CLI program marked for fast track

In September 2017 Pluristem announced that the FDA had given PLX-PAD a fast track designation for its Phase III CLI program. Fast track will enable an increased level of interaction with the FDA and a rolling review process. The program is also included in the EMA’s Adaptive Pathways scheme, which has a similar goal of streamlining the review process for programs of significant unmet medical need.

Valuation: $189m (NIS664m) or $1.94 (NIS6.81)

We have increased our valuation to $189m (NIS664m) or $1.94 (NIS6.81) per basic share, from $169m (NIS603m) or $1.75 (NIS6.26) per basic share. This is driven by advancing our NPVs to the most recent period as well as reducing the R&D costs for the FNF clinical program due to the contribution of the Horizon 2020 grant. We expect Pluristem to need $63m in financing to reach profitability in 2020.

18 October 2017

Price*	**$1.79/ NIS6.34**
Market cap	**$175m/ NIS618m**
* Priced as at 18 October 2017	
	NIS3.52/US$
Net cash ($m) at 30 June 2017	26.7
Shares in issue	97.5m
Free float	92%
Code	PSTI
Primary exchange	TASE
Secondary exchange	NASDAQ

Share price performance

%	1m	3m	12m
Abs	33.6	50.4	22.6
Rel (local)	30.5	44.5	1.9
52-week high/low		$1.9	$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	Early 2018
HCT Phase I interim readout	H217

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Edison profile page

US Department of Defense to investigate PLX-R18

Pluristem has developed PLX-R18 as a cell-based therapy derived from placenta, designed for the treatment of hematologic disorders. The product has been under investigation in studies sponsored by the Nation Institute of Health (NIH) for the treatment of acute radiation syndrome (ARS). The goal of the program is to provide a product that can aid in the recovery of hematopoietic cell populations following radiation exposure. Currently Neupogen (Amgen) is approved for this indication and is purchased by the US government as part of the Strategic National Stockpile in case of radiological emergencies.

Pluristem previously reported encouraging results in which PLX-R18 improved survival in non-human primates across three cells dosing levels when compared to placebo (see our previous report). These animals saw improvement in multiple cell lineages, unlike Neupogen, which only increases concentration of neutrophils. Importantly, the company also reported there were no safety issues and that the treatment did not increase leukocyte counts in non-irradiated animals. This opens the potential for PLX-R18 to be safely used in patients before the extent of their radiation exposure has been determined, which could prove advantageous for triage. By comparison, Neupogen must be accurately dosed to ensure patient safety.

These results garnered the attention of the US Department of Defense (DOD), which in August 2017 announced a pilot study to investigate PLX-R18 for ARS. This trial will be conducted under the FDA animal rule similar to previous studies. Additionally, the DOD study will examine the efficacy of PLX-R18 in supporting hematopoietic cells when administered before radiation exposure (as well as up to 24 hours after exposure). This will support the potential use of the product for the US military's unique needs to protect personnel from potential or imminent exposure. The DOD development program will be performed in parallel to any NIH sponsored program. If the DOD program is successful, this could result in additional purchasing agreements outside of Strategic National Stockpile agreements (estimated $155m value, based on previous Neupogen contracts). We expect future updates from the company following the results of the DOD pilot program as well as with the initiation of a pivotal non-human primate trial as part of the NIH sponsored program.

In additional news regarding the ARS program, Pluristem presented data on 12 additional primates at the Radiation Injury Treatment Network annual meeting in July 2017. These primates received a lower dose of radiation than those from the previous reported results of the ARS dosing study. The company stated that although the dose of radiation was not lethal in these animals, the PLX-R18 showed measurable improvement in the recovery of hematopoietic cells, although the company reported no numeric details or statistical analysis. Perhaps most encouraging from this study was that no safety issues were observed.

$16.6m in new grant money for studies using PLX-PAD

Pluristem announced that it would be sharing $8.7m in grant funding for the study of PLX-PAD for muscle regeneration following hip injury from the EU Horizon 2020 grant program (pending final approval of the grant agreement and research consortium). Additionally, the company announced that another Horizon 2020 grant for $7.9m would be awarded to a consortium studying the imaging of stem cells, called the nTrack project. PLX-PAD will be used in this study to predict muscle regeneration following injury of the gastrocnemius muscle. This brings the total financing from grants to study Pluristem products to $24.6 from Horizon 2020 and $27m in total. The recent awards are the second and third from Horizon 2020 to the company. Previously, a consortium of Pluristem, the Berlin-Brandenburg Center for Regenerative Therapies, and other parties was

awarded $8m for the study of PLX-PAD in critical limb ischemia. Of this amount, $2.2m was a direct grant to Pluristem, and $965,000 has been delivered as of the end of FY17. The new hip injury grant will also be awarded to a consortium led by the Berlin-Brandenburg Center for Regenerative Therapies, and we expect a similar direct contribution to the company. We do not expect grant financing for the imaging study to cover more than the cost of material used in the study, although any scientific findings may be useful to guide future research directions. There is the potential for cost savings on future clinical trial costs through the consortium's given infrastructure, but we expect these effects to be small.

FNF trial protocol announced following FDA feedback

The company also announced on 26 September 2017 that it had received "positive feedback" from the FDA and EMA regarding a proposed Phase III clinical trial for FNF. The trial will enroll 180 patients across the US and Europe who will receive an injection of 150m PLX-PAD cells 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 six months following injury. The SPPB is a series of simple physical tests of the lower extremities that mimic the physical requirements of daily activity and it 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. The company announced that it will be submitting an IND for the FNF clinical program in the coming months following the announcement, shortly after which we expect the Phase III trial to be initiated.

PLX-PAD gets a fast track designation

In September 2017, Pluristem announced that it has received a fast track designation from the FDA for the development of PLX-PAD for the treatment of CLI. Fast track is a program designed to facilitate the regulatory process for therapies that either address an unmet medical need or significantly improve on existing therapy. There is a significant need for medical interventions for CLI given the high incidence (500 to 1000 per million) [1] and lack of approved medical interventions. Only approximately half of CLI patients are fit for surgical revascularization. The designation will enable an increased level of interaction with the agency and allow the company to submit its NDA through a rolling review process (where portions of the application can be submitted in parts as they are completed). Also, if the program demonstrates a clear efficacy signal, it may additionally qualify for priority review, which will shorten the FDA review process (from ten to six months).

The CLI program was previously selected for the EMA's Adaptive Pathways initiative. Similar to fast track, this program is designed to provide an alternative regulatory process to speed market entry. This pathway also allows for increased agency interaction and staged approval. Moreover, the PLX-PAD qualifies as a regenerative medicine product in Japan, which has a streamlined regulatory process in which statistical safety and a signal of efficacy must be established before market entry. All of these programs speak to the fact that these agencies have recognized the significant need for medical revascularization treatments for CLI like PLX-PAD.

[1] Norgren L, et al (2007) Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) *J. Vasc. Surg.* 45(1), S5-S67.

Valuation

We have increased our valuation to $189m (NIS664m) or $1.94 (NIS6.81) per basic share, from $169m (NIS603m) or $1.75 (NIS6.26). This increase is driven by advancing our NPVs to the most recent period as well as reducing the R&D costs for the FNF clinical program due to the contribution of the Horizon 2020 grant proceeds. The unallocated costs have also been reduced (to a negative NPV of $10.71m from $23.36m) with increasing shift in R&D spending to allocated programs in FY2018 on the back of the expected initiation of FNF and stem cell transplant programs. Our development timeline for CLI is already consistent with the fast track pathway, although we may accelerate this timeline if the program shows exceptional efficacy or receives priority review. We may also update our valuation with the readout from the intermittent claudication (IC) Phase II clinical trial results, which are expected in early 2018.

Exhibit 1: 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 ($m)
CLI, US	2x Phase I	Phase III	10%	2021	22,500	235	2036	63%	42.02
CLI, Europe	2x Phase I	Phase III	10%	2021	13,500	247	2036	59%	39.88
CLI, Japan	2x Phase I	Phase I/II	20%	2021	22,500	76	2036	27%	9.27
CLI, development costs									-17.86
FNF (US and Europe)	Phase I for THR	Phase III ready	15%	2021	22,100	171	2036	55%	16.75
ARS	Primate Studies	Pivotal Primate Study	10%-20%	2020	N/A	155/ contract	2036	77%	34.75
IC, US	N/A	Phase II	7.5%	2022	11,500	443	2036	57%	36.08
IC, Europe	N/A	Phase II	7.5%	2022	6,900	466	2036	50%	32.00
IC, Japan	N/A	Phase II	15%	2022	11,500	144	2036	20%	6.81
IC, development costs									-34.88
HCT (US and Europe)	Mouse studies	Phase I ready	5%	2023	29,300	239	2036	61%	7.89
Unallocated costs									-10.71
Total									161.99
Net cash and equivalents (FY17) ($m)									26.67
Total firm value ($m)									188.66
Total basic shares (m, FY17)									97.5
Value per basic share ($)									1.94
Dilutive warrants from Offering									8.45
Diluted firm value ($m)									200.48
Value per diluted share ($)									$1.89

Source: Pluristem Therapeutics reports, Edison Investment Research

Financials

Pluristem reported a loss of $27.8m for the fiscal year ending 30 June 2017, compared to our previous estimates of $28.9m. The reason for the discrepancy was due to lower than expected R&D spending in Q4 ($4.6m). We have offset some of this spending to later years to keep the total costs of R&D programs within our estimates. R&D was the greatest expense for the period at $21.1m, which was an incremental increase over previous years ($19.2m and $19.6m in 2015 and 2016, respectively). We expect R&D spending to increase significantly to $33.8m in 2018 with the advancement of FNF and other clinical programs. These costs are partially offset by the new Horizon 2020 grants, which we currently model as providing $2.2m in direct support to Pluristem (spread out over the years of development). This grant has reduced our expected financing requirement to $63m ($33m in 2018 and $30m in 2019) from $65m previously. The company ended the year with $26.7m in cash and equivalents. We forecast profitability for the company in 2020 following a purchasing agreement for PLX-R18 for the Strategic National Stockpile.

Exhibit 2: Financial summary

$'000s	2015	2016	2017	2018e
Year end 30 June	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS				
Revenue	379	2,847	0	0
Cost of Sales	(13)	(100)	0	0
Gross Profit	366	2,747	0	0
Research and development	(19,173)	(19,580)	(21,092)	(33,754)
Selling, general & administrative	(6,460)	(6,486)	(6,927)	(7,151)
EBITDA	(27,341)	(25,469)	(30,196)	(42,443)
Operating Profit (before amort. and except.)	(25,267)	(23,319)	(28,019)	(40,905)
Intangible Amortisation	0	0	0	0
Exceptionals/Other	0	0	0	0
Operating Profit	(25,267)	(23,319)	(28,019)	(40,905)
Net Interest	590	73	205	(2,435)
Other (change in fair value of warrants)	0	0	0	0
Profit Before Tax (norm)	(24,677)	(23,246)	(27,814)	(43,340)
Profit Before Tax (IFRS)	(24,677)	(23,246)	(27,814)	(43,340)
Tax	0	0	0	0
Deferred tax	0	0	0	0
Profit After Tax (norm)	(24,677)	(23,246)	(27,814)	(43,340)
Profit After Tax (IFRS)	(24,677)	(23,246)	(27,814)	(43,340)
Average Number of Shares Outstanding (m)	70.3	79.5	87.4	99.2
EPS - normalised (c)	(35.11)	(29.22)	(31.81)	(43.68)
EPS - IFRS ($)	(0.35)	(0.29)	(0.32)	(0.44)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	11,287	10,345	8,518	7,247
Intangible Assets	0	0	0	0
Tangible Assets	10,173	9,216	7,277	6,006
Other	1,114	1,129	1,241	1,241
Current Assets	56,868	35,596	29,016	26,177
Stocks	0	0	0	0
Debtors	1,691	2,228	1,036	1,036
Cash	53,119	32,750	26,665	23,826
Other	2,058	618	1,315	1,315
Current Liabilities	(6,183)	(5,775)	(5,414)	(7,981)
Creditors	(6,183)	(5,775)	(5,414)	(7,981)
Short term borrowings	0	0	0	0
Long Term Liabilities	(3,829)	(2,010)	(1,869)	(34,869)
Long term borrowings	0	0	0	(33,000)
Other long term liabilities	(3,829)	(2,010)	(1,869)	(1,869)
Net Assets	58,143	38,156	30,251	(9,427)
CASH FLOW				
Operating Cash Flow	(20,605)	(18,522)	(21,611)	(35,572)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(831)	(1,750)	(378)	(267)
Acquisitions/disposals	0	0	0	0
Financing	17,201	807	15,728	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	(4,235)	(19,465)	(6,261)	(35,839)
Opening net debt/(cash)	(58,819)	(53,119)	(32,750)	(26,665)
HP finance leases initiated	5	0	0	0
Exchange rate movements	0	0	0	0
Other	(1,470)	(904)	176	0
Closing net debt/(cash)	(53,119)	(32,750)	(26,665)	9,174

Source: Pluristem, Edison Investment Research

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