

Pluristem Therapeutics

FY18 results and top-line claudication data

Pluristem ended FY18 with an operating loss of \$33.7m mostly attributed to R&D expenditure (\$22.6m) and as of 30 June 2018 had \$30.6m in net cash. The company recently announced its plans to present at several November conferences, including top-line data from its Phase II intermittent claudication (IC) study at the American Heart Association (AHA) Scientific Sessions, as well as an overview of its cell therapy products in clinical development at BioEurope.

Year end	Revenue (\$m)	PBT* (\$m)	EPS* (\$)	DPS (\$)	P/E (x)	Yield (%)
06/17	0.0	(24.2)	(0.32)	0.0	N/A	N/A
06/18	0.05	(19.6)	(0.25)	0.0	N/A	N/A
06/19e	0.0	(43.9)	(0.44)	0.0	N/A	N/A
06/20e	155.0	122.8	0.99	0.0	N/A	N/A

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

A total 172 patients over four arms over 52 weeks

Pluristem's Phase II clinical study examined 172 patients after 52 weeks for improvement in maximal walking distance (MWD). Each patient received two injections three months apart and were divided into four arms: two injections of 300m cells, two injections of 150m cells, one injection of 300m cells (and one sham) and two sham injections. Patients who received two injections of 300m cells showed a statistically significant improvement in MWD when compared to baseline ($p=0.0008$).

Significance seen in US, multi-placenta patients

The company performed a series of post hoc subgroup analyses and presented some of the data. For instance, patients on the 2x300m cell arm in the US showed a statistically significant response compared to placebo (effect size = 51.1%, $p=0.015$). Similarly, patients that received cells from two different placentas in the 2x300m cell arm had a significant response compared to placebo (effect size = 42.0%, $p=0.043$). No explanation was given for why US patients or patients receiving cells from multiple placentas would have increased responses.

Collaboration with Thermo Fisher Scientific

In July, Pluristem announced a strategic collaboration agreement with Thermo Fisher Scientific to evolve cell therapy manufacturing into a high throughput business that can support the production of therapeutic doses of regenerative medicines in mass volumes. The terms of the agreement have not been disclosed.

Valuation: Adjusted to \$212m or \$1.87 per share

We have slightly adjusted our valuation to \$212m or \$1.87 per basic share from \$212m or \$1.92 per basic share driven by rolling forward our NPVs, partially offset by a lower cash position and a change to PRV sale timing expectations. The decrease in share price is due to a rise in share count. We continue to expect the company to require \$50m in additional capital to reach profitability in 2020.

Clinical and earnings update

Pharma & biotech

7 November 2018

Price* **US\$1.4**

Market cap **US\$155m**

*Priced at 6 November 2018

	NSI3.57/US\$
Net cash (\$m) at end FY18	30.59
Shares in issue	113.6m
Free float	93%
Code	PSTI
Primary exchange	NASDAQ
Secondary exchange	TASE

Share price performance



%	1m	3m	12m
Abs	(5.7)	(5.7)	(26.6)
Rel (local)	(1.2)	(2.4)	(31.0)
52-week high/low	US\$1.6	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 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

PLX-PAD in IC Phase II top-line data presentation at AHA	10 November 2018
Initiate acute radiation syndrome Phase III study	Year-end 2018

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Intermittent claudication clinical results

In June 2018, Pluristem announced the top-line results from its Phase II study of PLX-PAD for the treatment of intermittent claudication (IC). IC is a peripheral vascular disease characterized by leg pain during exertion that subsides at rest. This pain is caused by partial occlusions of the vasculature in the leg and the disease can progress to more severe CLI. PLX-PAD is a faction of mesenchymal cells isolated from placenta, and the hope is that the cells will encourage the development of new vasculature in IC patients to alleviate pain and prevent progression to CLI.

The Phase II study enrolled 172 patients across the US, Germany, South Korea and Israel. The primary end-point of the study was increase in the MWD at 52 weeks over baseline. Each patient received two injections three months apart according to the following arms:

- two injections of 300m PLX-PAD cells;
- two injections of 150m PLX-PAD cells;
- one injection of 300m PLX-PAD cells and one sham injection;
- two sham injections (placebo).

The company presented a section of data from various subsets of patients. Patients in the 2x300m cell arm had a statistical significant improvement in MWD compared to baseline ($p=0.008$).

However, the company did not provide an effect size or a comparison of this arm to placebo, so we assume this arm did not meet its primary endpoint. Given that IC is effectively treated with exercise, we envision that the placebo response in this trial was significant (although it was not reported by the company). The company did state that patients on the 2x300m cell arm from US clinical sites saw a statically significant improvement vs placebo (effect size 51.1%, $n=73$, $p=0.015$), but no explanation for why higher responses would be seen in the US was provided and no comments information was included whether the result would still be significant after adjusting for multiple comparisons (such as a Bonferroni correction). Furthermore, the company neither reported top-line data from Germany, South Korea, and Israeli clinical sites nor alternative dosing regimens.

The company introduced a new secondary outcome measure in this release, which was the change in MWD in patients that received cells from two different placentas. The company has branded the approach of using two different placentas in its treatment is 'proprietary Bio-Therapeutic approach'. We are unaware of any previous mention of this as a particular approach under investigation. The company reported that patient who received cells from two different placentas in the 2x300m cell arm had a 42.0% improvement in MWD over placebo ($p=0.043$) and a 83% improvement over baseline ($p=0.0007$). We assume the corresponding population of patients that received cells from a single placenta did not meet these endpoints. The increased effect from two placentas is an interesting observation, although it is unclear at this time the precise reason why multiple placentas would provide an increased effect. The company did not report the number of patients in this subgroup, which would provide increased insight into the durability of this observation.

Finally, the company reported that the revascularization risk was reduced in the 2x300m cell arm by 49% at week 65, and that the subgroup that received cells from two placentas did not receive any revascularizations. The company did not state what this comparison was being made to, for instance placebo or historical controls. Moreover, the entry on clinicaltrials.gov only lists one end point at 52 weeks. No p-value was reported for these observations, so we conclude that it likely did not reach statistical significance.

The ability to interpret this top-line data is limited for reasons that are commonly associated with similar subgroup analyses. The data were segmented along the lines of the country where it was gathered, the number of placentas used and the number of cells administered, and each of these values was subsequently compared to both placebo and baseline. This is a large number of

comparisons; with increasing numbers of comparisons, the chance that any given one will have statistically significant results due to chance increases. This is why such subgroup analyses are not supportive of regulatory approval without significantly increased statistical rigor, such as adjustments for multiple comparisons and there is no suggestion these data were adjusted in such a way.

The company stated these data are supportive of the design of its ongoing Phase III study in CLI. Two administrations of 300m cells is the treatment chosen for the CLI study, and this was the optimal dose as reported in in this study. The company noted that two injections of 300m cells were statistically superior to one ($p=0.0331$). Moreover, the company notes that CLI study will be using cells from multiple placentas, similar to the subgroup examined in this study.

The company could increase our confidence in the IC and CLI programs with the release of more complete data from this study. We have little basis for understanding the results provided here, given no data on baseline responses, placebo responses, or patient characteristics were provided. However, perhaps the most definitive result from the current study was that there were no safety concerns observed, consistent with previous data. Pluristem is scheduled to present at the AHA Scientific Sessions on 10 November 2018, where we expect it to disclose top-line data from its Phase II study of PLX-PAD for the treatment of IC in its entirety.

PLX-PAD for FNF Phase III enrolment is ongoing

Pluristem recently announced that its PLX-PAD Phase III study, which is funded in part by an \$8.7m grant from the European Horizon 2020 Program, is continuing to enrol patients with muscle injury following hip arthroplasty due to femoral neck fracture (FNF). The company recently received clearance to begin patient enrolment in Denmark, Germany, and the UK. As a reminder, the Phase III trial will enrol 240 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.

PLX-PAD for CLI receives FDA clearance for EPA

On 16 October 2018, Pluristem announced an agreement with WideTrial Inc., which is a privately held third-party sponsor of authorised expanded access programmes (EPAs), to initiate an FDA cleared EPA for PLX-PAD for the treatment of CLI. The study will include 100 CLI patients with minor tissue loss up to the ankle (Rutherford category 5) whose condition is life threatening and would have been otherwise excluded from Pluristem's current Phase III trial. This program allows access to the treatment for patients outside of the clinical trials, and the potential for reimbursement to the company at cost.

As a reminder, Pluristem's [pivotal Phase III CLI trial](#) is ongoing in the US and EU. The trial is currently enrolling up to 246 patients who are otherwise unsuitable for revascularization, and will measure the time to amputation or death as the primary endpoint. The company has stated that it expects a single trial to be sufficient to support approval, and it has consulted with both the FDA and EMA regarding the pathway. In part, this is enabled by the large safety database (provided by a Phase II IC study) that will be provided by the ongoing intermittent claudication clinical trial. The program has fast-track in the US and has an adaptive pathway designation in the EU, which may entitle it to early provisional approval (after 123 events). Additionally the program received fast-track status from the FDA in September 2017. All of these special programs ensure an increased level of interaction with the regulatory agencies and guidance. The company also has plans to initiate a 75-person study in Japan, through a subsidiary co-owned by Sosei. This is also expected to be the only trial needed for approval, as in Japan, regenerative products face a lower bar of statistical evidence for approval (statistical safety and a signal of efficacy). We should note that the decision

to progress to a Phase III trial without a confirmatory Phase II study and without statistically demonstrating a treatment effect is exceptionally aggressive and the program is high risk.

Valuation

We have slightly adjusted our valuation to \$212m or \$1.87 per basic share from \$212m or \$1.92 per basic share. These changes are primarily driven by rolling forward our NPVs to the most recent period, which is partially offset by the lower cash position and the shift in priority review voucher (PRV) sale timing expectations to 2021 (from 2020) associated with the acute radiation syndrome (ARS) indication. The decrease in share price is due to the increase in total basic shares. We are not adjusting our probability of success for the IC program (7.5%) based on these data pending further information, as it appears the drug did not meet its primary endpoint, although this has not been confirmed. This study also does not appear to provide any evidence over previous data that speak to the approvability of PLX-PAD for IC or any other indication.

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%	47.27
CLI, Europe	2x Phase I	Phase III	10%	2021	13,500	247	2036	59%	44.86
CLI, Japan	2x Phase I	Phase I/II	20%	2021	22,500	76	2036	27%	10.43
CLI, development costs									(20.09)
FNF (US and Europe)	Phase I for THR	Phase III	15%	2021	22,100	171	2036	55%	18.84
ARS	Primate Studies	Pivotal Primate Study	10%-20%	2020	N/A	155/ contract	2036	77%	37.78
IC, US	N/A	Phase II	7.5%	2022	11,500	443	2036	57%	40.59
IC, Europe	N/A	Phase II	7.5%	2022	6,900	466	2036	50%	36.00
IC, Japan	N/A	Phase II	15%	2022	11,500	144	2036	20%	7.66
IC, development costs									(33.26)
HCT (US and Europe)	Mouse Studies	Phase I	5%	2023	29,300	239	2036	61%	8.88
Unallocated costs									(17.21)
Total									181.75
Net cash and equivalents (Q418) (\$m)									30.59
Total firm value (\$m)									212.34
Total basic shares (m, at 2 September 2018)									113.6
Value per basic share (\$)									1.87
Dilutive warrants									7.62
Diluted firm value (\$m)									223.01
Value per diluted share (\$)									\$1.84

Source: Edison Investment Research

Financials

Pluristem reported an operating loss of \$33.7m for its FY18 ending 30 June 2018. R&D spending for the year was the company's major expense at \$22.6m, which is in line with R&D spend for the prior year (FY17 R&D: \$21.1). Our previous FY18 R&D and SG&A estimates were considerably on par with what was reported at \$22.8m (compared to FY18 R&D reported: \$22.6m) and \$10.2m (compared to FY18 SG&A reported: \$11.2m), respectively. Pluristem reported \$50,000 in revenue for FY18 and is attributed to the sale of PLX cells for research use. This is the first time we are introducing 2020 estimates. We forecast revenues of \$155m for that year attributed to US stockpile awards for its PLX-R18 program that may be used in the case of nuclear attack for the treatment of ARS. We continue to expect the company to require \$50m in additional capital (in FY19, recorded as illustrative debt) to reach profitability in 2020.

Exhibit 3: Financial summary

	\$'000s	2016	2017	2018	2019e	2020e
Year end 30 June		US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS						
Revenue		2,847	0	50	0	155,000
Cost of Sales		(100)	0	(2)	0	15,500
Gross Profit		2,747	0	48	0	170,500
Research and development		(19,580)	(21,092)	(22,629)	(36,267)	(39,517)
Selling, general & administrative		(6,486)	(6,927)	(11,193)	(10,726)	(11,263)
EBITDA		(25,469)	(30,196)	(35,749)	(48,193)	117,674
Operating Profit (before amort. and except.)		(23,319)	(28,019)	(33,731)	(46,993)	119,721
Intangible Amortisation		0	0	0	0	0
Exceptionals/Other		0	0	0	0	0
Operating Profit		(23,319)	(28,019)	(33,731)	(46,993)	119,721
Financing income		73	205	7,605	(3,475)	(3,475)
Other (change in fair value of warrants)		0	0	0	0	0
Profit Before Tax (norm)		(20,173)	(24,152)	(19,578)	(43,920)	122,794
Profit Before Tax (IFRS)		(23,246)	(27,814)	(26,126)	(50,468)	116,246
Tax		0	0	0	0	0
Deferred tax		0	0	0	0	0
Profit After Tax (norm)		(20,173)	(24,152)	(19,578)	(43,920)	122,794
Profit After Tax (IFRS)		(23,246)	(27,814)	(26,126)	(50,468)	116,246
Average Number of Shares Outstanding (m)		79.5	87.4	105.9	114.5	117.9
EPS - normalised (c)		(25.36)	(27.63)	(18.48)	(38.36)	104.14
EPS - IFRS (\$)		(0.29)	(0.32)	(0.25)	(0.44)	0.99
Dividend per share (c)		0.0	0.0	0.0	0.0	0.0
Gross Margin (%)		N/A	N/A	N/A	N/A	N/A
EBITDA Margin (%)		N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A	N/A
BALANCE SHEET						
Fixed Assets		10,345	8,518	6,924	10,932	14,241
Intangible Assets		0	0	0	0	0
Tangible Assets		9,216	7,277	5,678	9,686	12,995
Other		1,129	1,241	1,246	1,246	1,246
Current Assets		35,596	29,016	32,036	34,650	143,371
Stocks		0	0	0	0	0
Debtors		2,228	1,036	58	58	58
Cash		32,750	26,665	30,587	33,201	141,922
Other		618	1,315	1,391	1,391	1,391
Current Liabilities		(5,775)	(5,414)	(8,548)	(9,090)	1,674
Creditors		(5,775)	(5,414)	(8,548)	(9,090)	1,674
Short term borrowings		0	0	0	0	0
Long Term Liabilities		(2,010)	(1,869)	(1,905)	(51,905)	(51,905)
Long term borrowings		0	0	0	(50,000)	(50,000)
Other long term liabilities		(2,010)	(1,869)	(1,905)	(1,905)	(1,905)
Net Assets		38,156	30,251	28,507	(15,413)	107,381
CASH FLOW						
Operating Cash Flow		(18,522)	(21,611)	(21,380)	(42,178)	114,077
Net Interest		0	0	0	0	0
Tax		0	0	0	0	0
Capex		(1,750)	(378)	(342)	(5,208)	(5,355)
Acquisitions/disposals		0	0	0	0	0
Financing		807	15,728	19,921	0	0
Dividends		0	0	0	0	0
Other		0	0	0	0	0
Net Cash Flow		(19,465)	(6,261)	(1,801)	(47,386)	108,722
Opening net debt/(cash)		(53,119)	(32,750)	(26,665)	(30,587)	16,799
HP finance leases initiated		0	0	0	0	0
Exchange rate movements		0	0	0	0	0
Other		(904)	176	5,723	0	0
Closing net debt/(cash)		(32,750)	(26,665)	(30,587)	16,799	(91,922)

Source: Company reports, Edison Investment Research

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