EDISON

Pluristem Therapeutics

Earnings update

Ready for a big 2017

Pharma & biotech

2017 will be a significant year for Pluristem as the company expands its clinical program with a transnational Phase III clinical trial of PLX-PAD for critical limb ischemia (CLI). Pluristem recently put protocols in place in the US and Europe with plans to initiate in the first half of 2017. Additionally, it continues to make progress in its intermittent claudication (IC) Phase II clinical trial, which was fully enrolled as of January 2017, with data expected in early 2018.

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
06/17e	0.0	(29.3)	(0.30)	0.0	N/A	N/A
06/18e	0.0	(41.5)	(0.41)	0.0	N/A	N/A

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

Ready to go for CLI

The medical authorities in the US, UK, and Germany have now signed off on Pluristem's clinical trial protocol for CLI. This is significant, because as it is designed, the trial should allow for approval in all territories with a single 250-person study. The endpoint for the study will be improvement in time-to-event, which should improve the statistical analysis enabling the small trial size. The study should start in the first half of CY17.

A new company to support Japanese development

Pluristem recently signed a binding term sheet with Sosei Corporate Venture Capital to form a new company to develop PLX-PAD for CLI in Japan. In return for the product licence, Pluristem will receive 35% of the company, royalties and Sosei will receive the remaining portion for $11m, enough capital to finance development. The plan is to perform a 75-person Phase I/II clinical trial, which should be sufficient for approval in Japan on the basis of demonstration of safety.

IC trial fully enrolled

After many years of difficulty enrolling, the company's 172-person Phase II trial of PLX-PAD for IC was fully enrolled as of 12 January 2017. The trial will measure maximum walking distance compared to baseline one year after injection of PLX-PAD cells. Therefore, we expect the study to be complete in early 2018.

Valuation: Reduced to $159m (NIS597m)

We have reduced our valuation to $159m (NIS597m) or $1.66 (NIS6.21) per basic share, from $182m (NIS683m), or $1.87 (NIS7.01) per basic share. This was largely due to a reduction in estimated cash due to the delay in the completion of $30m investment from Zheshang Venture Capital. Instead the company entered a bought offering of $17.25m for 14.1m shares and 8.5m warrants, bringing estimated cash to $37.6m. The company reported a loss of $6.6m for Q217, compared to $6.3m in the previous period.

28 February 2017

Price*	**US$1.12/ NIS4.17**
Market cap	**US$108m/ NIS401m**

*Priced at 24 February 2017.

	NIS3.75/US$
Net cash ($m) as at 31 December 2016	21.3
Shares in issue	96.1m
Free float	78%
Code	PSTI
Primary exchange	NASDAQ
Secondary exchange	TASE

Share price performance

%	1m	3m	12m
Abs	(2.3)	(29.3)	(13.2)
Rel (local)	(5.9)	(30.4)	(17.3)
52-week high/low		$1.85	$1.10

Business description

Pluristem 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) with a Phase III study on hip fracture. PLX-R18 is being advanced for acute radiation syndrome and hematopoietic cell transplant.

Next events

CLI Phase III initiation	End of H117
FNF Phase III initiation	Pending FDA meeting
IC Phase II top-line results	Early 2018

Analysts

Maxim Jacobs	+1 646 653 7027
Nathaniel Calloway	+1 646 653 7036

healthcare@edisongroup.com

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Progress on international fronts

Pluristem has been making progress toward the advancement of its clinical programs, including a number of regulatory and commercial hurdles towards the worldwide launch of its products. In 2017, the company should be able to initiate pivotal CLI trials in the US, Europe, and Japan, as well as enter the pivotal large animal study for acute radiation syndrome (ARS). We expect this to be shortly followed up with topline results from the Phase II IC trial at the beginning of 2018.

CLI protocols in place in US and Europe

Pluristem remains on track to begin a Phase III clinical trial of PLX-PAD for both US and European registration by the end of FY17. As part of this, it received clearance from the FDA for its proposed trial protocol. The trial is randomized, double blind, and placebo controlled. It will enroll 250 patients with severe CLI, who are unfit for revascularization, at 40 clinical sites in the US and Europe. Importantly, the FDA signed off on the plan to use a time-to-event (such as amputation or death) endpoint for the trial, as opposed to previous trials, which measured the fraction of patients with amputation-free survival at discrete time points. The new protocol should allow the generation of a Kaplan-Meier curve for the results, which has significantly improved statistics and ability to discriminate between arms over the time point analysis. Kaplan-Meyer analysis is less sensitive to the underlying baseline (assuming adequate randomization) because it does not presume the timing of the clinical benefit. A potential downside to this protocol is that the trial could run longer than expected if the rate of events is slower than expected. The company has stated that the trial should start in the first half of CY17.

Pluristem also received clearance in Germany for a similar clinical program. This marks the second country in Europe (after the UK) that has approved the protocol. The company intends to seek approval for the treatment using the same cohort of 250 patients that will be enrolled in the US trial, which should substantially limit costs. Additionally, the product has been selected by the EMA for approval via the new adaptive pathway. This program should allow provisional approval after the first 125 patients have been followed for one year. We consider early approval in Europe to be an upside to our base case, given the clinical data and the previously stated limitations of time point analysis, although approval of the protocol for this program speaks to the robustness of its design.

Japanese partner for CLI found: 35% equity stake for Pluristem

In December 2016, the company announced that it had signed a binding term sheet with Sosei Corporate Venture Capital to form a new company to develop and commercialize PLX-PAD in Japan for CLI (a definitive agreement is expected by the end of Q117). Japan is an important market for the product and regenerative therapies in general, because the Pharmaceuticals and Medical Devices Agency (PMDA) initiated a program to increase innovation in regenerative medicine to address the increasing issues of the country's ageing population. As such, regenerative products such as PLX-PAD can be approved on a safety basis with smaller clinical trials. We assume a higher rate of approval in Japan for this reason (20% compared to 10% in the US and Europe). Pluristem will receive a 35% stake in the new company, as well as royalties on future sales, in exchange for the rights to commercialize the product for CLI, whereas Sosei and partners will retain the remaining portion in exchange for $11m in capital. We predict that this capital should be sufficient to finance the company through the clinical development program, thereby limiting the additional outlay for Pluristem. Future capital (or alternatively dilution) may be necessary for commercialization. We have recorded Pluristem's stake in the new company as a long-term investment in our forecasts.

Progress with ongoing trials

Pluristem has also made announcements regard its ongoing clinical studies of PLX-PAD for intermittent claudication (IC) and PLX-R18 for ARS. It announced on 12 January 2017 that the 172 patient Phase II trial for IC was fully enrolled. Given that the protocol follows patients for one year, we expect the trial to be complete in early 2018, in line with previous estimates. This is a positive development, as the trial, initiated in 2012, had previously seen significant enrolment issues that have since been resolved.

The company also announced progress to the second animal cohort in the dosing study of PLX-R18 for ARS. The goal of this trial is to determine the correct dosage of cells to use in a pivotal large animal trial, based on preliminary data collected previously in mice. The current study is being conducted by the National Institute of Allergy and Infectious Diseases, and therefore Pluristem will not have to finance its completion. It expects that the study will be complete and it will be able to progress to the pivotal study in the second half of 2017. An additional Phase I study is ongoing in the US that will support the approval of PLX-R18 for emergency stock.

Valuation

We have reduced our valuation to $159m (NIS597m) or $1.66 (NIS6.21) per basic share from $182m (NIS683m), or $1.87 (NIS7.01) per basic share. A large portion of this adjustment is due to the difference in predicted cash balance between the periods. Our previous valuation included the $30m financing announced in October from Zheshang Venture Capital Co., Ltd. (ZSVC), which has subsequently been suspended. In lieu of this, the company raised a gross of $17.25m (expected $16.22m net) from a bought offering, although this resulted in significant share dilution (96.1m shares compared to 80.7m for Q117, and the 97.7m estimated amount from our last report assuming completion of the Chinese investment).

We have adjusted our future financing schedule to reflect the status of these recent deals. We expect the company will need to raise an additional $15m compared to prior estimates to make up for the difference between the sizes of the two deals. This brings the total future cash requirement to $65m ($35m in FY18 and $30m in FY19). At the current stock price, this financing schedule would require over 70% more shares.

We have also reduced the valuation of the femoral neck fracture (FNF) clinical program from $17.80m to $10.58m as we do not foresee the program initiating in FY17 given lack of feedback from the FDA at this time, and have therefore delayed our launch date to FY21. We have increased the value of CLI commercialization in Japan from $6.90m to $8.88m as we see the 35% equity stake (translating into 27% of sales) in the newly formed Japanese company as advantageous over our previous model of a 20% royalty stake. The remaining adjustments to our valuation reflect advancing our NPVs to the current period and adjustments to unallocated costs.

Exhibit 1: Pluristem valuation

Development program	Prior data	Clinical stage	Prob. of success	Launch year	Launch pricing ($)	Peak sales ($m)	Patent/ exclusivity protection	Royalty/ margin	rNPV ($m)
CLI, US	2x Phase I	Phase III	10%	2021	22,500	235	2036	63%	41.11
CLI, Europe	2x Phase I	Phase III	10%	2021	13,500	247	2036	59%	38.98
CLI, Japan	2x Phase I	Phase I/II	20%	2021	22,500	76	2036	27%	8.88
CLI, development costs									(19.92)
FNF (US and Europe)	Phase I for THR	Phase III ready	15%	2021	22,100	171	2036	55%	10.58
ARS	Mouse studies	Large animal study	10-20%	2020	N/A	155/contract	2036	77%	22.83
IC, US	N/A	Phase II	7.5%	2022	11,500	443	2036	57%	34.90
IC, Europe	N/A	Phase II	7.5%	2022	6,900	466	2036	50%	30.92
IC, Japan	N/A	Phase II	15%	2022	11,500	144	2036	20%	6.50
IC, development costs									(38.19)
HCT (US and Europe)	Mouse studies	Phase I ready	5%	2023	29,300	239	2036	61%	7.70
Unallocated costs									(22.68)
Total									**121.62**
Net cash and equivalents (Q217 + offering) ($m)									37.59
Total firm value ($m)									**159.2**
Total basic shares (m, Q217 + offering)									96.07
Value per basic share ($)									**$1.66**
Dilutive warrants from offering (m)									8.45
Diluted firm value ($m)									**171.03**
Value per diluted share ($)									**$1.64**

Source: Pluristem reports, Edison Investment Research

Financials

Pluristem reported a loss of $6.6m for Q217, which is a slight increase from the previous quarter ($6.3m). These losses are primarily associated with R&D spending associated with the ongoing IC clinical and the initiation of Phase III for CLI and Phase I in PLX-R18 for incomplete engraftment after Hematopoietic Cell Transplantation ($5.3m). We expect this spending to increase (to $23.4m for FY17) with the advancement of the CLI program to the clinic. We have reduced our estimates for FY17 R&D (from $25.3m) to reflect our delay in the timing of the initiation of the FNF clinical trial, but partially offset by an increase in unallocated R&D costs for the year. These adjustments have put an increased R&D burden in the 2018 financial year and we have increased estimates for that year to $31.8m from $30.8m.

The company announced in October 2016 a pending $30m financing transaction with Zheshang Venture Capital Co., a Chinese life sciences investment fund. However, it was subsequently announced in December that the financing had been put on hold due to changes in the Chinese regulations regarding overseas investments. The company has stated that it expects further clarification on the results of the new policies and the viability of the deal in the first half of CY17. We have removed the financing from our forecasts pending further clarity.

In the absence of this deal, the company decided to perform an offering in January 2017: 14.1m shares at $1.225 per share for gross proceeds of $17.25m before fees. The deal included 8.45m warrants exercisable at $1.40. Due to the funding shortfall from our previous report, we have increased the FY18 funding requirement to $35m (from $20m), which we record as illustrative debt.

Exhibit 2: Financial summary

$'000s	2014	2015	2016	2017e	2018e
Year end 30 June	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS					
Revenue	379	379	2,847	0	0
Cost of Sales	(11)	(13)	(100)	0	0
Gross Profit	368	366	2,747	0	0
Research and development	(19,542)	(19,173)	(19,580)	(22,772)	(31,835)
Selling, general & administrative	(8,676)	(6,460)	(6,486)	(6,810)	(7,151)
EBITDA	(29,752)	(27,341)	(25,469)	(31,530)	(40,872)
Operating Profit (before GW and except.)	(27,850)	(25,267)	(23,319)	(29,582)	(38,985)
Intangible Amortization	0	0	0	0	0
Exceptionals/Other	0	0	0	0	0
Operating Profit	(27,850)	(25,267)	(23,319)	(29,582)	(38,985)
Net Interest	918	590	73	276	(2,524)
Other (change in fair value of warrants)	0	0	0	0	0
Profit Before Tax (norm)	(26,932)	(24,677)	(23,246)	(29,306)	(41,509)
Profit Before Tax (IFRS)	(26,932)	(24,677)	(23,246)	(29,306)	(41,509)
Tax	0	0	0	0	0
Deferred tax	0	0	0	0	0
Profit After Tax (norm)	(26,932)	(24,677)	(23,246)	(29,306)	(41,509)
Profit After Tax (IFRS)	(26,932)	(24,677)	(23,246)	(29,306)	(41,509)
Average Number of Shares Outstanding (m)	63.5	70.3	79.5	97.5	100.4
EPS - normalized (c)	(42.40)	(35.11)	(29.22)	(30.06)	(41.33)
EPS - IFRS ($)	(0.42)	(0.35)	(0.29)	(0.30)	(0.41)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	12,036	11,287	10,345	13,835	13,644
Intangible Assets	0	0	0	0	0
Tangible Assets	10,823	10,173	9,216	8,926	8,735
Other	1,213	1,114	1,129	4,909	4,909
Current Assets	61,987	56,868	35,596	29,488	23,425
Stocks	0	0	0	0	0
Debtors	2,263	1,691	2,228	0	0
Cash	58,819	53,119	32,750	28,765	22,702
Other	905	2,058	618	723	723
Current Liabilities	(7,397)	(6,183)	(5,775)	(10,422)	(7,604)
Creditors	(7,397)	(6,183)	(5,775)	(10,422)	(7,604)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(4,503)	(3,829)	(2,010)	(1,928)	(36,928)
Long term borrowings	0	0	0	0	(35,000)
Other long term liabilities	(4,503)	(3,829)	(2,010)	(1,928)	(1,928)
Net Assets	62,123	58,143	38,156	30,973	(7,463)
CASH FLOW					
Operating Cash Flow	(19,121)	(20,605)	(18,522)	(17,615)	(39,368)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(1,573)	(831)	(1,750)	(1,750)	(1,695)
Acquisitions/disposals	0	0	0	0	0
Financing	12,624	17,201	807	16,219	0
Dividends	0	0	0	0	0
Other	0	0	0	0	0
Net Cash Flow	(8,070)	(4,235)	(19,465)	(3,146)	(41,063)
Opening net debt/(cash)	(54,213)	(58,819)	(53,119)	(32,750)	(28,765)
HP finance leases initiated	0	5	0	0	0
Exchange rate movements	0	0	0	0	0
Other	12,676	(1,470)	(904)	(839)	0
Closing net debt/(cash)	(58,819)	(53,119)	(32,750)	(28,765)	12,298

Source: Pluristem reports, Edison Investment Research

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
245 Park Avenue, 39th Floor
10167, New York
US

Sydney +61 (0)2 8249 8342
Level 12, Office 1205, 95 Pitt Street,
Sydney , NSW 2000,
Australia

Tel Aviv +44 (0)20 3734 1007
Medinat Hayehudim 60,
Herzilya Pituach, 46766
Israel