EDISON

Pluristem Therapeutics

Earnings update

Positive trends in radiation treatment

Pharma & biotech

Pluristem reported data from its pilot study of PLX-R18 for the treatment of acute radiation syndrome (ARS). The study included 48 non-human primates (NHP) who were dosed with 4m, 10m, and 20m cells per kg and showed an improvement in survival to 83%, 86% and 67%, respectively, from 50% in the control arm, although the study was not powered to significance. The company will need to perform a pivotal primate study and a human safety study for approval, which we expect in 2019-20.

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	(28.9)	(0.33)	0.0	N/A	N/A
06/18e	0.0	(41.5)	(0.42)	0.0	N/A	N/A

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

ARS data compares favourably to Neupogen

Neupogen is currently stockpiled for hematopoietic recovery following ARS. It was approved for this in 2015 on the basis of a 46-subject NHP study that showed an improvement of survival to 79% from 59% in control (p= 0.023). Also Pluristem stated that PLX-R18 supports the recovery of multiple cell lineages (Neupogen only supports white blood cells), although these data in NHP have not been released.

Benign safety profile could enable simple dosing

Pluristem stated that it did not observe any safety issues with PLX-R18 in healthy primates. This means that the treatment could potentially be administered without concern to a person's radiation exposure as it would not pose a risk to healthy individuals, compared to Neupogen, which requires frequent blood testing to avoid overdose risk. The ability to indiscriminately dose individuals is a distinct advantage to PLX-R18 in the event of an emergency radiation exposure.

ARS would qualify for a priority review voucher

The legislation regarding the award of priority review vouchers (PRVs) was expanded under the 21st Century Cures Act to include products that address a threat to national security. PLX-R18 should therefore be eligible for such a voucher. The most recent sale of a PRV was for $125m (from Sarepta to Gilead in February 2017), although we expect these prices to drop with the expansion of the program.

Valuation: $169m (NIS603m) or $1.75 (NIS6.26)

We have increased our valuation to $169m (NIS603m) or $1.75 (NIS6.26) per basic share, from $159m (NIS597m) or $1.66 (NIS6.21) per basic share. This adjustment is largely due to including the sale of a priority review voucher for PLX-R18 at $75m in our valuation. The company reported a loss of $7.9m for Q317, up from $6.6m the previous period, due to an increase in R&D spending associated with the PLX-PAD clinical program. We expect the company to require $65m in additional financing to reach profitability in 2020.

20 June 2017

Price*	**US$1.32/ NIS4.67**
Market cap	**US$127m/ NIS450m**

*Priced as at 19 June 2017.

	NIS3.58/US$
Net cash ($m) as at 31 March 2017	33.1
Shares in issue	96.3m
Free float	93%
Code	PSTI
Primary exchange	NASDAQ
Secondary exchange	TASE

Share price performance

%	1m	3m	12m
Abs	(3.1)	9.3	(3.1)
Rel (local)	(4.4)	7.0	(17.2)
52-week high/low		$1.7	$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 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

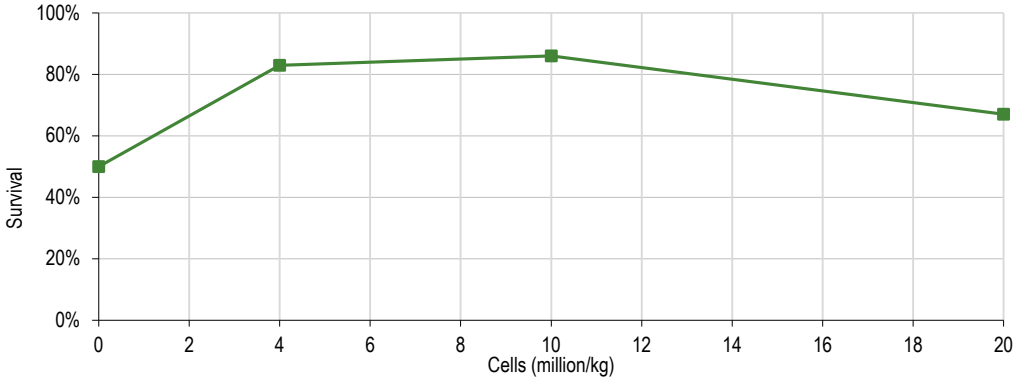
Edison profile page

Primate data for radiation treatment

Pluristem reported the results from its non-human primate (NHP) study of PLX-R18 for the treatment of acute radiation syndrome (ARS) in early May 2017. The product is being developed for ARS 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, so this NHP study is an important component of the approval package. Studies in NHPs are important to establish safety and as the basis for the human dose equivalent, as these animals provide the closest approximation to human subjects, and the purpose of this study was to determine the optimal dose.

The 48 animals were separated into four dosing arms (4, 10, 20 million cells per kilogram, and control) and were either irradiated or left intact. The study saw a trend toward increasing survival in the active arms of the trial: 83%, 86% and 67%, respectively, compared to 50% for the control (Exhibit 1). This “bell shaped” response in which higher doses can have lower efficacy is not uncommon with biologics, and these data provide an important insight into the correct dose to proceed with in future studies. Unfortunately, these data were not powered for statistical significance.

Exhibit 1: Survival of non-human primates with ARS following PLX-R18 dosing



Source: Pluristem Therapeutics

Importantly, the company also reported that there were no safety issues seen in the non-irradiated group (although detailed safety information was not released), and that leukocyte counts were not increased in these animals. This means that the treatment can potentially be administered before determining the degree of radiation exposure without concern for adverse reactions. The company also stated that PLX-R18 led to improvement in an array of hematopoietic cells, although further details were not provided.

These results compare favourably to Neupogen, which is the currently stockpiled treatment for hematopoietic recovery from ARS. Neupogen showed an improvement in survival to 79% from 59% in the control arm from a study of 46 NHPs (p=0.023).[1] On a placebo adjusted basis, Neupogen provided only a 20% improvement in survival compared to 36% for the optimal dose of PLX-R18. Moreover, PLX-R18 could provide a safer and more convenient dosing strategy than Neupogen, if PLX-R18 continues to show a benign safety profile. Neupogen has the potential to induce leucocytosis if overdosed, and requires blood tests every three days to ensure normal white blood cell counts. A drug that can be dosed without risk like PLX-R18 may be beneficial, especially in emergency radiation exposure situations. Finally, Neupogen only improves neutrophil cell counts, whereas the company stated that PLX-R18 improved multiple lineages, which would be a

[1] Neupogen label.

significant improvement over the former, although we would like to see data from NHP to back up these claims.

The company will need to perform an additional NHP study that is adequately powered for statistical significance to receive approval for ARS treatment. Additionally, a human safety database must be established, although data from other trials using PLX-R18 (such as the Phase I trial in hematopoietic stem cell transplant patients) can be used. And finally, a human/animal dose conversion study must be performed, which simply requires pharmacokinetic and pharmacodynamic comparisons between humans and animals. We currently model the first potential stockpile contract (for $155m as in previous reports, similar to Neupogen stockpile contracts) in as early as 2020.

An additional upside to the program is that it would qualify Pluristem to receive a priority review voucher (PRV) from the FDA. These vouchers are issued by the FDA to encourage certain development programs such as underserved indications and they allow the voucher holder to shorten the FDA period of review from 10 to six months. PRVs are not attached to a particular company and can be freely traded. In the recent 21st Century Cures Act, the agency expanded the PRV program to include products that are potentially important to national security, and agents used in the event of radiological threats expressly fall under this definition. Therefore, the company should be able to apply for such a voucher in the event that the product gains approval. The most recent voucher sale was for $125m from Sarepta Therapeutics to Gilead in February 2017. These vouchers have been less expensive lately (from a peak of $350m) and we expect prices to continue to trend lower with the recent expansion.

Valuation

We have increased our valuation to $169m (NIS603m) or $1.75 (NIS6.26) per basic share, from $159m (NIS597m) or $1.66 (NIS6.21) per basic share. This adjustment is largely due to including the sale of a priority review voucher for PLX-R18 in our valuation. We currently estimate a preliminary value for the voucher of $75m, although this may change based on how the market for these documents develops. This price is based on the current trend of dropping prices, which we expect to accelerate with an increased number of vouchers issued following passage of the 21st Century Cures Act. We have not increased the probability of success for PLX-R18 for the treatment of ARS at this time due to the lack of statistically significant data and in human safety data. However, we expect to update this in the future when these studies are performed. We have rolled forward our NPVs to Q317 and adjusted for new net cash. Our other assumptions remain unchanged.

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 ($m)
CLI, US	2x Phase I	Phase III	10%	2021	22,500	235	2036	63%	42.34
CLI, Europe	2x Phase I	Phase III	10%	2021	13,500	247	2036	59%	40.14
CLI, Japan	2x Phase I	Phase I/II	20%	2021	22,500	76	2036	27%	9.15
CLI, development costs									(20.52)
FNF (US and Europe)	Phase I for THR	Phase III ready	15%	2021	22,100	171	2036	55%	10.90
ARS	Primate studies	Pivotal primate study	10-20%	2020	N/A	155/ contract	2036	77%	33.74
IC, US	N/A	Phase II	7.5%	2022	11,500	443	2036	57%	35.94
IC, Europe	N/A	Phase II	7.5%	2022	6,900	466	2036	50%	31.85
IC, Japan	N/A	Phase II	15%	2022	11,500	144	2036	20%	6.70
IC, development costs									(39.33)
HCT (US and Europe)	Mouse studies	Phase I ready	5%	2023	29,300	239	2036	61%	7.93
Unallocated costs									(23.36)
Total									135.48
Net cash and equivalents (Q317) ($m)									33.06
Total firm value ($m)									**168.54**
Total basic shares (m, Q317)									96.3
Value per basic share ($)									**$1.75**
Dilutive warrants from offering (m)									8.45
Diluted firm value ($m)									180.37
Value per diluted share ($)									$1.72

Source: Pluristem Therapeutics reports, Edison Investment Research

Financials

The company reported a loss of $7.9m for the fiscal Q317 ending 31 March 2017. This is an increase over previous quarters ($6.3m for Q117 and $6.6m in Q217) largely driven by increases in R&D expenses of $6.3m (up from $5.0m in Q117 and $6.2m in Q217). We attribute this increased expense to the completion of enrolment of the intermittent claudication trial that occurred during the quarter. We expect R&D spending to remain at approximately these levels throughout the year ($22.7m total spending), but to increase in later years with the advancement of more programs to late-stage trials. We have made minor adjustments to future R&D spending based on the current run rate. The company completed a bought offering of 14.1m shares and 8.4m warrants (at $1.225) for net proceeds of $15.7m during the quarter. We currently forecast that the company will need $65m in additional financing to reach profitability in 2020.

Exhibit 3: Financial summary

$000s	2014	2015	2016	2017e	2018e
Year end 30 June	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS					
Revenue	379	379	2,847	0	0
Cost of Sales	(11)	(13)	(100)	0	0
Gross Profit	368	366	2,747	0	0
Research and development	(19,542)	(19,173)	(19,580)	(22,772)	(32,153)
Selling, general & administrative	(8,676)	(6,460)	(6,486)	(6,810)	(7,151)
EBITDA	(29,752)	(27,341)	(25,469)	(31,530)	(41,187)
Operating Profit (before GW and except.)	(27,850)	(25,267)	(23,319)	(29,582)	(39,303)
Intangible Amortisation	0	0	0	0	0
Exceptionals/Other	0	0	0	0	0
Operating Profit	(27,850)	(25,267)	(23,319)	(29,582)	(39,303)
Net Interest	918	590	73	635	(2,165)
Other (change in fair value of warrants)	0	0	0	0	0
Profit Before Tax (norm)	(26,932)	(24,677)	(23,246)	(28,947)	(41,468)
Profit Before Tax (IFRS)	(26,932)	(24,677)	(23,246)	(28,947)	(41,468)
Tax	0	0	0	0	0
Deferred tax	0	0	0	0	0
Profit After Tax (norm)	(26,932)	(24,677)	(23,246)	(28,947)	(41,468)
Profit After Tax (IFRS)	(26,932)	(24,677)	(23,246)	(28,947)	(41,468)
Average Number of Shares Outstanding (m)	63.5	70.3	79.5	87.4	99.2
EPS - normalised (c)	(42.40)	(35.11)	(29.22)	(33.10)	(41.79)
EPS - IFRS ($)	(0.42)	(0.35)	(0.29)	(0.33)	(0.42)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	12,036	11,287	10,345	10,023	9,832
Intangible Assets	0	0	0	0	0
Tangible Assets	10,823	10,173	9,216	8,913	8,722
Other	1,213	1,114	1,129	1,110	1,110
Current Assets	61,987	56,868	35,596	29,673	24,347
Stocks	0	0	0	0	0
Debtors	2,263	1,691	2,228	318	318
Cash	58,819	53,119	32,750	28,134	22,808
Other	905	2,058	618	1,221	1,221
Current Liabilities	(7,397)	(6,183)	(5,775)	(9,765)	(7,643)
Creditors	(7,397)	(6,183)	(5,775)	(9,765)	(7,643)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(4,503)	(3,829)	(2,010)	(1,966)	(36,966)
Long term borrowings	0	0	0	0	(35,000)
Other long term liabilities	(4,503)	(3,829)	(2,010)	(1,966)	(1,966)
Net Assets	62,123	58,143	38,156	27,965	(10,430)
CASH FLOW					
Operating Cash Flow	(19,121)	(20,605)	(18,522)	(18,761)	(38,634)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(1,573)	(831)	(1,750)	(1,750)	(1,693)
Acquisitions/disposals	0	0	0	0	0
Financing	12,624	17,201	807	15,728	0
Dividends	0	0	0	0	0
Other	0	0	0	0	0
Net Cash Flow	(8,070)	(4,235)	(19,465)	(4,783)	(40,326)
Opening net debt/(cash)	(54,213)	(58,819)	(53,119)	(32,750)	(28,134)
HP finance leases initiated	0	5	0	0	0
Exchange rate movements	0	0	0	0	0
Other	12,676	(1,470)	(904)	167	0
Closing net debt/(cash)	(58,819)	(53,119)	(32,750)	(28,134)	12,192

Source: Pluristem Therapeutics reports, Edison Investment Research

Edison is an investment research and advisory company, with offices in North America, Europe, the Middle East and AsiaPac. The heart of Edison is our world-renowned equity research platform and deep multi-sector expertise. At Edison Investment Research, our research is widely read by international investors, advisers and stakeholders. Edison Advisors leverages our core research platform to provide differentiated services including investor relations and strategic consulting. is authorised and regulated by the Financial Conduct Authority. Edison Investment Research (NZ) Limited (Edison NZ) is the New Zealand subsidiary of Edison. Edison NZ is registered on the New Zealand Financial Service Providers Register (FSP number 247505) and is registered to provide wholesale and/or generic financial adviser services only. Edison Investment Research Inc (Edison US) is the US subsidiary of Edison and is regulated by the Securities and Exchange Commission. Edison Investment Research Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison and is not regulated by the Australian Securities and Investment Commission. Edison Germany is a branch entity of Edison Investment Research Limited [4794244]. www.edisongroup.com

EDISON ISRAEL DISCLAIMER

Disclosure regarding the scheme to enhance the awareness of investors to public companies in the technology and biomed sectors that are listed on the Tel Aviv Stock Exchange and participate in the scheme (hereinafter respectively "the Scheme", "TASE", "Participant" and/or "Participants"). Edison Investment Research (Israel) Ltd, the Israeli subsidiary of Edison Investment Research Ltd (hereinafter respectively "Edison Israel" and "Edison"), has entered into an agreement with the TASE for the purpose of providing research analysis (hereinafter "the Agreement"), regarding the Participants and according to the Scheme (hereinafter "the Analysis" or "Analyses"). The Analysis will be distributed and published on the TASE website (Maya), Israel Security Authority (hereinafter "the ISA") website (Magna), and through various other distribution channels. The Analysis for each participant will be published at least four times a year, after publication of quarterly or annual financial reports, and shall be updated as necessary after publication of an immediate report with respect to the occurrence of a material event regarding a Participant. As set forth in the Agreement, Edison Israel is entitled to fees for providing its investment research services. The fees shall be paid by the Participants directly to the TASE, and TASE shall pay the fees directly to Edison. Subject to the terms and principals of the Agreement, the Annual fees that Edison Israel shall be entitled to for each Participant shall be in the range of $35,000-50,000. As set forth in the Agreement and subject to its terms, the Analyses shall include a description of the Participant and its business activities, which shall inter alia relate to matters such as: shareholders; management; products; relevant intellectual property; the business environment in which the Participant operates; the Participant's standing in such an environment including current and forecasted trends; a description of past and current financial positions of the Participant; and a forecast regarding future developments in and of such a position and any other matter which in the professional view of the Edison (as defined below) should be addressed in a research report (of the nature published) and which may affect the decision of a reasonable investor contemplating an investment in the Participant's securities. To the extent it is relevant, the Analysis shall include a schedule of scientific analysis of an expert in the field of life sciences. An "equity research abstract" shall accompany each Equity Research Report, describing the main points addressed. The full scope reports and reports where the investment case has materially changed will include a thorough analysis and discussion. Short update notes, where the investment case has not materially changed, will include a summary valuation discussion. The Agreement with TASE regarding the participation of Edison in the scheme for the research analysis of public companies does not and shall not constitute an approval or consent on the part of TASE or the ISA or any other exchange on which securities of the Company are listed, or any other securities' regulatory authority which regulates the issuance of securities by the Company to the content of the Report or to the recommendation contained therein. A summary of this report is also published in the Hebrew language. In the event of any contradiction, inconsistency, discrepancy, ambiguity or variance between the English Report and the Hebrew summary of said Report, the English version shall prevail; and a note to this effect shall appear in any Hebrew summary of a Report. Edison is regulated by the Financial Conduct Authority. According to Article 12.3.2, Chapter 12 of the Conduct of Business Sourcebook, Edison, which produces or disseminates non-independent research, must ensure that it: 1) is clearly identified as a marketing communication; and 2) contains a clear and prominent statement that (or, in the case of an oral recommendation, to the effect that) it: a) has not been prepared in accordance with legal requirements designed to promote the independence of investment research; and b) is not subject to any prohibition on dealing ahead of the dissemination of investment research. The financial promotion rules apply to non-independent research as though it were a marketing communication.

EDISON INVESTMENT RESEARCH DISCLAIMER

 This report has been prepared and issued by Edison for publication globally. All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report. Opinions contained in this report represent those of the research department of Edison at the time of publication. The securities described in the Investment Research may not be eligible for sale in all jurisdictions or to certain categories of investors. This research is issued in Australia by Edison Aus and any access to it, is intended only for "wholesale clients" within the meaning of the Australian Corporations Act. The Investment Research is distributed in the United States by Edison US to major US institutional investors only. Edison US is registered as an investment adviser with the Securities and Exchange Commission. Edison US relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. As such, Edison does not offer or provide personalised advice. We publish information about companies in which we believe our readers may be interested and this information reflects our sincere opinions. The information that we provide or that is derived from our website is not intended to be, and should not be construed in any manner whatsoever as, personalised advice. Also, our website and the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. This document is provided for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research. Edison has a restrictive policy relating to personal dealing. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report. Edison or its affiliates may perform services or solicit business from any of the companies mentioned in this report. The value of securities mentioned in this report can fall as well as rise and are subject to large and sudden swings. In addition it may be difficult or not possible to buy, sell or obtain accurate information about the value of securities mentioned in this report. Past performance is not necessarily a guide to future performance. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (ie without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision. To the maximum extent permitted by law, Edison, its affiliates and contractors, and their respective directors, officers and employees will not be liable for any loss or damage arising as a result of reliance being placed on any of the information contained in this report and do not guarantee the returns on investments in the products discussed in this publication. FTSE International Limited ("FTSE") © FTSE 2017. "FTSE®" is a trade mark of the London Stock Exchange Group companies and is used by FTSE International Limited under license. All rights in the FTSE indices and/or FTSE ratings vest in FTSE and/or its licensors. Neither FTSE nor its licensors accept any liability for any errors or omissions in the FTSE indices and/or FTSE ratings or underlying data. No further distribution of FTSE Data is permitted without FTSE's express written consent.

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
295 Madison Avenue, 18th Floor
10017, 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