EDISON

Sunesis Pharmaceuticals

Earnings update

SNS-062 trial up and running

Pharma & biotech

Sunesis announced on 18 July 2017 that the first patient had been dosed in its Phase Ib/II study of SNS-062 for the treatment of chronic lymphocytic leukemia (CLL) and other B-cell cancers. The trial is a dose-ranging and expansion study enrolling relapsed and refractory patients, and will enroll up to 124 patients. The company announced on the Q217 conference call that it expects to have identified the correct dose and to provide an update in spring 2018.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/15	3.1	(36.7)	(3.02)	0.0	N/A	N/A
12/16	2.5	(38.0)	(2.42)	0.0	N/A	N/A
12/17e	0.7	(33.8)	(1.58)	0.0	N/A	N/A
12/18e	0.0	(35.5)	(1.59)	0.0	N/A	N/A

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

Targeting Imbruvica resistant patients

SNS-062 is an inhibitor of Bruton's tyrosine kinase (BTK), similar to the blockbuster Imbruvica (ibrutinib, AbbVie/Janssen, $2.2bn 2016 sales). However unlike Imbruvica, SNS-062 binds non-covalently to BTK, which allows it to maintain efficacy in patients with the common resistance mutation C481S. The current clinical trial will only enroll patients with an identified C481S mutation.

The success of BTK inhibitors equals a bigger market

Imbruvica has only been approved as a first-line indication for CLL since March 2016, and therefore the degree of patient exposure to the drug has been limited. 25% of patients developed resistance to the drug at 26 months in early trials, and this number is expected to increase the longer it is in use. There is also increasing evidence that the vast majority of these resistant patients, up to 80%, harbor the C481S mutation that SNS-062 can address.

Decisions looming for SNS-229 and TAK-580

The company stated on its Q217 call that it expects to make a decision on whether to progress SNS-229 to human trials this coming fall. SNS-229 is a phosphoinositide dependent protein kinase 1 (PDK1) inhibitor in preclinical testing for hematological and solid tumors. Additionally, a decision from Takeda on whether to progress TAK-580 is expected by the end of the year. Takeda is currently investigating TAK-580, a pan-Raf inhibitor, with a combination of immuno-oncology and chemotherapeutic agents in Phase Ib studies.

Valuation: Reduced to $93.0m or $3.96/basic share

We have reduced our valuation to $93.0m or $3.96 per basic share, from $94.3m or $4.40/share, driven by lower net cash ($15.6m) and an increased share count, partially offset by advancing our NPVs. We estimate the company will require an additional $155m to reach profitability in 2023. We expect to provide an update to our valuation following the pipeline newsflow expected in the latter half of the year.

3 August 2017

Price	**US$2.47**
Market cap	**US$58m**

Net cash ($m) at end June 2017	15.6
Shares in issue	23.5m
Free float	61%
Code	SNSS
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(6.1)	(16.7)	(40.3)
Rel (local)	(7.9)	(19.6)	(48.1)
52-week high/low		US$5.5	US$2.5

Business description

Sunesis Pharmaceuticals is a pharmaceutical company focused on oncology. Its lead asset is SNS-062, a BTK inhibitor for CLL for Imbruvica refractory patients. The program is entering a dose escalation Phase Ib/II trial. It has also developed TAK-580 with partner Takeda, and the preclinical PDK1 inhibitor SNS-229.

Next events

SNS-229 IND decision	Fall 2017
TAK-580 option	By YE17
SNS-062 dosing update	Spring 2018

Analysts

Maxim Jacobs +1 646 653 7027

Nathaniel Calloway +1 646 653 7036

healthcare@edisongroup.com

Edison profile page

First patient enrolled in SNS-062 Phase Ib/II trial

Sunesis announced on 18 July 2017 that the first patient had been dosed on the Phase Ib/II clinical trial of SNS-062 in patients with relapsed and refractory chronic lymphocytic leukemia (CLL) and other B-cell malignancies (Waldenstrom's macroglobulinemia and mantle cell lymphoma). SNS-062 is an inhibitor of Bruton's tyrosine kinase (BTK), similar to Imbruvica (ibrutinib, AbbVie/Janssen, $2.2bn 2016 sales). A limitation of Imbruvica is that its activity depends on the formation of a covalent bond to cysteine 481 of BTK. The mutation of this amino acid residue to a serine (C481S) is a common resistance mechanism that emerges in patients that progress on Imbruvica. SNS-062 is specifically designed to bind to BTK non-covalently and has demonstrated that it can inhibit the C481S isoform. This opens the possibility that the drug could potentially be effective in patients who have progressed on Imbruvica, although not limited to this group. Approximately 25% of relapsed and refractory patients treated with Imbruvica progress on the drug at 26 months.[1] Although, the prevalence of the C481S mutation in this patient population is currently unknown, preliminary studies suggest that the rate is approximately 80%.[2,3] The activity of SNS-062 with other BTK mutations has not been disclosed.

The current Phase Ib/II study is a dose escalation trial with seven planned dosing cohorts, and once the maximum tolerated dose is found, it will expand into a total estimated enrolment of 124 patients. The study will enroll patients who have progressed and have documented C481S mutations. The program is taking place at some of the premier cancer institutes in the US: U.C. Irvine Cancer Center and The Ohio State University Comprehensive Cancer Center, Dana-Faber Cancer Institute, MD Anderson Cancer Center and Weill Cornell Cancer Center. The company announced on the Q217 conference call that it expects to provide an update on dosing that will be used in the escalation portion of the trial in spring 2018.

Pipeline decisions coming

Sunesis has two additional early stage programs: SNS-229, a phosphoinositide dependent protein kinase 1 (PDK1) inhibitor being investigated in preclinical development for a range of cancer indications; and TAK-580, a pan-Raf inhibitor for solid tumors. Both of these programs have upcoming decisions that will determine if the programs progress in the clinic.

SNS-229 is currently in canine dosing studies, which are expected to provide data to the company in August. Sunesis has announced that it will be making a "go/no-go" decision based on the preclinical data in fall 2017. If it decides to proceed, it plans to file an IND in 2018.

TAK-580 is out-licensed to Takeda, which is investigating the drug for a range of tumors in Phase Ib in six different drug combinations. Sunesis stated that it expects a go/no-go decision from Takeda regarding the program by the end of 2017. Sunesis is entitled to up to $57.5m in development milestones from the collaboration, of which some undisclosed portion will be triggered upon the initiation of a registration trial.

---

1 Byrd JC, et al. (2013) Targeting BTK with ibrutinib in relapsed chronic lymphocytic leukemia. *N. Engl. J.* Med. 369, 32-42.

2 Maddocks JK, et al. (2015) Etiology of Ibrutinib Therapy Discontinuation and Outcomes in Patients With Chronic Lymphocytic Leukemia. *J. Am. Med. Assoc. Onco*. 1, 80-87.

3 Woyach JA, et al. (2017) BTK^{C481S}-Mediated Resistance to Ibrutinib in Chronic Lymphocytic Leukemia. *J. Clin. Onco.* 35, 1437-1443.

Valuation

We have reduced our valuation to $93.0m or $3.96 per basic share, from $94.3m or $4.40 per share. The reduction is driven by lower net cash ($15.6m down from $20.7m) and an increase in share count. This reduction is offset by rolling forward our NPVs to the most recent quarter. We expect to update our valuation with the go/no-go decisions for SNS-229 and TAK-580 in fall and year-end 2017, respectively. In the event of a "go" decision, we would increase our probability of success to reflect the clinical progress.

Exhibit 1: Sunesis valuation

Development Program	Clinical stage	Expected commercialization	Prob. of success	Launch year	Launch pricing ($)	Peak sales ($m)	Patent/exclusivity protection	Royalty/ margin	rNPV ($m)
TAK-580	Phase Ib	Licensed to Takeda	15%	2021	138,000	727	2032	15%	$24
SNS-062	Phase Ib/II	Proprietary	20%	2022	152,000	605	2034	45%	$89
SNS-229	Preclinical	Proprietary	5%	2022	101,000	320	2031	44%	$7
Unallocated costs (discovery programs, administrative costs, etc)									($41)
Total									$77
Net cash and equivalents (Q217) ($m)									$15.6
Total firm value ($m)									**$93.0**
Total basic shares (m)									23.5
Value per basic share ($)									**$3.96**
Convertible pref stock (m)									4.3
Warrants and options (m)									0.8
Total diluted shares (m)									28.5
Value per diluted share ($)									$3.33

Source: Sunesis Pharmaceuticals reports, Edison Investment Research

Financials

Sunesis reported an operational loss of $8.6m for Q217. This is down from $9.4m during the previous period, primarily due to the discontinuation of operations related to the vosaroxin program. Some of these operations occurred during the current periods and we expect a further reduction in coming quarters, which will be progressively offset by increases in spending associated with the SNS-062 clinical trial and potentially SNS-229. We have increased our forecasted operational loss for 2017 to $32.8m from $29.2m to reflect a higher than expected spending, partially attributable to a bigger tail on vosaroxin. The company has raised $8.1m through its ATM facility in H117 and $9.5m remains in the facility. We currently project that the company will require $155m in additional funding (reduced from $160m due to recent financing) to reach profitability in 2023. This is in addition to the Takeda milestones ($57.5m), a portion of which we may explicitly add to our near-term financial forecasts as more information from the companies becomes available.

Exhibit 2: Financial summary

$'000s	2013	2014	2015	2016	2017e	2018e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS						
Revenue	7,956	5,734	3,061	2,536	669	0
Cost of Sales	0	0	0	0	0	0
Gross Profit	7,956	5,734	3,061	2,536	669	0
Research and development	(28,891)	(27,665)	(23,701)	(22,881)	(19,705)	(18,920)
Selling, general & administrative	(10,838)	(23,112)	(18,662)	(16,115)	(13,773)	(14,186)
EBITDA	(31,701)	(41,312)	(35,764)	(36,313)	(32,816)	(33,113)
Operating Profit (before GW and except.)	(31,681)	(41,283)	(35,737)	(36,302)	(32,808)	(33,105)
Intangible Amortisation	0	0	0	0	0	0
Exceptionals/Other	0	0	0	0	0	0
Operating Profit	(31,681)	(41,283)	(35,737)	(36,302)	(32,808)	(33,105)
Net Interest	(2,917)	(1,719)	(939)	(1,721)	(952)	(2,410)
Other (change in fair value of warrants)	0	0	0	0	0	0
Profit Before Tax (norm)	(34,598)	(43,002)	(36,676)	(38,023)	(33,760)	(35,515)
Profit Before Tax (IFRS)	(34,598)	(43,002)	(36,676)	(38,023)	(33,760)	(35,515)
Tax	0	0	0	0	0	0
Deferred tax	0	0	0	0	0	0
Profit After Tax (norm)	(34,598)	(43,002)	(36,676)	(38,023)	(33,760)	(35,515)
Profit After Tax (IFRS)	(34,598)	(43,002)	(36,676)	(38,023)	(33,760)	(35,515)
Average Number of Shares Outstanding (m)	8.7	10.0	12.2	15.7	21.4	22.4
EPS - normalised ($)	(3.97)	(4.30)	(3.02)	(2.42)	(1.58)	(1.59)
EPS - IFRS ($)	(3.97)	(4.30)	(3.02)	(2.42)	(1.58)	(1.59)
Dividend per share ($)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets	33	42	14	3	1,392	13
Intangible Assets	0	0	0	0	0	0
Tangible Assets	23	42	14	3	21	13
Other	10	0	0	0	1,371	0
Current Assets	40,492	44,204	46,988	43,231	9,861	2,444
Stocks	0	0	0	0	0	0
Debtors	0	0	0	0	0	0
Cash	39,293	42,981	46,430	42,588	9,021	1,604
Other	1,199	1,223	558	643	840	840
Current Liabilities	(25,858)	(19,395)	(12,728)	(5,814)	(4,925)	(5,281)
Creditors	(16,840)	(10,138)	(4,894)	(2,481)	(1,357)	(1,690)
Short term borrowings	(9,018)	(9,257)	(7,834)	(3,333)	(3,568)	(3,591)
Long Term Liabilities	(12,737)	(2,563)	(610)	(11,271)	(3,596)	(24,656)
Long term borrowings	(9,025)	0	0	(11,102)	(3,564)	(24,624)
Other long term liabilities	(3,712)	(2,563)	(610)	(169)	(32)	(32)
Net Assets	1,930	22,288	33,664	26,149	2,732	(27,481)
CASH FLOW						
Operating Cash Flow	(37,423)	(43,181)	(38,731)	(36,962)	(34,128)	(28,500)
Net Interest	0	0	0	0	0	0
Tax	0	0	0	0	0	0
Capex	0	(48)	0	0	(26)	0
Acquisitions/disposals	0	0	0	0	0	0
Financing	12,570	56,277	43,826	26,111	8,189	0
Dividends	0	0	0	0	0	0
Other	0	0	0	0	0	0
Net Cash Flow	(24,853)	13,048	5,095	(10,851)	(25,965)	(28,500)
Opening net debt/(cash)	(46,966)	(21,250)	(33,724)	(38,596)	(28,153)	(2,188)
HP finance leases initiated	0	0	0	0	0	0
Exchange rate movements	0	0	0	0	0	0
Other	(863)	(574)	(223)	408	0	0
Closing net debt/(cash)	(21,250)	(33,724)	(38,596)	(28,153)	(2,188)	26,312

Source: Edison Investment Research

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