EDISON

Sunesis Pharmaceuticals

Earnings report

Redirection after EMA application pulled

Pharma & biotech

Sunesis reported in May 2017 that it has pulled its application to the EMA for the approval of vosaroxin for the treatment of acute myeloid leukemia, based on feedback from the agency. The program has been de-emphasized and the new lead is SNS-062, the company's Bruton's tyrosine kinase (BTK) inhibitor with potential efficacy in Imbruvica-resistant chronic lymphocytic leukemia (CLL). The SNS-062 program will be initiating a Phase Ib/II clinical trial in Q217.

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	(30.9)	(1.44)	0.0	N/A	N/A
12/18e	0.0	(32.5)	(1.45)	0.0	N/A	N/A

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

Vosaroxin application pulled

The company's MAA for vosaroxin was voluntarily recalled by the company following meetings with the EMA's rapporteurs and consultants, in which it became clear that the product will not get sufficient support at the agency to receive approval. The drug is being studied in two investigator-sponsored trials, which will continue unchanged although expense will be minimal, so there might be more data from the program but all other operations for the program will cease.

SNS-062 now the lead: Entering Phase Ib/II

The company has reprioritized and the SNS-062 program for CLL is now the lead clinical program. The drug is an inhibitor of BTK that binds and inhibits the enzyme even in the presence of mutations that confer resistance to the currently approved BTK inhibitor, Imbruvica. The drug is entering a Phase Ib/II dose escalation/ expansion trial starting in Q217 targeting completion by September 2018. The trial will enrol up to seven dose cohorts and up to 124 patients with confirmed Imbruvica resistance mutations.

Q117 results: Runway into 2018

The company ended Q117 with $35.2m in cash ($20.7m net), which it stated should be sufficient runway to reach mid-2018. Operational losses for the quarter were $9.4m. We expect cash burn to be lower in the coming quarters with the simplified pipeline and forecast operational losses of $29.2m for 2017. We have increased our future financing estimates for the company to $160m required before profitability (from $65m).

Valuation: Reduced to $94.3m/$4.40 per basic share

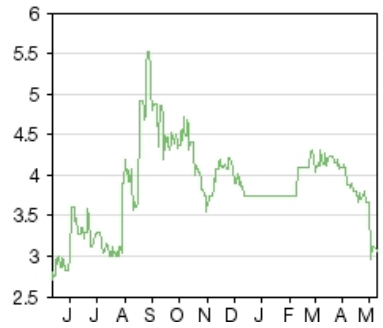
We have reduced our valuation to $94.3m or $4.40 per basic share ($3.66 diluted) from $219.0m or $10.47 per basic share ($8.42 diluted). This reduction is from the removal of vosaroxin from our model (former value of $137m), and partially offset by a reduction in unallocated cost.

10 May 2017

Price	**US$3.06**
Market cap	**US$66m**

Net cash ($m) at 31 March 2017	20.7
Shares in issue	21.5m
Free float	58%
Code	SNSS
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(21.1)	(25.2)	3.0
Rel (local)	(22.5)	(28.0)	(11.5)
52-week high/low	US$5.5		US$2.7

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. It has also developed TAK-580 with partner Takeda, and the preclinical PDK1 inhibitor SNS-229.

Next events

SNS-062 Phase Ib/II trial initiation	Q217

Analysts

Maxim Jacobs +1 646 653 7027

Nathaniel Calloway +1 646 653 7036

healthcare@edisongroup.com

Edison profile page

A change in company direction

The company announced on 1 May 2017 that it would be withdrawing its EMA marketing application following feedback from the agency, which made it clear that it was unlikely to approve vosaroxin (Qinprezo) with the current data. There remains some possibility that the drug could be approved with new data, although the company has stepped away from internal development of the drug for the time being. There are two ongoing investigator-sponsored trials (at Vanderbilt-Ingram Cancer Center and University Hospital, Angers) that will continue as planned and could build a future value proposition for the asset. However, company investment into the program will be purely supportive to these investigator-sponsored studies in the future.

Refocus on SNS-062

The company has refocused its efforts squarely on SNS-062, which will now be the lead development program. The non-covalent Bruton's tyrosine kinase (BTK) inhibitor has the potential to be effective in patients that become resistant to other covalent BTK inhibitors such as Imbruvica (ibrutinib; AbbVie, Janssen). A common mutation in patients who become resistant to Imbruvica is cysteine 481 to serine (C481S), and SNS-062 has been shown to be active in this BTK isoform including the most recent data presented at the American Association for Cancer Research Annual Meeting. The company has a Phase Ib/II clinical trial that will begin in Q217 in patients with confirmed C481S mutations. It 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 program is taking place at some of the premiere cancer institutes in the US: UC Irvine Cancer Center and The Ohio State University Comprehensive Cancer Center, Dana-Farber Cancer Institute, MD Anderson Cancer Center and Weill Cornell Cancer Center. The target completion date for the study is September 2018, although this will be highly dependent on how quickly the appropriate dose is found.

Valuation

We have reduced our valuation to $94.3m or $4.40 per basic share ($3.66 diluted) from $219.0m or $10.47 per basic share ($8.42 diluted). This reduction is due to removing the vosaroxin program from our model. Although there is a possibility that the program may be restarted following results from investigator-sponsored trials or out-licensed for further development, given the current outlook we are not attaching any value. This adjustment was offset by a reduction in our unallocated costs (a negative NPV of $44m from $60m) due to adjustments in administrative expenses and working cash flow due to the company realignment, and advancing our NPVs to the latest period.

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%	$25
SNS-062	Phase Ib/II	Proprietary	20%	2022	152,000	605	2034	45%	$86
SNS-229	Preclinical	Proprietary	5%	2022	101,000	320	2031	44%	$6
Unallocated costs (discovery programs, administrative costs, etc.)									($44)
Total									$74
Net cash and equivalents (Q117) ($m)									$20.7
Total firm value ($m)									$94.3
Total basic shares (m)									21.5
Value per basic share ($)									$4.40
Convertible Pref stock (m)									4.3
Warrants									0.2
Total diluted shares									25.9
Value per diluted share									$3.66

Source: Sunesis reports, Edison Investment Research

Financials

The company reported operational losses of $9.4m in Q117, which is a slight increase from previous quarters ($8.1m in Q416). We have adjusted our spending forecasts to reflect the removal of the vosaroxin program from the model and now estimate operating losses of $29.2m for 2017 (down from $47.0m). The company ended Q117 with $35.2m in cash ($20.7m net of debt), which it stated would provide a runway into June 2018. At the current run rate, we expect the company to require $160m in financing before profitability in 2024, which we record as illustrative debt spread in yearly tranches of $10m to $40m. This is a $95m increase from previous financing estimates due to the lack of revenue expected from vosaroxin.

Exhibit 2: Financial summary

$'000s	2013	2014	2015	2016	2017e	2018e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS						
Revenue	7,956	5,734	3,061	2,536	669	0
Cost of Sales	0	0	0	0	0	0
Gross Profit	7,956	5,734	3,061	2,536	669	0
Research and development	(28,891)	(27,665)	(23,701)	(22,881)	(17,617)	(16,936)
Selling, general & administrative	(10,838)	(23,112)	(18,662)	(16,115)	(12,242)	(12,610)
EBITDA	(31,701)	(41,312)	(35,764)	(36,313)	(29,190)	(29,545)
Operating Profit (before GW and except.)	(31,681)	(41,283)	(35,737)	(36,302)	(29,190)	(29,545)
Intangible Amortisation	0	0	0	0	0	0
Exceptionals/Other	0	0	0	0	0	0
Operating Profit	(31,681)	(41,283)	(35,737)	(36,302)	(29,190)	(29,545)
Net Interest	(2,917)	(1,719)	(939)	(1,721)	(1,719)	(2,923)
Other (change in fair value of warrants)	0	0	0	0	0	0
Profit Before Tax (norm)	(34,598)	(43,002)	(36,676)	(38,023)	(30,909)	(32,469)
Profit Before Tax (IFRS)	(34,598)	(43,002)	(36,676)	(38,023)	(30,909)	(32,469)
Tax	0	0	0	0	0	0
Deferred tax	0	0	0	0	0	0
Profit After Tax (norm)	(34,598)	(43,002)	(36,676)	(38,023)	(30,909)	(32,469)
Profit After Tax (IFRS)	(34,598)	(43,002)	(36,676)	(38,023)	(30,909)	(32,469)
Average Number of Shares Outstanding (m)	8.7	10.0	12.2	15.7	21.4	22.4
EPS - normalised ($)	(3.97)	(4.30)	(3.02)	(2.42)	(1.44)	(1.45)
EPS - IFRS ($)	(3.97)	(4.30)	(3.02)	(2.42)	(1.44)	(1.45)
Dividend per share ($)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets	33	42	14	3	3	3
Intangible Assets	0	0	0	0	0	0
Tangible Assets	23	42	14	3	3	3
Other	10	0	0	0	0	0
Current Assets	40,492	44,204	46,988	43,231	20,554	6,909
Stocks	0	0	0	0	0	0
Debtors	0	0	0	0	0	0
Cash	39,293	42,981	46,430	42,588	19,911	6,266
Other	1,199	1,223	558	643	643	643
Current Liabilities	(25,858)	(19,395)	(12,728)	(5,814)	(6,525)	(6,509)
Creditors	(16,840)	(10,138)	(4,894)	(2,481)	(1,525)	(1,509)
Short term borrowings	(9,018)	(9,257)	(7,834)	(3,333)	(5,000)	(5,000)
Long Term Liabilities	(12,737)	(2,563)	(610)	(11,271)	(15,351)	(29,458)
Long term borrowings	(9,025)	0	0	(11,102)	(15,125)	(29,232)
Other long term liabilities	(3,712)	(2,563)	(610)	(169)	(226)	(226)
Net Assets	1,930	22,288	33,664	26,149	(1,318)	(29,055)
CASH FLOW						
Operating Cash Flow	(37,423)	(43,181)	(38,731)	(36,962)	(28,367)	(27,752)
Net Interest	0	0	0	0	0	0
Tax	0	0	0	0	0	0
Capex	0	(48)	0	0	0	0
Acquisitions/disposals	0	0	0	0	0	0
Financing	12,570	56,277	43,826	26,111	0	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)	(28,367)	(27,752)
Opening net debt/(cash)	(46,966)	(21,250)	(33,724)	(38,596)	(28,153)	214
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)	214	27,966

Source: Sunesis reports, 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
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