EDISON

Sunesis Pharmaceuticals

Q4 update

Getting closer to EU approval

Pharma & biotech

The company's application for EU approval for vosaroxin approval in AML continues to progress. The company will go before the Oncology Division of the Scientific Advisory Group (SAG-O) in April with a Committee for Medicinal Products for Human Use (CHMP) decision likely by mid-year. We continue to expect a launch in H217. Also, the company plans to initiate a Phase Ib/II study of SNS-062, their BTK inhibitor, in patients with various advanced B-cell malignancies in H117.

Year end	Revenue ($m)	PTP* ($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	1.7	(48.8)	(2.28)	0.0	N/A	N/A
12/17e	8.3	(42.5)	(1.90)	0.0	N/A	N/A

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

Wrapping up the European application process

The company announced that its responses to the Day 180 list of outstanding issues should be completed by the end of the month. It is also preparing to go before the SAG-O in April, with a CHMP decision likely by mid-year. As Vosaroxin has shown a durable survival benefit in relapsed/refractory acute myeloid leukemia (AML) patients over 60, its proposed indication, there is a strong argument for approval.

Potential vosaroxin EU partnership possible in 2017

The company is targeting a European partnership around the time of the CHMP opinion and product approval, which would put a partnership announcement around the Q3 time frame. The company is currently in advanced discussions with multiple potential partners.

SNS-062 Phase Ib/II trial initiation coming soon

The Phase Ib/II trial of SNS-062 in patients with advanced B-cell malignancies is expected to begin in H117. Due to its differentiated binding mechanism, SNS-062 has the potential to treat patients with Imbruvica-resistant forms of disease (~25% of those treated with Imbruvica).

Valuation: $10.47 per share

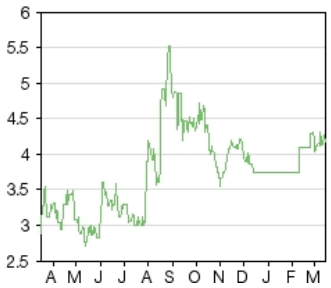
We have increased our valuation slightly to $219m or $10.47 per basic share, from $217m or $10.40 per basic share. The increase is mainly due to rolling forward our NPV valuations to 2017, offset partly by a decrease in cash. Key upcoming catalysts include the upcoming CHMP decision, as well as a potential partnership. Also, there will be a poster presentation of SNS-062 preclinical data at the American Association of Cancer Research Annual Meeting on April 3.

15 March 2017

Price	**US$4.17**
Market cap	**US$87m**

Net cash ($m) at December 2016	28.2
Shares in issue	20.9m
Free float	58%
Code	SNSS
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	2.2	19.5	19.8
Rel (local)	1.0	13.8	2.3
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 vosaroxin, a chemotherapy for AML, and is in the approval process in the EU. Sunesis has also developed SNS-062, a BTK inhibitor for CLL for Imbruvica refractory patients, entering Phase Ib/II.

Next events

AACR Data	April 3, 2017
CHMP decision	Mid-year 2017

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Edison profile page

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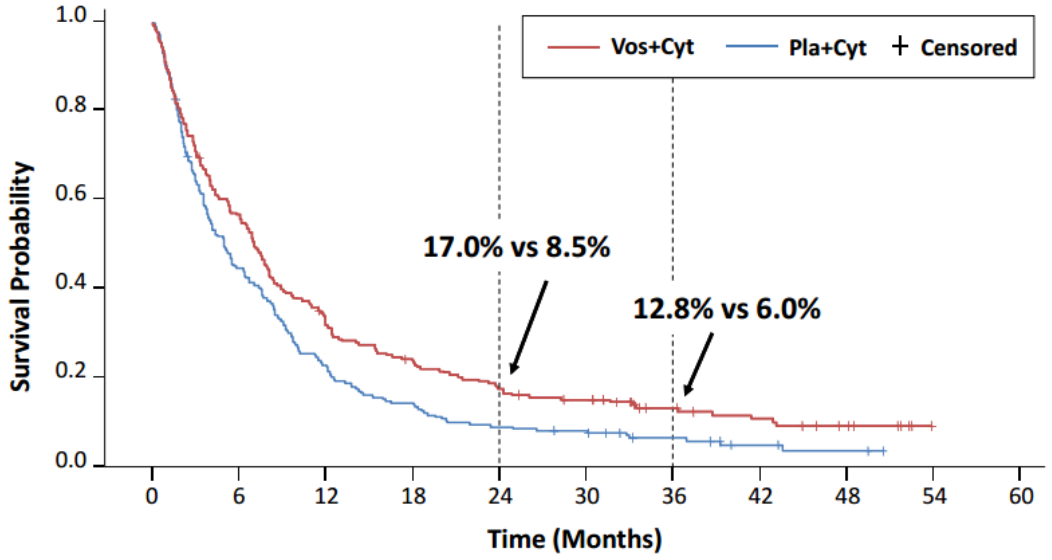
EU Approval in View

With a meeting of the SAG-O scheduled for April and a subsequent CHMP decision likely around mid-year, vosaroxin approval in relapsed/refractory AML patients over 60 is within reach. As a reminder, the company recently released an updated survival analysis of patients from the VALOR study of vosaroxin for the treatment of AML at the American Society of Hematology (ASH) meeting in December 2016. The company reported the overall survival of patients 60 years and older treated with vosaroxin and cytarabine has maintained superiority over placebo and cytarabine with a median follow-up time of 39.9 months (Exhibit 1).

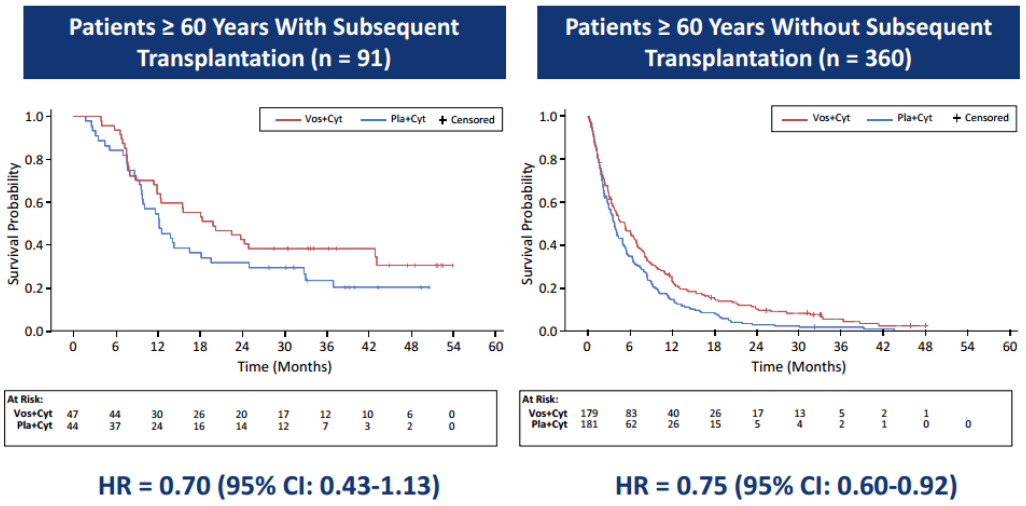
Exhibit 1: Extended overall survival data for vosaroxin + cytarabine



Source: Sunesis Pharmaceuticals

Importantly, the company also released an analysis of the effect of subsequent transplantation on the survival of patients over 60 (Exhibit 2). The analysis found that vosaroxin improved survival regardless of whether a patient was followed up with hematopoietic cell transplantation (HCT). This analysis is important because the approval of Vidaza and Dacogen in Europe depended on an analysis of the effect of subsequent therapy in both cases, because subsequent treatments such as HCT often reduced the separation between drug and placebo. Sunesis did not release a complete statistical analysis of the data, but we find the fact that a treatment effect is apparent both with and without transplantation as supportive.

Exhibit 2: Effect of HCT on overall survival with vosaroxin + cytarabine



Source: Sunesis Pharmaceuticals

The company is targeting a European partnership around the time of the CHMP opinion and product approval, which would put a partnership announcement around the Q3 time frame. The company is currently in advanced discussions with multiple potential partners, with a goal of finding a partner who is motivated, well-resourced, experienced and able to launch vasoroxin this year.

SNS-062 advancing

SNS-062 is a next-generation BTK inhibitor, SNS-062, which unlike Imbruvica, does not form a covalent bond with cysteine-481 of BTK, but retains significant binding affinity to both native and mutant forms of the enzyme (note that additional preclinical data on the potency of SNS-062 versus ibrutinib specifically related to the cysteine-481 mutation will be presented at AACR on April 3). Moreover, it prevents the generation of activated BTK (auto-phosphorylated BTK, pBTK) in the presence of the mutant, whereas this effect is completely lost by Imbruvica. This positions SNS-062 as a potential treatment for Imbruvica-resistant forms of the disease. Approximately 25% of relapsed and refractory patients treated with Imbruvica progress on the drug at 26 months. And a recent Journal of Clinical Oncology publication presented the results of the follow-up of 308 patients (with a median length of 3.4 years) who were enrolled in clinical studies of Imbruvica in chronic lymphocytic leukemia (CLL).[1] Of the 158 patients who had discontinued Imbruvica at the time of the report, 83 discontinued due to disease progression. 37 of the 46 patients (80%) evaluable for DNA sequencing had C481 mutations (leaving around 20% of Imbruvica patients appropriate for SNS-062).

The company is expected to begin enrollment of their Phase Ib/II trial of SNS-062 in patients with advanced B-cell malignancies in H117. Specifically, they will enroll patients with CLL/small lymphocytic lymphoma, lymphoplasmacytoid lymphoma/Waldenström's macroglobulinemia, and mantle cell lymphoma who have failed at least two lines of standard systemic therapy (including prior BTK inhibitor therapy).

1 Woyach JA, et al, BTK^{C481S}-Mediated Resistance to Ibrutinib in Chronic Lymphocytic Leukemia, Journal of Clinical Oncology DOI: 10.1200/JCO.2016.70.2282

Valuation

We have increased our valuation slightly to $219m or $10.47 per basic share, from $217m or $10.40 per basic share. The increase is mainly due to rolling forward our NPV valuations to 2017, offset partly by a decrease in cash. We are not adjusting any of our sales or risk assumptions at this point but key upcoming catalysts that could lead to changes in our valuation model include the upcoming CHMP decision as well as a potential partnership.

Exhibit 3: Sunesis valuation table

Development program	Clinical stage	Expected commercialization	Prob. of success	Launch year	Launch pricing ($)	Peak sales ($m)	Patent/ exclusivity protection	Royalty/ margin	rNPV ($m)
vosaroxin, Rel/Ref AML EU	MAA submitted	Partnered	60%	2017	53,000	190	2027	30%	$64
vosaroxin, Frontline AML EU	Phase III	Partnered	45%	2021	57,000	220	2027	30%	$24
vosaroxin, MDS EU	Phase I/II	Partnered	30%	2021	57,000	152	2027	30%	$9
vosaroxin, Rel/Ref AML US	Phase III	Partnered	30%	2021	82,000	175	2028	30%	$13
vosaroxin, Frontline AML US	Phase III	Partnered	25%	2021	82,000	269	2028	30%	$17
vosaroxin, MDS US	Phase I/II	Partnered	25%	2021	82,000	174	2028	30%	$10
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%	$84
SNS-229	Preclinical	Proprietary	5%	2022	101,000	320	2031	44%	$6
Unallocated costs (discovery programs, administrative costs, etc.)									($60)
Total									$191
Net cash and equivalents (Q416) ($m)									$28.2
Total firm value ($m)									$219.0
Total basic shares (m)									20.9
Value per basic share ($)									$10.47
Convertible Pref stock (m)									4.9
Warrants									0.3
Total diluted shares									26.1
Value per diluted share									$8.42

Source: Edison Investment Research, Sunesis Pharmaceuticals reports

Financials

Sunesis reported an operational loss of $8.1m for Q416, with the majority of the expense associated with R&D ($4.8m), although this is a reduction from previous quarters ($6.1m in Q2 and $5.3m in Q3). We have made minor adjustments to our financial forecasts post-2016, and we also introduce our 2018 estimates. The company ended the quarter with $42.6m in cash and investments, offset by $14.4m in debt. We currently model $65m in capital requirements, $10m in 2017, $20m in 2018 and $35m in 2020, although this may change with the signing of an EU partnership for vosaroxin.

Exhibit 4: Financial summary

$'000s	2013	2014	2015	2016	2017e	2018e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS						
Revenue	7,956	5,734	3,061	2,536	1,697	8,341
Cost of Sales	0	0	0	0	(3,353)	(2,711)
Gross Profit	7,956	5,734	3,061	2,536	(1,657)	5,630
Research and development	(28,891)	(27,665)	(23,701)	(22,881)	(29,536)	(28,859)
Selling, general & administrative	(10,838)	(23,112)	(18,662)	(16,115)	(15,762)	(16,235)
EBITDA	(31,701)	(41,312)	(35,764)	(36,313)	(46,954)	(39,464)
Operating Profit (before GW and except.)	(31,681)	(41,283)	(35,737)	(36,302)	(46,954)	(39,464)
Intangible Amortisation	0	0	0	0	0	0
Exceptionals/Other	0	0	0	0	0	0
Operating Profit	(31,681)	(41,283)	(35,737)	(36,302)	(46,954)	(39,464)
Net Interest	(2,917)	(1,719)	(939)	(1,721)	(1,802)	(3,083)
Other (change in fair value of warrants)	0	0	0	0	0	0
Pre-Tax Profit (norm)	(34,598)	(43,002)	(36,676)	(38,023)	(48,756)	(42,547)
Pre-Tax Profit (IFRS)	(34,598)	(43,002)	(36,676)	(38,023)	(48,756)	(42,547)
Tax	0	0	0	0	0	0
Deferred tax	0	0	0	0	0	0
Profit After Tax (norm)	(34,598)	(43,002)	(36,676)	(38,023)	(48,756)	(42,547)
Profit After Tax (IFRS)	(34,598)	(43,002)	(36,676)	(38,023)	(48,756)	(42,547)
Average Number of Shares Outstanding (m)	8.7	10.0	12.2	15.7	21.4	22.4
EPS - normalized ($)	(3.97)	(4.30)	(3.02)	(2.42)	(2.28)	(1.90)
EPS - IFRS ($)	(3.97)	(4.30)	(3.02)	(2.42)	(2.28)	(1.90)
Dividend per share ($)	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	6,474	(16,340)
Stocks	0	0	0	0	0	0
Debtors	0	0	0	0	0	0
Cash	39,293	42,981	46,430	42,588	5,831	(16,983)
Other	1,199	1,223	558	643	643	643
Current Liabilities	(25,858)	(19,395)	(12,728)	(5,814)	(7,313)	(7,302)
Creditors	(16,840)	(10,138)	(4,894)	(2,481)	(2,313)	(2,302)
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)	(16,271)	(31,271)
Long term borrowings	(9,025)	0	0	(11,102)	(16,102)	(31,102)
Other long term liabilities	(3,712)	(2,563)	(610)	(169)	(169)	(169)
Net Assets	1,930	22,288	33,664	26,149	(17,107)	(54,910)
CASH FLOW						
Operating Cash Flow	(37,423)	(43,181)	(38,731)	(36,962)	(43,424)	(37,814)
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)	(43,424)	(37,814)
Opening net debt/(cash)	(46,966)	(21,250)	(33,724)	(38,596)	(27,980)	15,444
HP finance leases initiated	0	0	0	0	0	0
Exchange rate movements	0	0	0	0	0	0
Other	(863)	(574)	(223)	235	0	0
Closing net debt/(cash)	(21,250)	(33,724)	(38,596)	(27,980)	15,444	53,258

Source: Edison Investment Research, Sunesis Pharmaceuticals reports

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