

# Sunesis Pharmaceuticals

Earnings update

On track with vecabrutinib

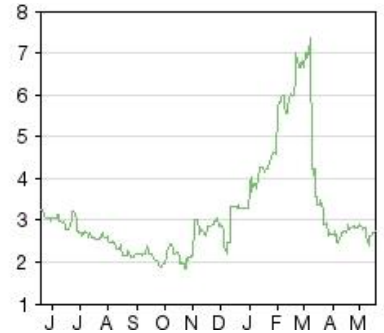
Pharma &amp; biotech

18 May 2018

**Price** **US\$2.73**  
**Market cap** **US\$94m**

Net cash (\$m) at March 2018	18.1
Shares in issue	34.4m
Free float	55%
Code	SNSS
Primary exchange	NASDAQ
Secondary exchange	N/A

## Share price performance



%	1m	3m	12m
Abs	(3.2)	(54.3)	(12.2)
Rel (local)	(3.7)	(54.1)	(23.9)
52-week high/low	US\$7.4	US\$1.8	

## Business description

Sunesis Pharmaceuticals is a pharmaceutical company focused on oncology. Its lead asset is SNS-062, a BTK inhibitor for chronic lymphocytic leukemia 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-510.

## Next events

Vecabrutinib Phase II dose announced	Autumn 2018
TAK-580 program update	Mid-/late 2018
SNS-510 IND filing	2019

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On the Q118 conference call, Sunesis provided an update of its ongoing vecabrutinib Phase Ib/II trial. The study is continuing to enrol the 50mg cohort in the dose-ranging Phase I portion of the study. This cohort was previously expanded to six patients per the protocol due to an adverse event, but no further dose-limiting events have been reported. The company reiterated guidance that the dose ranging would be complete in autumn 2018 and that it will present preliminary efficacy data at a medical conference.

Year end	Revenue (\$m)	PBT* (\$m)	EPS* (\$)	DPS (\$)	P/E (x)	Yield (%)
12/16	2.5	(38.0)	(2.42)	0.00	N/A	N/A
12/17	0.7	(35.5)	(1.45)	0.00	N/A	N/A
12/18e	0.2	(35.2)	(0.98)	0.00	N/A	N/A
12/19e	0.0	(38.4)	(1.02)	0.00	N/A	N/A

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

## Vecabrutinib 50mg cohort expansion ongoing

The company previously announced the 50mg cohort would be expanded following a dose limiting toxicity (DLT) that was observed in the study, which is the standard protocol for this trial design. We remain confident that it is too early to draw conclusions about the safety or tolerability of the drug given that this was an isolated occurrence; the continued enrolment of this cohort without incident to date supports this.

## Phase II to examine multiple angles

The primary focus of the vecabrutinib development program has been examining if it is active in ibrutinib refractory patients, particularly those with the C481S mutation. However, Sunesis will be using data from the Phase I portion of the trial to inform what cohorts to examine in Phase II. These also include patients refractory to venetoclax and those whose disease has progressed via Richter's transformation to more severe B-cell malignancies.

## Continued commitment to expanding pipeline

Although vecabrutinib remains the company's main focus, Sunesis has restated its commitment to expanding its portfolio. It previously partnered its pan-Raf inhibitor TAK-580 to Takeda and expects an update on the program before the end of 2018. It is also in IND-enabling studies of its PDK1 inhibitor SNS-510, which it states will be ready for IND filing in 2019.

## Valuation: Small change to \$236.6m or \$6.88/share

Our valuation has changed negligibly to \$236.6m or \$6.88 per basic share from \$237.8m or \$6.92 per share. This was largely driven by advancing our NPVs to the most recent period and offset by lower net cash (\$18.1m vs \$24.5m). We have delayed our expected commercialization of SNS-510 to 2024 from 2023. We expect the company to require \$135m in additional financing before profitability in 2023.

## Vecabrutinib on target for autumn readout

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Sunesis provided an update of its vecabrutinib Phase Ib/II clinical trial in its Q118 earnings release and conference call. Vecabrutinib is a non-covalent Bruton's tyrosine kinase (BTK) inhibitor, being investigated for a range of B-cell malignancies. There are two approved BTK inhibitors: Imbruvica (ibrutinib, AbbVie/Janssen) with sales of approximately \$3.2bn in 2017, and Calquence (acalabrutinib, AstraZeneca), which was launched in October 2017 (with negligible sales). However, when patients progress on these drugs, they develop the C481S mutation in BTK as the most common form of drug resistance. Vecabrutinib seeks to treat these refractory patients and is known to bind and inhibit this mutant BTK at nanomolar concentrations. The biggest target market under investigations is refractory chronic lymphocytic leukemia (CLL) patients with the C481S mutation, and this will be one arm of the upcoming Phase II portion of the trial. However, there is also potential in a range of other indications, including CLL in the front line as well as other B-cell malignancies. The company recently expanded the enrolment in the trial to include diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma. One potential market for patients that have DLBCL is those that have undergone Richter's transformation, an event in which a patient with CLL spontaneously develops the much more aggressive DLBCL. The company stated that patients following Richter's transformation are being considered for an arm in the upcoming Phase II. The company also stated that it may examine patients following progression on Venclexta (venetoclax, AbbVie/Roche), a Bcl-2 inhibitor making inroads into the CLL market.

Regarding the current status of the trial, the company is in the Phase Ib dose-ranging portion of the study, which will examine doses from 25mg to 500mg (or the maximally tolerated dose, MTD), although the effective dose is expected to be in the range of 100-300mg. The study is on the 50mg (second) cohort following an expansion of dose to six patients. This expansion was triggered by the protocol because of an adverse event that was counted as a potential DLT seen in a single patient. This form of dosing cohort expansion is not uncommon given the random nature of many adverse events, and that they are frequently not drug related. Imbruvica, for instance, had multiple DLTs in its dose-ranging study, which then never found an MTD. On the update, the company stated that the 50mg cohort continues to enrol well and it remains on track to announce the Phase II dose in autumn 2018. Additionally, the company stated it will be presenting interim data from the study at a medical conference around that time as well.

## Valuation

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Our valuation has changed negligibly to \$236.6m or \$6.88 per basic share from to \$237.8m or \$6.92. This was driven by advancing our NPVs to the most recent period and offset by lower net cash (\$18.1m vs \$24.5m). Additionally, we have delayed the commercialization of SNS-510 to 2024 from 2023 based on the guidance that the IND will be filed in 2019. Otherwise, our fundamental assumptions remain unchanged. We expect to update our valuation following data from the ongoing vecabrutinib trial and following any announcement regarding TAK-580 from Takeda.

**Exhibit 1: Valuation of Sunesis**

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	146,000	777	2032	15%	\$39
Vecabrutinib	Phase Ib/II	Proprietary	20%	2022	152,000	666	2034	56%	\$181
SNS-510	IND ready	Proprietary	10%	2024	130,000	361	2031	51%	\$23
Unallocated costs (discovery programs, administrative costs, etc.)									(\$25)
Total (\$m)									\$218
Net cash and equivalents (Q118) (\$m)									\$18.1
Total firm value (\$m)									\$236.6
Total basic shares (m)									34.4
Value per basic share (\$)									\$6.88
Convertible Pref stock (m)									6.3
Warrants and Options									8.5
Total diluted shares									49.2
Value per diluted share (\$)									5.54

Source: Sunesis reports, Edison Investment Research

## Financials

Sunesis reported an operating loss of \$7.1m for Q118, corresponding to R&D spending of \$4.0m and G&A spending of \$3.4m. We expect R&D to increase following advancement of the Phase Ib/II trial later in the year and forecast total R&D of \$19.1m for 2018. The company ended the period with \$25.4m in cash, partly offset by \$7.3m in debt (at 8.54%+LIBOR). Principal payments will start in October 2018, unless the company can raise at least \$6.5m in additional capital from equity (which will delay principle payments until January 2019). We expect the company to require at least \$135m in additional financing before profitability in 2023, which we record as illustrative debt (\$25m, \$20m, \$30m, \$40m and \$20m in 2018-2022 respectively).

**Exhibit 2: Financial summary**

	\$'000s	2016	2017	2018e	2019e
Year end 31 December		US GAAP	US GAAP	US GAAP	US GAAP
<b>PROFIT &amp; LOSS</b>					
Revenue		2,536	669	237	0
Cost of Sales		0	0	0	0
Gross Profit		2,536	669	237	0
Research and development		(22,881)	(21,540)	(19,074)	(19,295)
Selling, general & administrative		(16,115)	(13,548)	(13,634)	(14,043)
EBITDA		(36,313)	(34,428)	(32,480)	(33,347)
Operating Profit (before GW and except.)		(36,302)	(34,419)	(32,471)	(33,338)
Intangible Amortisation		0	0	0	0
Exceptionals/Other		0	0	0	0
Operating Profit		(36,302)	(34,419)	(32,471)	(33,338)
Net Interest		(1,721)	(1,039)	(2,709)	(5,078)
Other (change in fair value of warrants)		0	0	0	0
Profit Before Tax (norm)		(38,023)	(35,458)	(35,180)	(38,416)
Profit Before Tax (IFRS)		(38,023)	(35,458)	(35,180)	(38,416)
Tax		0	0	0	0
Deferred tax		0	0	0	0
Profit After Tax (norm)		(38,023)	(35,458)	(35,180)	(38,416)
Profit After Tax (IFRS)		(38,023)	(35,458)	(35,180)	(38,416)
Average Number of Shares Outstanding (m)		15.7	24.5	36.0	37.6
EPS - normalised (\$)		(2.42)	(1.45)	(0.98)	(1.02)
EPS - IFRS (\$)		(2.42)	(1.45)	(0.98)	(1.02)
Dividend per share (\$)		0.0	0.0	0.0	0.0
<b>BALANCE SHEET</b>					
Fixed Assets		3	1,401	11	2
Intangible Assets		0	0	0	0
Tangible Assets		3	20	11	2
Other		0	1,381	0	0
Current Assets		43,231	32,933	35,718	21,448
Stocks		0	0	0	0
Debtors		0	0	0	0
Cash		42,588	31,750	34,238	19,968
Other		643	1,183	1,480	1,480
Current Liabilities		(5,814)	(8,901)	(1,670)	(1,702)
Creditors		(2,481)	(1,697)	(1,670)	(1,702)
Short term borrowings		(3,333)	(7,204)	0	0
Long Term Liabilities		(11,271)	(112)	(39,456)	(59,456)
Long term borrowings		(11,102)	0	(39,456)	(59,456)
Other long term liabilities		(169)	(112)	0	0
Net Assets		26,149	25,321	(5,397)	(39,708)
<b>CASH FLOW</b>					
Operating Cash Flow		(36,962)	(36,142)	(29,914)	(34,270)
Net Interest		0	0	0	0
Tax		0	0	0	0
Capex		0	(26)	0	0
Acquisitions/disposals		0	0	0	0
Financing		26,111	32,930	196	0
Dividends		0	0	0	0
Other		0	0	0	0
Net Cash Flow		(10,851)	(3,238)	(29,718)	(34,270)
Opening net debt/(cash)		(38,596)	(28,153)	(24,546)	5,218
HP finance leases initiated		0	0	0	0
Exchange rate movements		0	0	0	0
Other		408	(369)	(46)	0
Closing net debt/(cash)		(28,153)	(24,546)	5,218	39,488

Source: Sunesis reports, Edison Investment Research

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