EDISON

# Sunesis Pharmaceuticals

Earnings update

## On track with vecabrutinib

Pharma & biotech

**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 ready for IND filing in 2019.

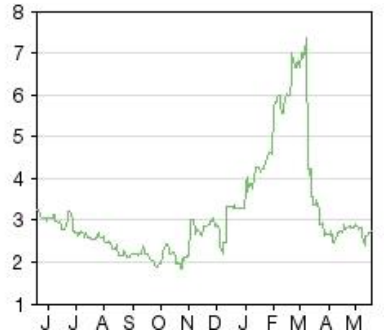
## Valuation: Small change to $236.6m or $6.88/share

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.

**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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Edison profile page

## Vecabrutinib on target for autumn readout

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

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

| $'000s | 2016 | 2017 | 2018e | 2019e |
|---|---|---|---|---|
| Year end 31 December | US GAAP | US GAAP | US GAAP | US GAAP |
| **PROFIT & LOSS** | | | | |
| Revenue | 2,536 | 669 | 237 | 0 |
| Cost of Sales | 0 | 0 | 0 | 0 |
| Gross Profit | 2,536 | 669 | 237 | 0 |
| Research and development | (22,881) | (21,540) | (19,074) | (19,295) |
| Selling, general & administrative | (16,115) | (13,548) | (13,634) | (14,043) |
| EBITDA | (36,313) | (34,428) | (32,480) | (33,347) |
| Operating Profit (before GW and except.) | (36,302) | (34,419) | (32,471) | (33,338) |
| Intangible Amortisation | 0 | 0 | 0 | 0 |
| Exceptionals/Other | 0 | 0 | 0 | 0 |
| Operating Profit | (36,302) | (34,419) | (32,471) | (33,338) |
| Net Interest | (1,721) | (1,039) | (2,709) | (5,078) |
| Other (change in fair value of warrants) | 0 | 0 | 0 | 0 |
| Profit Before Tax (norm) | (38,023) | (35,458) | (35,180) | (38,416) |
| Profit Before Tax (IFRS) | (38,023) | (35,458) | (35,180) | (38,416) |
| Tax | 0 | 0 | 0 | 0 |
| Deferred tax | 0 | 0 | 0 | 0 |
| Profit After Tax (norm) | (38,023) | (35,458) | (35,180) | (38,416) |
| Profit After Tax (IFRS) | (38,023) | (35,458) | (35,180) | (38,416) |
| Average Number of Shares Outstanding (m) | 15.7 | 24.5 | 36.0 | 37.6 |
| EPS - normalised ($) | (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 |
| **BALANCE SHEET** | | | | |
| 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) |
| **CASH FLOW** | | | | |
| 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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