EDISON

Sunesis Pharmaceuticals

Clinical update

Vecabrutinib study advances

Pharma & biotech

In January 2019 Sunesis announced that its Phase Ib/II study of vecabrutinib for B-cell cancers advanced to the 100mg cohort. The company experienced a series of unavoidable clinical delays in the 50mg arm but was eventually able expand the number of clinical sites and overenroll the cohort. The 100mg dose is the first that is expected to potentially provide indications of efficacy and Sunesis will provide a clinical update in Q219.

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	(28.3)	(0.80)	0.00	N/A	N/A
12/19e	0.0	(31.1)	(0.49)	0.00	N/A	N/A

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

Advancement in line with expectations

The announcement of the advancement of the Phase Ib/II study confirms both company guidance and our expectations. The delays in the 50mg arm of the study were not indicative of any issues with the drug in our assessment and instead were a reflection of unavoidable clinical risks. These included a per-protocol cohort expansion followed by early progression in a series of patents. As the 50mg dose was below the effective dose (expected between 100mg and 300mg), it was too early to draw conclusions on safety or efficacy, but the upcoming 100mg dose should provide more insight.

Further progress expected to be smoother

The company instituted a series of amendments to its clinical trial in 2018 that should enhance the ability of the program to progress smoothly. It added three clinical sites, bringing the total to eight. This should aid enrolment, and the company was able to overenroll the 50mg cohort. We expect the company to continue to overenroll. Additionally, Sunesis expanded the indications being examined in the study to include diffuse large B-cell lymphoma and follicular lymphoma. Although no patients from these indications yet have been treated, we expect inclusion to also improve enrolment and for any data on these diseases to illuminate to potential future indications beyond the main target of chronic lymphocytic leukemia (CLL).

Valuation: $243m or $4.02 ($2.97 diluted)

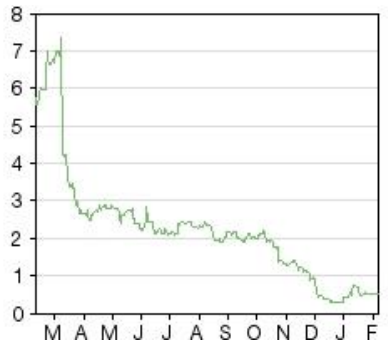
Following the recent financing, our valuation is now $243m or $4.02 per basic share ($2.97 diluted) from $224m and $5.99 ($4.98 diluted). The company priced an offering of 23m shares of common stock and 17,000 shares of convertible preferred stock (equivalent to 17m common) at $0.50 per common share or equivalent for gross proceeds of $20m, providing a cash runway into 2020. We expect the company to require an additional $115m before profitability in 2023.

7 February 2019

Price	**US$0.50**
Market cap	**US$30m**

Net cash ($m) Q318 + offering	31.6
Basic shares in issue	60.4m
Free float	84.6%
Code	SNSS
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	13.7	(63.0)	(91.6)
Rel (local)	5.4	(62.6)	(91.7)
52-week high/low		US$7.4	US$0.2

Business description

Sunesis Pharmaceuticals is a pharmaceutical company focused on oncology. Its lead asset is vecabrutinib, a Bruton's tyrosine kinase 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 clinical update	Q219

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Edison profile page

100mg at long last

In early January 2019 Sunesis announced that the ongoing Phase Ib/II study of vecabrutinib had advanced to the 100mg dosing cohort. The company quickly filled the three required slots in early January, with the first doses expected to be received in the following two to four weeks. The BTK inhibitor is being examined for CLL and a series of other B-cell malignancies, and the previous 50mg cohort was plagued by unforeseen and unavoidable delays throughout 2018. An ALT elevation prevented a patient from receiving the required number of doses, triggering a cohort expansion to six patients (per the 3+3 dose escalation protocol). Of the new patients, three progressed before they could be evaluated. In 2018 the company expanded the number of clinical sites on the study (to eight), which should improve enrolment; this may have been reflected in the fact that the company was able to ultimately overenroll the 50mg cohort. If the company continues to overenroll the 100mg and later arms, this should hedge against further setbacks. The increase in clinical sites is also important for the eventual progression of the trial to the Phase II portion of the study, once the effective dose has been identified.

The company expects the active dose of the drug to be found in the range of 100mg to 300mg, meaning the 100mg cohort could show signs of efficacy. Even if 100mg is not the optimal dose, we expect increasing signs of clinical activity; at the 50mg level, the company presented data showing a reduction in cytokine production (ASH 2018), a downstream indicator of BTK inhibition. Given that the clinical mechanism of BTK inhibition has already been vetted with Imbruvica (ibrutinib), we find even early signs of activity to be highly encouraging. The company stated that it will provide a clinical update at a medical conference in Q219.

Valuation

Our valuation has increased to $243m from $224m following the stock offering in January, but has decreased on a per share basis to $4.02 per basic share ($2.97 diluted) from $5.99 ($4.98 diluted). Otherwise our model remains unchanged. We expect to update our valuation with increasing evidence regarding the activity of vecabrutinib, and advancement to the Phase II portion of the study.

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 ($m)
TAK-580	Phase I/II	Licensed to Takeda	10%	2025	500,000	603	2032	15%	19
Vecabrutinib	Phase Ib/II	Proprietary	20%	2023	152,000	666	2034	56%	187
SNS-510	IND ready	Proprietary	10%	2024	130,000	361	2031	51%	25
Unallocated costs (discovery programs, administrative costs, etc.)									(20)
Total									211
Net cash and equivalents (Q318 + offering) ($m)									31.6
Total firm value ($m)									242.8
Total basic shares (m)									60.4
Value per basic share ($)									4.02
Convertible pref stock (m)									23.3
Warrants and options (m)									3.7
Total diluted shares (m)									87.4
Value per diluted share* ($)									2.97

Source: Edison Investment Research, Sunesis reports. Note: *Includes $17m cash on exercise of warrants and option.

Financials

On 17 January, the company announced the pricing of the offering of common and preferred stock with gross proceeds of $20m. The offering included 23m shares of common stock and 17,000 shares (equivalent to 17m common shares) of convertible preferred stock at an offering price of $0.50 per common share or equivalent. Based on our financial projections, this should provide a cash runway throughout 2019 and into 2020. The company ended Q318 with $20.2m in cash (and $7.3m in debt). We have adjusted our financing schedule as a result and expect the company to need $115m in additional capital to reach profitability in 2023 ($40m in 2020, $40m in 2021, $35m in 2022), down from $135m previously.

Exhibit 2: Financial summary

$'000s	2016	2017	2018e	2019e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS				
Revenue	2,536	669	237	0
Cost of Sales	0	0	0	0
Gross Profit	2,536	669	237	0
Research and development	(22,881)	(21,540)	(15,123)	(17,485)
Selling, general & administrative	(16,115)	(13,548)	(12,575)	(12,952)
EBITDA	(36,313)	(34,428)	(27,470)	(30,447)
Operating Profit (before GW and except.)	(36,302)	(34,419)	(27,461)	(30,438)
Intangible Amortisation	0	0	0	0
Exceptionals/Other	0	0	0	0
Operating Profit	(36,302)	(34,419)	(27,461)	(30,438)
Net Interest	(1,721)	(1,039)	(826)	(632)
Other (change in fair value of warrants)	0	0	0	0
Profit Before Tax (norm)	(38,023)	(35,458)	(28,287)	(31,069)
Profit Before Tax (IFRS)	(38,023)	(35,458)	(28,287)	(31,069)
Tax	0	0	0	0
Deferred tax	0	0	0	0
Profit After Tax (norm)	(38,023)	(35,458)	(28,287)	(31,069)
Profit After Tax (IFRS)	(38,023)	(35,458)	(28,287)	(31,069)
Average Number of Shares Outstanding (m)	15.7	24.5	35.6	63.4
EPS - normalised ($)	(2.42)	(1.45)	(0.80)	(0.49)
EPS - IFRS ($)	(2.42)	(1.45)	(0.80)	(0.49)
Dividend per share ($)	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	14,523	6,495
Stocks	0	0	0	0
Debtors	0	0	0	0
Cash	42,588	31,750	13,221	5,193
Other	643	1,183	1,302	1,302
Current Liabilities	(5,814)	(8,901)	(1,414)	(1,554)
Creditors	(2,481)	(1,697)	(1,414)	(1,554)
Short term borrowings	(3,333)	(7,204)	0	0
Long Term Liabilities	(11,271)	(112)	(7,400)	(7,400)
Long term borrowings	(11,102)	0	(7,396)	(7,396)
Other long term liabilities	(169)	(112)	(4)	(4)
Net Assets	26,149	25,321	5,720	(2,457)
CASH FLOW				
Operating Cash Flow	(36,962)	(36,142)	(24,839)	(26,828)
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	6,303	18,800
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	(10,851)	(3,238)	(18,536)	(8,028)
Opening net debt/(cash)	(38,596)	(28,153)	(24,546)	(5,825)
HP finance leases initiated	0	0	0	0
Exchange rate movements	0	0	0	0
Other	408	(369)	(185)	0
Closing net debt/(cash)	(28,153)	(24,546)	(5,825)	2,203

Source: Company data, Edison Investment Research

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