

SymBio Pharmaceuticals

Treakisym label expansion submitted

SymBio announced on 11 May 2020 that it submitted an application to expand the label for Treakisym in Japan to include the treatment of relapsed and refractory diffuse large B-cell lymphoma (DLBCL) in combination with rituximab. This follows the positive results seen in the Phase III study for the combination reported in November 2019. We expect this label expansion to more than double the sales potential for the drug.

| Year end | Revenue (\$m) | PTP* (\$m) | EPADR (\$) | DPADR (\$) | P/E (x) | Gross yield (%) |
|----------|---------------|------------|------------|------------|---------|-----------------|
| 12/18 | 34.8 | (24.9) | (1.50) | 0.0 | N/A | N/A |
| 12/19 | 25.7 | (39.7) | (1.72) | 0.0 | N/A | N/A |
| 12/20e | 23.7 | (47.7) | (1.65) | 0.0 | N/A | N/A |
| 12/21e | 83.8 | 9.9 | 0.17 | 0.0 | N/A | N/A |

Note: Converted at **/US\$. Dividend yield excludes withholding tax. Investors should consult their tax advisor regarding the application of any domestic and foreign tax laws.

DLBCL key to future growth

Treakisym (bendamustine) is currently approved in Japan for low-grade non-Hodgkin lymphoma (NHL) or mantle cell lymphoma and chronic lymphocytic leukemia. We estimate the label expansion would approximately double the target market with 11,200 second-line DLBCL patients. While the company did not publish detailed results from its Phase III study, it reported that it met its primary endpoints and the combination has established efficacy in the literature.

Label expansion part of multi-pronged strategy

The label expansion is one aspect of the company's ongoing strategy to reach profitability. The drug is currently sold by Eisai, with SymBio regaining full control at the end of 2020, after which the product will be sold by an internal salesforce. The company has also licensed the rights to two proprietary formulations of bendamustine from Eagle Pharmaceuticals and plans to convert providers to the new, more convenient formulations prior to the October 2020 loss of exclusivity for the current formulation.

Supply issues continue to affect sales, margins

The company reported with Q120 results that quality control issues of Treakisym sourced from Astellas have continued to affect the ability of the company to deliver product to Eisai. This problem has persisted since mid-2019. The company reported revenue of \$5.0m for the quarter, down from \$15.0m for Q119, and a gross profit of \$1.2m (down from \$5.7m), citing lack of inventory as the cause.

Valuation: Increased to \$354.2m

We have increased our valuation to \$354m (¥39.0bn) from \$338m (¥37.2bn) previously, although it is lower on a per share basis: \$10.40 (¥1,144) from \$12.28 (¥1,351). We estimate a cash balance of \$50.8m following multiple recent rights exercises (\$15.5m raised since Q120 cash of \$35.3m). We expect this to be sufficient for the company to deliver on its strategy to reach profitability in 2021.

Earnings and regulatory update

Pharma & biotech

22 May 2020

Price **\$4.33***

Market cap **\$148m**

*Underlying ¥ price converted at ¥110/US\$
ADR/Ord conversion ratio 1:1

Net cash (\$m) at 31 March 2020 + subsequent exercises 50.8

ADRs in issue 34.1m

ADR code SYMQY

ADR exchange OTC

Underlying exchange Tokyo

Depository BNY

Business description

SymBio Pharmaceuticals is a Japanese specialty pharma company with a focus on oncology and hematology. The Treakisym powder formulation was in-licensed from Astellas in 2005; liquid Treakisym was in-licensed from Eagle Pharmaceuticals in 2017. Rigosertib was in-licensed from Onconova. And brincidofovir was licensed from Chimex in 2019.

Next events

Rigosertib Phase III results H220

Treakisym RTD approval decision October 2020

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Treakisym DLBCL label expansion submitted

SymBio announced in May 2020 that it had completed and submitted its application to the PMDA to expand the addressable indications for Treakisym to include relapsed and refractory DLBCL (in combination with rituximab). SymBio previously announced that it had met its primary endpoint in its Phase III study of Treakisym (bendamustine). The primary endpoint was overall response rate, with progression free survival and overall survival as secondary endpoints, but a detailed report was not presented. The study was open label and single arm, but this may be able to support a label expansion for the drug to this indication considering the well-demonstrated activity in other studies. Although bendamustine is not approved explicitly for DLBCL in the US (although it is approved for indolent NHL), it has been demonstrated to have activity when combined with rituximab,¹ similar to the company's pivotal study. The company previously announced an overall response rate (ORR) of 62.7% and complete response (CR) of 37.3% was observed in the earlier Phase II study. We estimate a target market of 11,200 second-line DLBCL patients in Japan, which would approximately double the current addressable market. We expect an approval decision from the PMDA within 12 months.

Frustrating quality control issues continue

The quality control issues the company has experienced with shipments of bendamustine from its supplier Astellas continue unabated. This has significantly affected the ability of the company to deliver drug to Eisai and the associated revenue from that agreement. The company reported revenue of \$5.0m for Q1 (Q119: \$15.0m), and a gross profit of \$1.2m (Q119: \$5.7m).

This has been an issue since mid-2019, which the company first identified quality issues in shipments of drug from Astellas. SymBio has repeatedly sought to resolve the issue, but apparently to no effect. We have lost confidence that this issue can be resolved in a timely manner and have reduced our forecasted revenue for 2020 to \$23.7m from \$31m previously, and our gross profit to \$5.9m from \$9.4m.

However, the company has planned to transition to using the formulations licensed from Eagle once they are approved. We expect a decision on the approval of the ready-to-dilute (RTD) formulation by the end of September 2020.

Valuation

We have increased our valuation to \$354m (¥39.0bn) from \$338m (¥37.2bn) previously, although it is lower on a per share basis: \$10.40 (¥1,144) from \$12.28 (¥1,351). The increase in total valuation is from rolling forward our NPVs. Although we now forecast lower revenue in 2020 than previously, this impact is limited to the current year (FY20), dampening the overall effect on the valuation. The increase in shares outstanding is driven by the recent large rights exercises in the ongoing rights offering: 5.61m new shares to date in April and May, bringing the total outstanding to an estimated 34.1m. We expect to update our valuation with the top-line results from the Phase III study of rigosertib (in development at and licensed from Onconova) expected in H220 (delayed from H120 previously).

¹ Arcari A. et al. (2014) Safety and Efficacy of Rituximab Plus Bendamustine in Relapsed or Refractory Diffuse Large B-Cell Lymphoma Patients. *Blood* 124, 3074.

Exhibit 1: Valuation of Symbio

| Product | Indication | Launch | Peak Sales (\$m) | Value (\$m) | Probability | rNPV (\$m) | NPV/ADR (\$/ADR) |
|--|--|--------|------------------|-------------|-------------|------------|------------------|
| Treakisym | Low grade NHL/MCL (r/r and 1st line); CLL | 2010 | 78 | 177.9 | 100-95% | 170.2 | 5.00 |
| Treakisym (DLCL) | r/r DLCL | 2021 | 87 | 121.7 | 90% | 108.9 | 3.20 |
| Rigosertib (IV) | r/r HR-MDS | 2023 | 35 | 26.4 | 50% | 12.4 | 0.36 |
| Rigosertib (oral) | LR-MDS (mono) or First-line HR-MDS (combo) | 2025 | 68 | 39.1 | 15% | 4.0 | 0.12 |
| Brincidofovir | vHC | 2025 | 38 | 30.8 | 30% | 8.0 | 0.24 |
| Net Cash (March 2020 + subsequent exercises) | | | | 50.8 | 100% | 50.8 | 1.49 |
| Valuation | | | | 446.7 | | 354.2 | 10.40 |

Source: Symbio Pharmaceuticals reports, Edison Investment Research

Financials

The company ended the quarter with \$35.3m and subsequently raised \$15.5m in equity through rights exercises. We expect this to be sufficient cash for the company to continue its commercial buildout in preparation for the 2021 relaunch of Treakisym, and we expect sustained profitability thereafter. We previously included \$5.5m in additional capital needed to provide a cash buffer going into the launch, which has been removed given the raised cash. Other changes to our forecasts (besides those described above) include adjusting 2020 SG&A spending (\$30m from \$32m), other minor changes to reflect Q120 results, and an update to our tax treatment to align better with Japanese GAAP and tax law changes. We have slightly increased 2021 expected revenue (\$84m from \$83m) to reflect warehoused patients unable to get treatment with the current supply issues.

Exhibit 1: Financial summary

| Accounts: JPN GAAP, year end: 31 December, \$'000s | | 2018 | 2019 | 2020e | 2021e |
|--|-----|----------|----------|----------|----------|
| Total revenues | | 34,868 | 25,798 | 23,710 | 83,889 |
| Cost of sales | | (24,206) | (17,936) | (17,782) | (14,716) |
| Gross profit | | 10,662 | 7,861 | 5,927 | 69,173 |
| SG&A (expenses) | | (18,147) | (24,771) | (30,226) | (52,477) |
| R&D costs | | (16,661) | (22,196) | (23,664) | (6,955) |
| Other income/(expense) included in adjusted | | 0 | 0 | 0 | 0 |
| Other income/(expense) excluded from adjusted | | 0 | 0 | 0 | 0 |
| Reported EBIT | | (24,146) | (39,106) | (47,962) | 9,742 |
| Finance income/ (expense) | | 6 | 2 | 178 | 171 |
| Other income/(expense) included in adjusted | | (0) | 38 | 0 | 0 |
| Other income/(expense) excluded from adjusted | | (848) | (684) | 0 | 0 |
| Reported PBT | | (24,988) | (39,750) | (47,784) | 9,913 |
| Income tax expense | | (35) | (35) | (35) | (3,973) |
| Reported net income | | (25,023) | (39,784) | (47,818) | 5,940 |
| Average number of ADRs - basic (m) | | 16.6 | 23.2 | 29.0 | 34.1 |
| Basic Earnings per ADR | USD | (1.50) | (1.72) | (1.65) | 0.17 |
| Adjusted EBITDA | | (23,831) | (3,876) | (4,708) | 1,059 |
| Adjusted EBIT | | (24,146) | (3,911) | (4,796) | 974 |
| Adjusted PBT | | (24,988) | (3,979) | (4,778) | 991 |
| Adjusted Earnings per ADR | USD | (1.50) | (1.72) | (1.65) | 0.17 |
| Adjusted diluted Earnings per ADR | USD | (1.50) | (1.72) | (1.65) | 0.17 |
| BALANCE SHEET | | | | | |
| Property, plant and equipment | | 518 | 686 | 730 | 1,237 |
| Goodwill | | 0 | 0 | 0 | 0 |
| Intangible assets | | 649 | 2,187 | 1,918 | 1,738 |
| Other non-current assets | | 660 | 640 | 640 | 640 |
| Total non-current assets | | 1,827 | 3,513 | 3,288 | 3,615 |
| Cash and equivalents | | 43,831 | 35,553 | 17,044 | 16,865 |
| Inventories | | 4,853 | 0 | 1,997 | 1,653 |
| Trade and other receivables | | 3,743 | 4,993 | 2,598 | 9,193 |
| Other current assets | | 2,469 | 3,885 | 3,885 | 3,885 |
| Total current assets | | 54,895 | 44,432 | 25,525 | 31,596 |
| Non-current loans and borrowings | | 0 | 0 | 0 | 0 |
| Trade and other payables | | 0 | 0 | 0 | 0 |
| Other non-current liabilities | | 12 | 15 | 15 | 15 |
| Total non-current liabilities | | 12 | 15 | 15 | 15 |
| Trade and other payables | | 6,601 | 1,099 | 4,357 | 4,815 |
| Current loans and borrowings | | 0 | 0 | 0 | 0 |
| Other current liabilities | | 5,548 | 6,830 | 6,830 | 6,830 |
| Total current liabilities | | 12,149 | 7,929 | 11,187 | 11,645 |
| Equity attributable to company | | 44,562 | 40,001 | 17,612 | 23,552 |
| Non-controlling interest | | 0 | 0 | 0 | 0 |
| CASHFLOW STATEMENT | | | | | |
| Profit before tax | | (24,988) | (39,750) | (47,784) | 9,913 |
| Depreciation and Amortisation | | 315 | 346 | 882 | 849 |
| Share based payments | | 1,342 | 0 | 0 | 0 |
| Other adjustments | | 552 | 2,081 | (178) | (171) |
| Movements in working capital | | 1,677 | (2,201) | 3,655 | (5,792) |
| Net cash from operating activities (pre-tax) | | (21,102) | (39,523) | (43,425) | 4,799 |
| Interest paid / received | | 5 | 5 | 178 | 171 |
| Income taxes paid | | (35) | (35) | (35) | (3,973) |
| Cash from operations (CFO) | | (21,132) | (39,552) | (43,281) | 997 |
| Capex | | (362) | (1,968) | (656) | (1,176) |
| Acquisitions & disposals net | | 0 | 0 | 0 | 0 |
| Other investing activities | | 124 | 0 | 0 | 0 |
| Cash used in investing activities (CFIA) | | (238) | (1,968) | (656) | (1,176) |
| Net proceeds from issue of shares | | 38,837 | 33,982 | 25,429 | 0 |
| Movements in debt | | 0 | 0 | 0 | 0 |
| Other financing activities | | 0 | 19 | 0 | 0 |
| Cash from financing activities (CFF) | | 38,837 | 34,000 | 25,429 | 0 |
| Currency translation differences and other | | (428) | (758) | 0 | 0 |
| Increase/(decrease) in cash and equivalents | | 17,039 | (8,278) | (18,509) | (179) |
| Cash and equivalents at end of period | | 43,831 | 35,553 | 17,044 | 16,865 |
| Net (debt) cash | | 43,831 | 35,553 | 17,044 | 16,865 |
| Movement in net (debt) cash over period | | 17,039 | (8,278) | (18,509) | (179) |

Source: SymBio Pharmaceuticals reports, Edison Investment Research

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