EDISON

# SUDA Pharmaceuticals

Financial update

## Half-year update

Pharma & biotech

**SUDA continues to make progress with anagrelide. In an animal model, SUDA was able to show that an oral spray formulation had 43% higher bioavailability over a capsule form while only showing a 28% increase in exposure of the cardiostimulatory metabolite. This provides evidence that this formulation may allow for a lower dose of anagrelide, maintaining efficacy, but with reduced cardiotoxicity, a significant issue with the capsule formulation. In February, the company announced that it has contracted with MedPharm to perform additional formulation work to stabilise and optimise the oral spray formulation.**

| Year end | Revenue (A$m) | PBT* (A$m) | EPS* (A$) | DPS (A$) | P/E (x) | Yield (%) |
|---|---|---|---|---|---|---|
| 06/19 | 1.2 | (2.4) | (0.02) | 0.0 | N/A | N/A |
| 06/20 | 0.5 | (4.7) | (0.03) | 0.0 | N/A | N/A |
| 06/21e | 0.5 | (4.3) | (0.01) | 0.0 | N/A | N/A |
| 06/22e | 1.0 | (4.6) | (0.01) | 0.0 | N/A | N/A |

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

## Potentially reducing anagrelide cardiotoxicity

Anagrelide is an effective agent used to reduce elevated levels of platelets in essential thrombocythemia, but use has been limited by cardiotoxicity. SUDA believes that an oro-mucosal spray version could minimise these issues by reducing first-pass generation of a highly potent cardio-excitatory metabolite of the drug in the liver, 3-hydroxy anagrelide. The recently announced data may be supportive of this hypothesis.

## ZolpiMist rights outside of North America

SUDA has the rights outside North America and has out-licensed rights in Mexico, Brazil and Chile to Teva, and in South Korea to Mitsubishi Tanabe Pharma Korea. Royalties are typically double digit and include a handling fee. The recent TGA approval will assist SUDA's current partners in their submissions in the territories for which they are responsible.

## Mitsubishi Tanabe Singapore not going forward

SUDA had a licence and supply agreement for Singapore, Malaysia and the Philippines with Mitsubishi Tanabe Pharma Singapore, but that agreement was terminated by the partner in January because of 'a change in the business strategy across the ASEAN [Association of Southeast Asian Nations] region'.

## Valuation: A$23m or A$0.06 per basic share

We have adjusted our valuation for SUDA from A$24m or A$0.08 per basic share (A$0.06 per diluted share) to A$23m or A$0.06 per basic share (A$0.05 per diluted share). This is mainly due to the Mitsubishi Tanabe Singapore termination and a greater number of shares outstanding following a A$2.8m financing in December. The company had A$5.5m in cash on hand at 31 December 2020. We currently forecast an additional A$12.5m in financing through FY23 (previously A$18.5m).

**11 March 2021**

| | |
|---|---|
| **Price** | **A$0.04** |
| **Market cap** | **A$16m** |
| | A$1.26/US$ |
| Net cash (A$m) at 31 December 2020 + February 2021 offering | 5.5 |
| Shares in issue | 384.7m |
| Free float | 89.6% |
| Code | SUD |
| Primary exchange | ASX |
| Secondary exchange | N/A |

### Share price performance


| % | 1m | 3m | 12m |
|---|---|---|---|
| Abs | (17.6) | 5.0 | (6.5) |
| Rel (local) | (15.4) | 4.5 | (19.3) |
| 52-week high/low | A$0.06 | | A$0.03 |

### Business description

SUDA Pharmaceuticals has historically been a drug delivery company focusing on developing oro-mucosal spray versions of established medicines. It has the rights to ZolpiMist, the spray version of Ambien for insomnia, outside of North America. SUDA is also working on formulating an oro-mucosal version of anagrelide for the treatment of solid tumours, sumatriptan for migraine, cannabinoids for various conditions, as well as other projects.

### Next events

| | |
|---|---|
| Additional licensing deals | FY21/22 |

### Analysts


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## H1 results

SUDA Pharmaceuticals has historically been a drug delivery company focusing on reformulating established drugs into oro-mucosal spray (via its OroMist platform) formulations for better bioavailability. Its lead commercial-stage product is ZolpiMist, an oro-mucosal spray version of Ambien for the treatment of insomnia that it has partnered in certain regions with Teva and Mitsubishi Tanabe Pharma Korea (SUDA obtained the rights outside of North America). It is also working on a number of other projects using OroMist including anagrelide (for the treatment of high platelet counts in cancer patients), sumatriptan (migraine), cannabinoids and others.

**Exhibit 1: SUDA Pharmaceuticals pipeline**

| Programme | Indication | Status | Partners | Comments |
|---|---|---|---|---|
| ZolpiMist | Insomnia | Approved (Australia)/ registration | Teva (Mexico, Chile, Brazil), Mitsubishi Tanabe Pharma (Korea) | Faster onset than standard version. Approved in one country, the US, where rights sit with Aytu. Exact timelines for registration in partner areas unclear due to confidentiality. SUDA received TGA approval in Australia. |
| Anagrelide | High platelet counts in cancer | Formulation | None | Possibly fewer cardiac side effects than standard version. Possible use in a variety of different cancers where high platelet counts are correlated with poor outcomes such as ovarian, lung and pancreatic cancer. |
| Sumatriptan | Migraine | Formulation | Strides (United States) | Faster onset than oral version but without needing to resort to injection. |
| Cannabinoids | Various | Feasibility | Cann Pharma Australia | Early stage deals to convert cannabinoid products into oro-mucosal sprays. |
| Undisclosed | Undisclosed | Feasibility | Sanofi | Using OroMist technology on undisclosed active ingredient for Sanofi. |

Source: SUDA Pharmaceuticals

ZolpiMist is the oro-mucosal spray version of zolpidem tartrate (the branded form is the blockbuster insomnia drug Ambien), which has 30m prescriptions written for it in the US annually. Approximately 2.5m prescriptions are written for novel formulations, such as controlled release and sublingual tablets. The main benefit of ZolpiMist is the fast onset of action. Therapeutic levels were reached within 15 minutes following administration of the 10mg dose of ZolpiMist in 79% of patients compared to only 26% with the tablet version.[1]

ZolpiMist has been approved in the US since 2008 (where Aytu BioScience has the rights) and the July 2020 approval in Australia is the first outside the US and the first by SUDA (the company has not provided guidance on a commercial strategy for Australia). SUDA has out-licensed ZolpiMist to Teva for Mexico, Chile and Brazil, and to Mitsubishi Tanabe Pharma Korea for South Korea. Note that SUDA had a license and supply agreement for Singapore, Malaysia and the Philippines with Mitsubishi Tanabe Pharma Singapore, but that agreement was terminated by the partner in January because of 'a change in the business strategy across the ASEAN region'. While a negative, this partnership was the one where we had our lowest expectations for future royalties so the impact on both peak sales and the valuation for the company is relatively small.

While upfront payments have been small, the royalty rates are all double digit and SUDA will also receive a handling fee. The company has stated that it is in discussions for licensing deals for additional territories (SUDA has rights outside the US and Canada), in line with the strategy of commercialising the product globally.

1 Neubauer et al., ZolpiMist: a new formulation of zolpidem tartrate for the short-term treatment of insomnia in the US. *Nature and Science of Sleep* 2010:2 79–84.

**Exhibit 2: ZolpiMist licensing deals**

| Partner | Countries | Populations | Terms | Comments |
|---|---|---|---|---|
| Teva | Mexico, Chile and Brazil | Mexico: 123m, Chile: 17m, Brazil: 213m | US$300,000 upfront, commercial milestones of US$700,000 and double-digit royalties | Agreement signed in 2017. Teva is currently working on approval in the three countries; launch timing undisclosed. |
| Mitsubishi Tanabe Pharma Korea | South Korea | South Korea: 51m | US$100,000 upfront, US$100,000 on approval, up to US$300,000 in commercial milestones, a 12% royalty and a handling fee | Signed in 2020. Timing of approval and launch tbd. |

Source: SUDA Pharmaceuticals

## Anagrelide

SUDA is also developing an oro-mucosal spray formulation of anagrelide for the treatment of solid tumours in patients who have elevated platelet levels. Anagrelide is currently used as an anti-thrombotic agent to reduce elevated levels of platelets in essential thrombocythemia (a rare chronic blood cancer where the bone marrow produces too many platelets). The oral version of the drug was developed by Shire and received FDA approval in essential thrombocythemia in 1997 under the brand name Agrylin in the US (Xagrid in Europe). While anagrelide is effective it is known to have cardiotoxicity, which has limited its uptake. In clinical trials, 26% of patients reported heart palpitations, 8% reported tachycardia and 8% reported chest pain (though in the real-world setting post approval, reports of palpitations were as high as 70% in some studies[2]).

In an animal model, SUDA was able to recently show that an oral spray formulation had 43% higher bioavailability over a capsule form, while only showing a 28% increase in exposure of the cardiostimulatory metabolite. This provides evidence that this formulation may allow for a lower dose of anagrelide, maintaining efficacy, but with reduced cardiotoxicity, a significant issue with the capsule formulation (however, the clinical significance of this in humans has yet to be demonstrated). In February, the company announced that it has contracted with MedPharm to perform additional formulation work to stabilise and optimise the oral spray formulation. Note that we do not include Anagrelide in our valuation due to its early stage and that the timing of entry into human clinical trials is uncertain.

## Other collaborations

The company has feasibility studies ongoing with Sanofi (undisclosed target/compound) and Cann Pharma Australia (cannabinoids), but Zelira and Ordesa have chosen not to proceed with their collaborations. None of these feasibility studies have been included in our valuation due to their early stage.

# Valuation

We have adjusted our valuation for SUDA from A$24m or A$0.08 per basic share (A$0.06 per diluted share) to A$23m or A$0.06 per basic share (A$0.05 per diluted share). This is mainly due to the Mitsubishi Tanabe Pharma Singapore termination and a greater number of shares outstanding following a A$2.8m financing in December. Following the end of the Mitsubishi Tanabe Pharma Singapore collaboration, our peak sales estimate for ZolpiMist is now A$17.3m versus A$19.5m previously.

2 Birgegard et al., Adverse effects and benefits of two years of anagrelide treatment for thrombocythemia in chronic myeloproliferative disorders. *Haematologica*. 2004 May;89(5):520–7

**Exhibit 3: SUDA valuation table**

| Product | Main indication | Status | Probability of successful commercialisation | Approval year | Peak sales (A$m) | Economics | rNPV ($m) |
|---|---|---|---|---|---|---|---|
| ZolpiMist | Insomnia | Registered (Australia), pre-registration (other regions) | 70% | 2020 | 17.3 | Double-digit royalties | 17.9 |
| Total | | | | | | | 17.9 |
| Net cash (as of 31 December 2020 + offering) | | | | | | | 5.5 |
| Total firm value (A$m) | | | | | | | 23.40 |
| Total basic shares (m) | | | | | | | 384.7 |
| Value per basic share (A$) | | | | | | | 0.06 |
| Options (m) | | | | | | | 68.1 |
| Total number of shares (m) | | | | | | | 452.8 |
| Diluted value per share (A$) | | | | | | | 0.05 |

Source: Edison Investment Research

# Financials

For the period ending 31 December 2020 (H1 of FY21), the company reported A$0.2m in revenue (down 34% compared to the same period a year ago, mainly due to the timing of licensing, upfront and milestone payments) and a loss of A$1.7m, down from a loss of A$7.7m previously (A$5.5m of that loss in H120 was due to intangible asset impairment related to ArTiMist). Operating cash burn for the half year was A$1.9m. We have slightly lowered our FY21 and FY22 revenue estimates but also reduced our FY21 and FY22 SG&A estimates due to better expense controls.

The company had A$5.5m in cash on hand at 31 December 2020. Earlier in December, the company raised A$2.8m through the issuance of 76.7m shares at A$0.036 per share. As part of this placement plan, the company issued an additional 1.1m in shares to the directors at the same price in February. We currently forecast an additional A$12.5m in financing through FY23 (previously A$18.5m, with the difference coming from the new raise and as well as lower expense expectations).

## Exhibit 4: Financial summary

| A$'000s | 2019 | 2020 | 2021e | 2022e |
|---|---|---|---|---|
| Year end 30 June | AIFRS | AIFRS | AIFRS | AIFRS |
| **PROFIT & LOSS** | | | | |
| Revenue | 1,219 | 533 | 485 | 1,041 |
| Cost of Sales | 0 | 0 | 0 | 0 |
| Gross Profit | 1,219 | 533 | 485 | 1,041 |
| Sales, General and Administrative Expenses | (3,129) | (4,788) | (3,825) | (3,978) |
| Research and Development Expense | 0 | 0 | (500) | (1,020) |
| EBITDA | (1,878) | (4,112) | (3,618) | (3,957) |
| Operating Profit (before amort. and except.) | (2,349) | (4,684) | (4,248) | (4,588) |
| Intangible Amortisation | 0 | 0 | 0 | 0 |
| Other | 32 | 143 | 222 | 0 |
| Exceptionals | (6,277) | (5,938) | 0 | 0 |
| Operating Profit | (8,626) | (10,622) | (4,248) | (4,588) |
| Net Interest | (94) | 22 | (43) | (45) |
| Other | 0 | 0 | 0 | 0 |
| Profit Before Tax (norm) | (2,443) | (4,662) | (4,291) | (4,632) |
| Profit Before Tax (FRS 3) | (8,720) | (10,600) | (4,291) | (4,632) |
| Tax | 925 | 656 | 0 | 0 |
| Deferred tax | (0) | (0) | (0) | (0) |
| Profit After Tax (norm) | (1,518) | (4,006) | (4,291) | (4,632) |
| Profit After Tax (FRS 3) | (7,795) | (9,944) | (4,291) | (4,632) |
| Average Number of Shares Outstanding (m) | 98.6 | 142.3 | 331.2 | 388.5 |
| EPS - normalised ($) | (0.02) | (0.03) | (0.01) | (0.01) |
| EPS - Reported ($) | (0.08) | (0.07) | (0.01) | (0.01) |
| Dividend per share (c) | 0.0 | 0.0 | 0.0 | 0.0 |
| **BALANCE SHEET** | | | | |
| Fixed Assets | 10,658 | 4,673 | 4,893 | 5,243 |
| Intangible Assets | 10,291 | 4,251 | 4,385 | 4,613 |
| Tangible Assets | 367 | 365 | 421 | 543 |
| Other | 0 | 57 | 87 | 87 |
| Current Assets | 5,595 | 2,035 | 3,608 | 6,622 |
| Stocks | 45 | 22 | 22 | 22 |
| Debtors | 1,121 | 869 | 62 | 104 |
| Cash | 4,314 | 977 | 3,318 | 6,290 |
| Other | 115 | 166 | 206 | 206 |
| Current Liabilities | (1,349) | (2,022) | (1,513) | (1,513) |
| Creditors | (1,312) | (2,010) | (1,513) | (1,513) |
| Short term borrowings | (36) | (12) | 0 | 0 |
| Long Term Liabilities | (927) | (550) | (46) | (7,550) |
| Long term borrowings | (17) | (4) | (4) | (7,504) |
| Other long term liabilities | (910) | (545) | (42) | (47) |
| Net Assets | 13,978 | 4,135 | 6,942 | 2,802 |
| **CASH FLOW** | | | | |
| Operating Cash Flow | (2,495) | (2,884) | (3,819) | (4,039) |
| Net Interest | 0 | 0 | 0 | 0 |
| Tax | 0 | 0 | 0 | 0 |
| Capex | (1,384) | (388) | (484) | (489) |
| Acquisitions/disposals | 0 | 0 | 0 | 0 |
| Financing | 8,095 | 0 | 6,694 | 0 |
| Dividends | 0 | 0 | 0 | 0 |
| Other | 0 | 0 | 0 | 0 |
| Net Cash Flow | 4,215 | (3,272) | 2,391 | (4,528) |
| Opening net debt/(cash) | 1,951 | (4,260) | (961) | (3,314) |
| HP finance leases initiated | 0 | 0 | 0 | 0 |
| Exchange rate movements | 0 | 0 | 19 | 0 |
| Other | 1996 | -27 | -57 | 0 |
| Closing net debt/(cash) | (4,260) | (961) | (3,314) | 1,213 |

Source: Company reports, Edison Investment Research

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