NDF RESEARCH

Providing independent research coverage of
ASX-listed Life Science companies

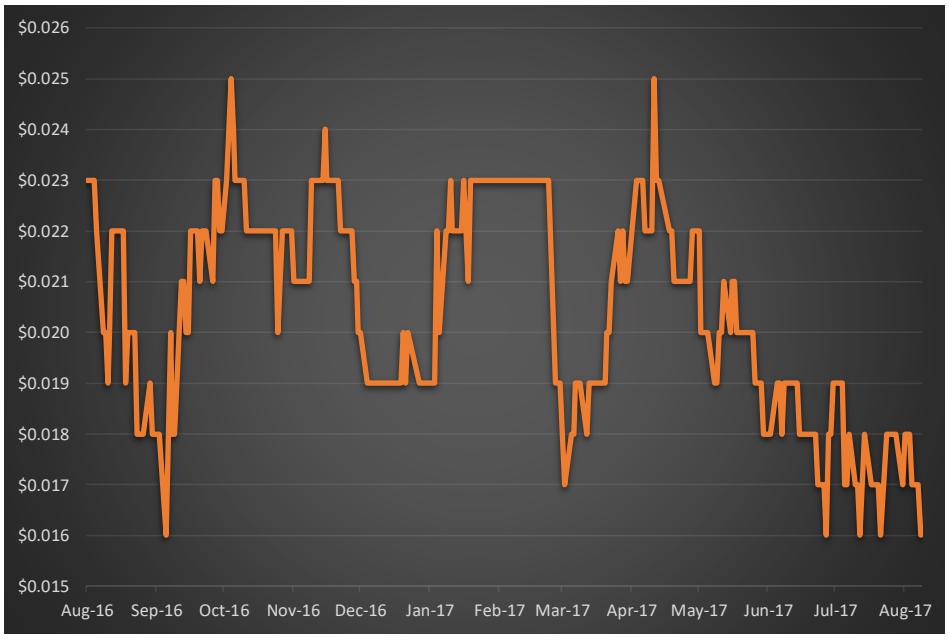
# SUDA Pharmaceuticals (ASX: SUD)

**Update note – Thursday 15 February 2018**

## SUDA takes control of the Anagrelide project

**This note updates our 14 August 2017 note headlined 'Faster, safer delivery for ex-blockbusters'**. SUDA Pharmaceuticals is a drug delivery company focused on oral spray formulations of existing drugs. Over the last few years the company has generated considerable *in vivo* evidence that its technology can create safer and much faster-acting versions of the original drug. Commercially this platform has started to deliver for SUDA shareholders, as evidenced by a mid-2017 licensing deal with Teva. We believe more such deals are in the offing. An encouraging aspect of SUDA's development since 2010 has been the opportunistic way in which it has improved its technology base over time. A good example of that is SUDA's Anagrelide Project, which it initiated in June 2017 and where the aim is to take a drug approved for a rare blood disorder and turn it into a cancer drug. In this update note we look at the Anagrelide Project in more detail. Our 17 cents per share price target remains in place.

| Rating | Risk | Current price | Target price |
|---|---|---|---|
| Buy | Medium | $0.014 | $0.17 |




### Stock details

Daily Turnover: ~A$30,000
Market Cap: A$17.1m
Shares Issued: 1,221.4m
52-Week High: $0.025
52-Week Low: $0.014

**Analyst:** Stuart Roberts
stuart@ndfresearch.com
+61 447 247 909

**Please note:** This report has been commissioned by SUDA Pharmaceuticals and NDF Research will receive payment for its preparation. Please refer below for risks related to SUDA Pharmaceuticals as well our General Advice Warning, disclaimer and full disclosures. Also, please be aware that the investment opinion in this report is current as at the date of publication but that the circumstances of the company may change over time, which may in turn affect our investment opinion.

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NDF is an independent equity research firm based in Sydney, Australia. It focuses on Life Science companies that are publicly traded on the Australian Securities Exchange (ASX), most of which are headquartered in Australia and New Zealand. ASX hosts one of the world's premier equity markets for biotech and medical device companies and is home to world-beating companies such as CSL and ResMed and emerging pioneers such as Mesoblast and Impedimed.

NDF's Founder and Senior Analyst, Stuart Roberts, has been involved in Life Sciences since 2002 as a sell-side analyst as well as an executive of two ASX-listed immuno-oncology drug developers.

NDF believes that ASX-listed companies have been largely overlooked in the global Life Sciences boom that began in late 2008, partly because of insufficient quality research. NDF's goal is to provide such research, and introduce investors around the world to potential future billion-dollar companies from 'Down Under'.

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*Ferry at the end of a rainbow on Sydney Harbour, August 2014*

# In this report

# SUDA takes control of the Anagrelide Project

**SUDA is a drug delivery company focused on oral spray formulations of existing drugs**. Between 2013 and 2016 the company worked primarily on a suite of oral sprays that it had acquired from a US company called NovaDel Pharma. More recently SUDA developed its own drug delivery technology called 'Hydrotrope' and this is the basis of current work. SUDA's foundation product, ArTiMist, a sub-lingual oral spray for the delivery of the anti-malarial drug artemether, did not come from the NovaDel technology but was the first product that SUDA developed.

SUDA IS A DRUG DELIVERY COMPANY

**SUDA is pre-clinical with an anagrelide oro-mucosal spray, which could be a powerful new treatment option for many cancers**. In our 14 August 2017 initiation piece on SUDA we commented that '*an encouraging aspect of SUDA's development since 2010 has been the opportunistic way in which it has improved its technology base over time'*. A good example of that, which we did not focus on very deeply in the 14 August note, is SUDA's anagrelide Project, which it initiated in June 2017 and where the aim is to take a drug approved for a rare blood disorder and turn it into a cancer drug. In this update note we look at the Anagrelide Project in more detail.

**Anagrelide is a currently an Orphan drug, in tablet form, for a rare blood disorder.** Anagrelide, marketed by Shire[1] as Agrylin in the US and as Xagrid in other territories, is a small molecule drug for the treatment for Essential Thrombocythemia, a rare blood disorder where too many platelets are produced in the bone marrow[2]. Platelets are essential to control bleeding, but too many platelets can result in abnormal blood clotting that can be fatal. In addition, Essential Thrombocythemia can also transition to Acute Myeloid Leukemia (AML) in a small minority of patients[3]. Anagrelide, which belongs to a drug class called the 'imidazoquinolines'[4], lowers platelet counts by inhibiting the maturation of a platelet precursor cell called the 'megakaryocyte', as well as the formation of an intermediate product called the 'proplatelet'[5]. The drug was originally developed by Bristol-Myers Squibb in the 1970s and 1980s[6] and outlicensed in 1991 to a specialty pharma company called Roberts Pharmaceutical. Roberts gained FDA approval for Agrylin in 1997, a couple of years before the company was acquired by Shire[7]. That company gained European approval for Xagrid in 2004. Anagrelide is one of two standard-of-care drugs used in Essential Thrombocythemia, the other being hydroxyurea, an inhibitor of DNA synthesis. Whilst there are many that regard hydroxyurea as safer than anagrelide[8], the former drug does not have the specificity to target platelet production that differentiates anagrelide. The main issue with anagrelide is the cardiac side effects - which includes palpitations and arrhythmias, fluid retention, heart failure, and headaches[9] - arising from the drug's vasodilatory and positive inotropic properties[10].

ANAGRELIDE IS AN APPROVED PLATELET-LOWERING DRUG

**Why Anagrelide could be a significant new cancer drug.** A significant body of work over the years has identified overproduction of platelets as being important in cancer – not just AML but multiple tumour types of high

[1] Shire (Dublin, Ireland, Nasdaq:SHPG, www.shire.com) is the world's 22nd largest pharma company with US$10.9bn in 2016 revenue (source: Pharmaceutical Executive magazine).
[2] The disease is 'essential' in the sense that it has no obvious cause.
[3] Mayo Clin Proc. 2006 Feb;81(2):159-66.
[4] The best known member of which is imiquimod, indicated (as Aldara) for the treatment of superficial basal cell carcinoma.
[5] J Thromb Haemost. 2015 Apr;13(4):631-42. Epub 2015 Feb 18.
[6] Thromb Res. 1979;15(3-4):373-88.
[7] At that time Roberts' other market products were Pentasa, an enteric-coated 5-aminosalicylic acid formulation approved for the treatment of ulcerative colitis, and ProAmatine, an alpha-receptor agonist for low blood pressure.
[8] See N Engl J Med. 1995 Apr 27;332(17):1132-6 and J Thromb Thrombolysis. 2015 Nov;40(4):474-9.
[9] Blood. 2001 Feb 15;97(4):863-6.
[10] That is, the drug widens blood vessels and also increasing the force of cardiac muscle contraction.

prevalence including breast[11] and lung cancer[12]. We've long known that 'paraneoplastic thrombocytosis'[13] is commonplace in cancer, with that condition tending to predict poorer outcomes for patients[14]. More recently, a good deal of the relationship between cancer and platelets has been elucidated: Tumours are able to stimulate platelet production and activation[15], and the platelets in turn confer significant advantages to the tumour:

- Platelets, when they adhere to cancer cells, form a protective cloak that helps the cancer escape immune surveillance and destruction by Natural Killer cells[16];
- Platelets help in the process of tumour angiogenesis, that is, the formation of new blood vessels to feed the tumour[17];
- Platelets help cancers gain the ability to metastasise[18];
- Platelets enhance the tumour microenvironment[19];
- Platelets secrete many growth factors that stimulate cancer cell proliferation[20]

This evidence has suggested that drugs which act to reduce platelet numbers could significantly enhance conventional chemotherapy. Around 2014 that thinking led Dr Stephen Damment, formerly Shire's Head of Biosciences[21], to start a company called Aluztra Bio in order to reprofile anagrelide as an anti-cancer agent. Working with former colleague Richard Franklin and with Professor Jorge Erusalimsky of Cardiff Metropolitan University, an authority on megakaryocyte biology, Aluztra Bio performed several experiments to demonstrate that reprofiled anagrelide would work in this setting, and filed for the relevant patent protection[22], with the support of the charity Cancer Research UK.

**Anagrelide can work best as an anti-cancer agent if it is an oral spray**. Anagrelide makes an ideal platelet lowering drug for anti-cancer purposes because it is highly selective – it only inhibits platelets, leaving other blood cell lines untouched[23]. The problem, as we noted above, is the high level of cardio-stimulation, which makes anagrelide unsuitable for patients with any kind of heart trouble and may historically have caused around a quarter of patients to discontinue treatment[24]. The unwanted cardiovascular side effects arise because anagrelide is a PDE3 inhibitor. Phosphodiesterase type 3 is an enzyme that regulates heart muscle. Knock down PDE3, and the resulting increase in a secondary messenger[25] called cyclic AMP causes increased calcium influx into the cardiac cells, prompting the heart to beat faster. For anagrelide, work in which Franklin and Erusalimsky were involved established way back in 2005 that much of the cardio-stimulation came from BCH24426, one of the metabolites of anagrelide created by the patient's livers[26]. That metabolite typically showed up in the patient's

**ANAGRELIDE CAN WORK BEST AS AN ORAL SPRAY**

[11] Blood Coagul Fibrinolysis. 2004 Sep;15(6):513-8.
[12] Med Oncol. 2010 Jun;27(2):357-62. Epub 2009 Apr 21.
[13] Semin Thromb Hemost. 2004 Feb;30(1):95-108.
[14] Int J Clin Exp Med. 2015 Apr 15;8(4):5379-87.
[15] Blood. 2014 Jul 10;124(2):184-7Epub 2014 May 27.
[16] Sci Immunol. 2017 May 5;2(11).
[17] Cancer Metastasis Rev. 2017 Jun;36(2):249-262..
[18] Cancer Cell. 2011 Nov 15;20(5):576-90.
[19] Biochim Biophys Acta. 2016 Mar;1863(3):392-400.
[20] See, for example, Blood. 2012 Dec 6;120(24):4869-72. Epub 2012 Sep 10.
[21] He is now SVP, Translational Medicine, at Midatech Pharma plc (Abingdon, UK, LSE: MTPH, www.midatechpharma.com), a company has been built around technology to conjugate drugs to gold nanoparticles for targeted release.
[22] See WO/2016/1029521, *Prevention and treatment of metastatic disease in thrombocytotic cancer*, priority date 22 December 2014.
[23] Leukemia. 2006 Jun;20(6):1117-22.
[24] Haematologica. 2004 May;89(5):520-7.
[25] Second messengers are intracellular signaling molecules that get their message from 'first messengers originating outside the cell.
[26] Br J Pharmacol. 2005 Oct;146(3):324-32.

bloodstreams at much higher levels than the original drug[27]. Which suggested a very simple solution – if anagrelide could be formulated as an oral spray or as a transdermal drug, the first pass metabolism in the liver that results when a drug is delivered as a pill would be avoided. This made anagrelide a highly attractive drug for SUDA with its OroMist platform, which allows reformulation of drugs so that they are delivered via the oro-mucosal route, and was the main reason why SUDA acquired the rights to the Aluztra Bio intellectual property. SUDA signed MoU with Aluztra last June and completed the acquisition of the IP In January 2018. Should SUDA develop a drug from this IP, it will pay a low single-digit percentage royalty on sales or a share of income from commercialisation.

**SUDA can now proceed to realise Aluztra Bio's vision**. SUDA has commenced the formulation work for an OroMist spray of anagrelide. Once it identifies a formulation with the right pharmacodynamic properties, including efficient permeation across the oral mucosa membrane and a low level of cardio-stimulation in the animal models, it will then need to pick an appropriate cancer in which to study the anti-cancer properties of the drug. We believe there are multiple paths it can then pursue. An obvious one is to try the drug out in a more aggressive cancer where platelets overproduction is known to be highly prevalence, such as ovarian cancer. An early experiment which we expect the company will perform will be to evaluate anagrelide in conjunction with the checkpoint inhibitors to see if anagrelide-induced changes in the tumour microenvironment will improve the effectiveness of these drugs. We expect that 2018 will see SUDA able to publicly discuss its preferred development pathway for the anagrelide project.

**SUDA IS NOW WORKING ON A DEVELOPMENT PATHWAY FOR ANAGRELIDE**

**SUDA could also make anagrelide a more effective drug for Essential Thrombocythemia**. In spite of the cardiovascular drawbacks of Agrylin/Xagrid, the product enjoyed US$152.5m in global sales for Shire prior to its going generic in the US in 2005. The prevalence of Essential Thrombocythemia is about 22 per 100,000 people[28], which makes for a patient population in advanced industrial countries of around 230,000, and a rest-of-world population of 1.4 million. It's not unreasonable that an OroMist-formulated anagrelide could becoming the product of choice for Essential Thrombocythemia instead of hydroxyurea, considerably expanding the market opportunity.

**We've included some additional valuation for the Anagrelide Project in our model,** since the project has now moved beyond the conceptual and is being formulated and optimised. Due to the early stage of the anagrelide project we have only put a notional valuation on the project. We reserve the right to review this valuation as the project progresses. We also think anagrelide can provide an important validation of the thinking behind our current 17 cent share price target, which reflects early-stage valuations for a range of SUDA projects.

# Background to SUDA Pharmaceuticals (ASX: SUD)

**Why are oral sprays potentially valuable?** Small molecule drugs are able to enter the bloodstream much faster through the oral-mucosal layer in the mouth than through the gut as per most pills. This means that potentially smaller doses can be administered for the same amount of efficacy with a potential faster onset of action, which

[27] Clin Drug Investig. 2013 Jan;33(1):45-54.
[28] Am J Hematol. 2008 May;83(5):359-62.

has safety advantages. Also, there are benefits for such drugs in terms of patient convenience given that many children and adults will have difficulty swallowing. For these reasons, any platform that can reformulate a drug for delivery via an oral spray has potential to create significant value. SUDA argues that its technology provides both a 'life cycle extension' tool for drugs nearing the end of market exclusivity as well as a novel route of administration for innovator drugs.

**What products are currently in the SUDA pipeline?** As well as the ArTiMist sub-lingual product, SUDA is also working on oral sprays for sildenafil (erectile dysfunction and Pulmonary Arterial Hypertension or PAH), ondansetron (nausea), sumatriptan (migraine), zolpidem (insomnia), midazolam (epileptic seizures and anxiety) and anagrelide (cancer and Essential Thrombocythemia).

**Why did SUDA add a new technology platform in 2016?** An encouraging aspect of SUDA's development since 2010 has been the opportunistic way in which it has improved its technology base over time. The 2013 NovaDel transaction represented a way for SUDA to quickly develop capability in oral spray formulation. NovaDel Pharma[29] had sold most of its assets to SUDA for a nominal value after failing to raise capital in the wake of a number of business-related issues[30]. SUDA thereby inherited, at virtually no cost[31], a suite of new products based on drugs that, when they were still on patent, were blockbusters. There were limits, however, on the patent life of some of those products[32]. SUDA's new and internally-developed Hydrotrope technology, which is the basis for all current work and has been SUDA's main platform since 2016, has close to 20 years of patent life[33].

**How advanced is SUDA commercially**? In July 2017 SUDA inked a licensing deal with a Top 20 pharmaceutical company which we think shows the potential of its reformulation technology. The deal saw ZolpiMist, the company's zolpidem oral spray, licensed to Teva, a leading global player in the generic drug space, for large emerging market opportunities in Latin America. The deal came with relatively modest upfronts and milestone payments, but SUDA will supply the product to Teva and receive a double-digit royalty on Teva's net sales less the supply price. SUDA has granted Teva a license to ZolpiMist in Brazil, Mexico and Chile, together with an 18-month option to license the product in Argentina, Israel and Australia. Teva's first filing for marketing authorisation was made in December 2017. Prior to the Teva deal SUDA also announced deals with the major Chinese pharma company Eddingpharm in November 2016 and signed a feasibility and option agreement with Pfizer Consumer Healthcare in March 2017.

**SUDA LICENSED ITS ZOLPIDEM ORAL SPRAY TO TEVA IN JUNE 2017**

**If SUDA is so good, how come the market capitalisation of the company is only A$17.1m/US$13.4m**? We think the current low market capitalisation of SUDA mostly reflects the fact that it has only struck its landmark

[29] This US company had gone public on Nasdaq in late 1997. Over the next 15 years it made some progress developing its technology, which it called NovaMist, licensing and registering three products in the US market: Nitromist (a nitroglycerine spray), ZolpiMist (a Zolpidem Tartrate spray) and OroCam (a Meloxicam spray).
[30] Most notably the Pfizer patent extension for sildenafil in the US. An August 2011 Federal court judgement prevented Teva from receiving approval for its generic version of Viagra before October 2019. In February 2012, this expiry date was lengthened by six months, to April 2020, due to evidence that sildenafil is safe and effective for the treatment of pediatric Pulmonary Arterial Hypertension. We argue that these extensions were the primary reason that NovaDel lost its funding support. NovaDel had also stopped working on products where those products had deals in place, and as a result had not capitalised on negotiated milestone payments (e.g. US$26m for an ondansetron reformulation in Europe).
[31] SUDA optioned the NovaMist technology in December 2012 (see the company's market release dated 20 December 2012 and headlined '*SUDA signs option to acquire NovaMist technology)* and agreed to acquire it in April 2013 for A$0.4m cash, 50 million SUDA shares and 10 million December 2015 SUDA options with a 5-cent exercise price (see the company's 8 April 2013 market release headlined '*SUDA signs Sale and Purchase Agreement for NovaMist oro-mucosal platform technology*'). The transaction closed in August 2013. SUDA subsequently renamed the platform 'OroMist'.
[32] The earliest priority date for the NovaDel platform was 1 October 1997. That said, some NovaDel-developed products are covered by patents in key jurisdictions that will last until 2026 and in some cases until 2032.
[33] SUDA is, however, still using the NovaDel technology on a number of projects - sildenafil for PAH, ondansetron, ZolpiMist and sumatriptan will be covered by both.

partnering deals in 2016 and 2017, after around three years of work on its drug reformulation technology. We think that with subsequent deals the stock can significantly re-rate, particularly as the company does more work on marketing the story to the investment community.

# Valuing SUDA

**We value SUDA at 8 cents per share base case and 25 cents per share optimistic case.** Our target price of 17 cents per share sits at around the mid-point of our valuation range. The slight reduction in our valuation range largely reflects the change in the Australian ten-year bond rate from 2.6% in August 2017 to 2.9% today, offset by the value we've added for Anagrelide.

*Table 1: Our valuation of SUDA*

| | Base case | Optimistic case |
|---|---|---|
| Zolpimist (Teva) (A$m) | 33.2 | 102.7 |
| Zolpimist (Eddingpharm) (A$m) | 16.0 | 52.4 |
| Zolpimist (EU) (A$m) | 14.8 | 43.3 |
| Ondansetron (A$m) | 2.5 | 11.3 |
| Sumitriptan (A$m) | 3.1 | 8.1 |
| Sildenafil - ED (A$m) | 6.9 | 19.1 |
| Sildenafil - PAH (A$m) | 4.8 | 12.2 |
| Midazolam (A$m) | 1.7 | 7.0 |
| Pfizer (A$m) | 2.4 | 6.2 |
| ArTiMist (A$m) | 18.8 | 49.6 |
| Anagrelide (A$m) | 2.0 | 8.6 |
| Westcoast ($Am) | 1.8 | 4.3 |
| Total programme value | 108.1 | 324.8 |
| Value of tax losses | 12.7 | 12.7 |
| Corporate overhead | -15.7 | -15.7 |
| Cash now (A$m) | 0.6 | 0.6 |
| Cash to be raised (A$m) | 0.0 | 0.0 |
| Option exercises (A$m) | 6.2 | 6.2 |
| Total value (A$m) | 112.0 | 328.7 |
| Total diluted shares (million) | 1,339.3 | 1,339.3 |
| Value per share | $0.084 | $0.245 |
| Valuation midpoint | $0.165 | |
| Share price now (A$ per share) | $0.014 | |
| Upside to midpoint | 1075.0% | |

**Our basic valuation approach**

We valued SUDA using a probability-weighted DCF approach. For each indication modelled, we used 15 years of commercial exclusivity for the products followed by a negative 3-5% pa terminal growth rate. Our WACC was 13.4%, a 'High' risk rating[34].

**Products valued**

- **Core products.** We assumed payoffs from ArTiMist and the ZolpiMist transactions with Teva and Eddingpharm[35], as well as a future partnership for EU rights to the product.
- **'Platform' products**. In addition to the above we assumed payoffs for sildenafil (erectile dysfunction and PAH), ondansetron (nausea), sumatriptan (migraine), midazolam (epilepsy and anxiety), the Pfizer Consumer Health collaboration and Anagrlide (cancer) but discounted the future payoffs from these products on the assumption that not all of them would proceed. We conservatively used the number one in five as the projects in this category that would succeed. That discount merely reflects the fact that NovaDel Pharma was not able to survive as an independent company, despite good clinical data for most of that company's life and its ability to develop products that gained regulatory approval. We see the potential for our platform discount to be improved over time, as more clinical, and particularly commercial, success is registered by SUDA. Moreover, in our thinking, future announced partnership arrangements would move these products into the 'core'.

**Commercial outcomes**

We lay out our assumptions for the valued indications in the Figures below. We believe our assumptions on peak sales are justified by the historic size of the markets for the relevant product.

**Risk weightings for clinical and regulatory**

For each indication, we assigned a 90% probability of success, to account for the potential for rejection of the company's filings for marketing approval[36].

**Further capital**

We assume that after the April 2017 placement at 2 cents per share no further capital needs to be raised but that revenue from partnering deals and collaborations can take the company forward from here.

**Westcoast**

We conducted a DCF valuation of Westcoast assuming moderate growth assumptions for that business, which we assumed stayed profitable from here.

[34] For a relevant discount rate, we use WACCs of between 11.2% and 15.6% depending on the risk for Life Science companies. This is derived from a RFR of 2.9%; a MRP of 7.5%-11.5% (7.5% for 'medium risk' companies, 9.5% for 'high risk' companies and 11.5% for 'speculative' companies; and an ungeared beta of 1.1. We regard Life Science companies with existing businesses, or who have enough capital to reach the market with their products, as 'Medium' risk. Companies that have small revenue streams from marketed products, or have optioned their products to larger partners, but that are still potentially in need of capital are 'High' risk. Everything else is 'Speculative'.
[35] Here our royalty estimates reflect the combination of supplying the product as well as receiving royalties on net sales less the supply price.
[36] See Clin Pharmacol Ther. 2010 Mar;87(3):272-7. Epub 2010 Feb 3.

# Valuation – Project parameters

*Figure 1: Teva project parameters*

| | Base case | Optimistic case |
|---|---|---|
| SUD investment required (AUDm) | 0 | 0 |
| License date | 2018 | 2018 |
| License upfront (USDm) | 0.30 | 0.30 |
| License milestones (USDm) | 1.75 | 1.75 |
| Royalty rate | 20.0% | 30.0% |
| Earliest approval | 2020 | 2019 |
| Peak sales (USDm) | 100 | 160 |

*Figure 2: Eddingpharm project parameters*

| | Base case | Optimistic case |
|---|---|---|
| SUD investment required (AUDm) | 0 | 0 |
| License date | 2018 | 2018 |
| License upfront (USDm) | 0.30 | 0.30 |
| License milestones (USDm) | 0.20 | 0.20 |
| Royalty rate | 15.0% | 20.0% |
| Earliest approval | 2020 | 2019 |
| Peak sales (USDm) | 60 | 120 |

*Figure 3: ZolpiMist EU project parameters*

| | Base case | Optimistic case |
|---|---|---|
| SUD investment required (AUDm) | 0 | 0 |
| License date | 2020 | 2019 |
| License upfront (USDm) | 3.00 | 5.00 |
| License milestones (USDm) | 5.00 | 10.00 |
| Royalty rate | 12.0% | 20.0% |
| Earliest approval | 2023 | 2022 |
| Peak sales (USDm) | 80 | 110 |

*Figure 4: Ondansetron project parameters*

| | Base case | Optimistic case |
|---|---|---|
| SUD investment required (AUDm) | 2 | 1 |
| License date | 2022 | 2021 |
| License upfront (USDm) | 1.00 | 2.00 |
| License milestones (USDm) | 3.00 | 5.00 |
| Royalty rate | 20.0% | 30.0% |
| Earliest approval | 2023 | 2022 |
| Peak sales (USDm) | 60 | 120 |

*Figure 5: Sumatriptan project parameters*

| | Base case | Optimistic case |
|---|---|---|
| SUD investment required (AUDm) | 2 | 1 |
| License date | 2022 | 2021 |
| License upfront (USDm) | 2.00 | 3.00 |
| License milestones (USDm) | 5.00 | 10.00 |
| Royalty rate | 20.0% | 30.0% |
| Earliest approval | 2024 | 2023 |
| Peak sales (USDm) | 70 | 90 |

*Figure 6: Sildenafil ED project parameters*

| | Base case | Optimistic case |
|---|---|---|
| SUD investment required (AUDm) | 2 | 1 |
| License date | 2020 | 2019 |
| License upfront (USDm) | 2.00 | 3.00 |
| License milestones (USDm) | 5.00 | 10.00 |
| Royalty rate | 20.0% | 30.0% |
| Earliest approval | 2021 | 2020 |
| Peak sales (USDm) | 110 | 150 |

*Figure 7: Sildenafil PAH project parameters*

| | Base case | Optimistic case |
|---|---|---|
| SUD investment required (AUDm) | 2 | 1 |
| License date | 2020 | 2019 |
| License upfront (USDm) | 2.00 | 3.00 |
| License milestones (USDm) | 5.00 | 10.00 |
| Royalty rate | 20.0% | 30.0% |
| Earliest approval | 2021 | 2020 |
| Peak sales (USDm) | 70 | 90 |

*Figure 8: Midazolam project parameters*

| | Base case | Optimistic case |
|---|---|---|
| SUD investment required (AUDm) | 2 | 1 |
| License date | 2020 | 2019 |
| License upfront (USDm) | 2.00 | 3.00 |
| License milestones (USDm) | 5.00 | 10.00 |
| Royalty rate | 20.0% | 30.0% |
| Earliest approval | 2024 | 2023 |
| Peak sales (USDm) | 40 | 80 |

*Figure 9: Pfizer project parameters*

| | Base case | Optimistic case |
|---|---|---|
| SUD investment required (AUDm) | 0 | 0 |
| License date | 2020 | 2019 |
| License upfront (USDm) | 2.00 | 3.00 |
| License milestones (USDm) | 5.00 | 10.00 |
| Royalty rate | 20.0% | 30.0% |
| Earliest approval | 2021 | 2020 |
| Peak sales (USDm) | 30 | 40 |

*Figure 10: ArtiMist project parameters*

| | Base case | Optimistic case |
|---|---|---|
| SUD investment required (AUDm) | 0 | 0 |
| License date | 2021 | 2020 |
| License upfront (USDm) | 2.00 | 3.00 |
| License milestones (USDm) | 5.00 | 10.00 |
| Royalty rate | 20.0% | 30.0% |
| Earliest approval | 2021 | 2020 |
| Peak sales (USDm) | 60 | 80 |

*Figure 11: Anagrelide project parameters*

| | Base case | Optimistic case |
|---|---|---|
| SUD investment required (AUDm) | 2 | 1 |
| License date | 2021 | 2020 |
| License upfront (USDm) | 2.00 | 3.00 |
| License milestones (USDm) | 5.00 | 10.00 |
| Royalty rate | 20.0% | 30.0% |
| Earliest approval | 2022 | 2021 |
| Peak sales (USDm) | 30 | 70 |

# Risks related to SUDA

**Risks specific to SUDA**. We see five major risks for SUDA as a company and as a listed stock:

- **Commercial**. The level of competition in the generic markets in which SUDA competes may prove too high for SUDA's products to enjoy premium pricing.
- **Technological**. There is the risk that the Hydrotrope platform may require more work to develop products that are reliably better than tablets.
- **Funding**. More capital will likely be needed to fully build out the SUDA platform from the Hydrotrope platform.
- **Regulatory**. There is a risk that a tightening of America's 505(b)(2) pathway may mean more data is required before SUDA can gain US approval for its products.
- **Legal risk**. There is the risk that a legal matter in Germany related to ArTiMist, about which SUDA made announcements on 3 June 2016 and 27 February 2017, may result in a judgement against the company.

**Risks related to pre-revenue Life Science companies in general**

- The stocks of biotechnology and medical device companies without revenue streams from product sales or ongoing service revenue should always be regarded as speculative in character.
- Since most biotechnology and medical device companies listed on the Australian Securities Exchange fit this description, the term 'speculative' can reasonably be applied to the entire sector.
- The fact that the intellectual property base of most biotechnology and medical device lies in science not generally regarded as accessible to the layman adds further to the riskiness with which the sector ought to be regarded.

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