ANNOUNCEMENT

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ASX Market Announcements
ASX Limited
Level 4
North Tower, Rialto
525 Collins Street
Melbourne VIC 3000

RE: EDISON RESEARCH INITIATES COVERAGE OF ADHERIUM

Melbourne, Australia, 21 April 2016, Edison Investment Research has initiated coverage* of Adherium Limited (ASX: ADR), a global leader in digital health technologies addressing sub-optimal medication use in chronic disease.

- Adherium is well positioned with approved devices on the market
- Existing commercial relationship with AstraZeneca and strong relationships with other pharma companies positioning the Company for revenue growth
- Strong evidence Smartinhaler™ improves adherence
- Market forces likely to drive strong uptake of the Smartinhaler™ platform
- Valuation: A$188m or $1.33 per share

The full report entitled *Smartinhaler improves medication adherence* is attached or can be read by clicking
http://www.edisoninvestmentresearch.com/research/report/adherium/full

An interview with Garth Sutherland, Group CEO of Adherium, can be viewed at
http://www.edisoninvestmentresearch.com/edison-tv/clip/executive-interview-adherium

Yours faithfully

Bronwyn Le Grice
Joint Company Secretary

**The report is sponsored research by Adherium which does not expressly or by implication warrant or assume any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, assumption, data, forecast, estimate or projection contained in the report, and the dissemination of the report does not necessarily constitute or imply the Company's endorsement or recommendation.*

ASX: ADR

ABN
24 605 352 510

Company Overview
Adherium is a global leader in digital health technologies which address sub optimal medication use in chronic disease.

Directors
Dr J Doug Wilson (Chair)
Mr Garth Sutherland (Group CEO)
Prof John Mills
Mr Jeremy Curnock Cook
Mr Bruce McHarrie
Mr Bryan Mogridge
Dr Bill Hunter

Joint Company Secretaries
Mr Rob Turnbull
Ms Bronwyn Le Grice

Registered Office
BDO
L14, 140 William Street
Melbourne

NZ Office
Level 2, 204 Quay Street
Auckland 1010
New Zealand

Investor Relations Contact
Ms Bronwyn Le Grice
+61 424 862 600

Email
investors@adherium.com

Websites
www.smartinhaler.com
www.adherium.com

EDISON

Adherium

Initiation of coverage

Smartinhaler improves medication adherence

Healthcare equipment & services

Adherium has developed the market-leading Smartinhaler platform that monitors usage of inhaled asthma and COPD medications and provides reminders and feedback that improve patient adherence. With an existing commercial relationship with AstraZeneca and strong relationships with other pharma companies and key opinion leaders through sales for clinical trials, Adherium is positioned for strong revenue growth. We value Adherium at A$188m, or A$1.31 per share.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
03/14	0.6	(2.1)	(3.2)	0.0	N/A	N/A
03/15	3.1	(1.3)	(1.9)	0.0	N/A	N/A
06/16e**	3.2	(6.1)	(4.8)	0.0	N/A	N/A
06/17e	7.3	(9.7)	(6.8)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. **FY16 is 15 months to June 2016.

Well positioned with approved devices on the market

Adherium is well positioned with approved Smartinhaler devices targeting the US$23bn asthma and COPD markets, a 10-year supply agreement with key customer AstraZeneca, and ongoing relationships with other respiratory pharma companies and key opinion leaders through supply of the platform for clinical trials. Although there are a small number of companies developing competing devices, none appear to have significant advantages over Adherium's platform, and none can match its 14 years of development experience or clinical evidence of efficacy.

Strong evidence Smartinhaler improves adherence

Adherium has assembled strong evidence from independent clinical trials that reminders and feedback from the Smartinhaler platform improve patient adherence to prescribed maintenance asthma medications, with adherence increased by 180% in a study of children with asthma, and by 59% in a study in adults; patients receiving reminders and feedback also had fewer disease exacerbations.

Market forces likely to drive strong uptake

We forecast clip-on Smartinhalers sold to AstraZeneca to be used by 30% of Symbicort patients in Europe and the US by 2020, with a Symbicort inhaler containing embedded Smartinhaler technology launched in 2020 and used by 100% of patients by 2023. We also forecast hospitals and managed care to supply Smartinhaler devices to 230,000 (1%) of asthma patients in the US and 115,000 in other markets by 2021, driven by anticipated improvements in patient outcomes.

Valuation: A$188m, A$1.31 per share

Our DCF model, based on the uptake assumptions listed above, values Adherium at A$188m, which is equal to A$1.31/share (undiluted) and A$1.26/share after diluting for the 7.0m options on issue (exercise price 8-67c). Adherium had A$30.8m cash on 31 December 2015 and has outlined a 24-month programme of intensive growth and investment that would see the funds expended by late 2017. We forecast revenue growth to extend this cash runway to break-even point in FY19.

20 April 2016

Price	**A$0.51**
Market cap	**A$73m**
	US$0.72/A$
Net cash (A$m) as at 31 December 2015	30.8
Shares in issue	143.9m
Free float	75%
Code	ADR
Primary exchange	ASX
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	4.8	(15.6)	N/A
Rel (local)	5.2	(10.5)	N/A
52-week high/low	A$0.72	A$0.47	

Business description

Adherium is a digital health company developing technologies that address suboptimal medication use and remote patient management in chronic diseases. Clinical evidence shows that its Smartinhaler substantially increases adherence and reduces severe exacerbations in asthma.

Next events

AZN rollout of Turbu+ in selected countries	H116
Additional major commercialisation agreements	Next 18 months

Analysts

Dennis Hulme +61 (0)2 9258 1161

Beth Senko +1 646 653 7033

healthcare@edisongroup.com

Edison profile page

Investment summary

Company description: Smartinhaler platform poised for growth

Adherium is a digital health company developing technologies that address suboptimal medication use and remote patient management in chronic diseases. Clinical evidence shows that its Smartinhaler platform substantially increases adherence and reduce exacerbations in adults and children with asthma. Adherium aims to sell its devices to international pharmaceutical and medical technology companies, which provide them to patients via their own distribution networks. Adherium and AstraZeneca (AZN) entered a 10-year commercial product development and supply agreement in July 2015. The initial Product Supply Schedule under the agreement covers Adherium's Turbu+ (SmartTurbo) devices tailored to AZN's turbuhaler dry powder inhaler sold with its Symbicort and Pulmicort drugs outside the US. AZN is expected to begin expanding the commercial rollout of the Turbu+ programme in selected countries in H1 of CY16. Adherium listed on the ASX in August 2015, raising A$35m at A$0.50/share, including a US$3m investment by AZN. Prior to listing it acquired 100% of Adherium (NZ) Limited, which was founded in 2001 by Adherium CEO Garth Sutherland.

Valuation: A$188m based on our DCF model

We value Adherium at A$188m based on a risk-adjusted DCF model, which includes our forecast costs and revenue streams from sales of devices and data management services. We assume that by 2020 clip-on Smartinhaler devices will be used by 30% of Symbicort patients in the US (risked to 90%) Europe and Japan, and that by 2021 the technology will be embedded in AZN's drug delivery inhalers, lifting uptake to 100% of Symbicort patients by 2023 (risked to 75%). We also forecast that by 2021 hospitals, managed care, etc will supply the Smartinhaler platform to 230,000 asthma patients (1% of all patients) in the US and 115,000 patients in ex US markets to improve patient outcomes. Our valuation is equal to A$1.31 per share (undiluted) and A$1.26 per share after diluting for the 7.0m options on issue (exercise price 8-67c).

Financials: Funds for intensive growth & investment programme

In FY15 the company sold 34,000 devices for use in clinical trials at an average of A$85 per device, generating sales of A$2.9m at a gross profit margin of 53% and a net loss of A$1.3m. In the nine months to December 2015 it sold 48,000 devices at an average of A$33 each. The average price was much lower than in FY15 because 52% of devices sold so far in FY16 were low-cost, reminder-only devices without data connectivity (not expected to be a significant product line in future periods), as well commencing commercial supply at volume-based pricing. Net loss in the period was A$3.8m on total sales of A$1.6m. Adherium had A$30.8m cash at 31 December 2015. In the IPO prospectus, Adherium projects operating funds usage of A$29.7m over the 2 year period to late 2017 in an intensive growth and investment program. We forecast Adherium profitability in FY19.

Sensitivities: Embedded Smartinhaler line in development

Adherium's business is subject to the usual risks associated with any emerging technology: slower than expected commercialisation timelines, lower rates of adoption, technology leap-frogging, patent litigation, and regulatory and commercial risks. While the company is at an early stage of commercialisation, its clinical trials business has a track record of revenue growth and positive gross profit margins. There is little detail available regarding AZN's plans for the rollout of the SmartTurbo devices for use with its Turbuhaler inhaler. The price that Adherium will receive for sales to AZN is unknown and there is no track record of patient uptake rates, so we rely on our own assumptions for these key factors. The Product Supply Schedule under the agreement with AZN does not yet include a Smartinhaler device suitable for the US market, although our analysis shows that AZN has a strong financial incentive to expand the programme to the US market.

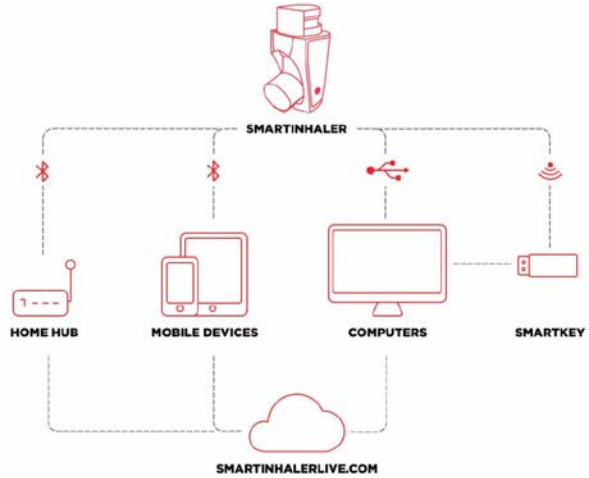
Smartinhaler improves adherence & health outcomes

Adherium develops, manufactures and supplies digital health technologies that address suboptimal medicine use in chronic disease. The company's first product range is its Smartinhaler platform that clips on to a wide range of prescription inhalers used in the treatment of respiratory diseases such as asthma and COPD. Smartinhaler devices record inhaler use and provide audio and visual reminders if the patient has missed a dose of the prescribed drug. The date and time of inhaler use is transmitted to a mobile device or computer network in the patient's home where the patient can view it in an app, and onto Adherium cloud-based servers where it can be accessed by the patient's physician or medical provider via a proprietary web portal (Exhibit 1), for the first time giving physicians accurate information about patients' inhaler usage patterns.

Asthma and COPD represent enormous target markets dominated by inhaled therapies. Market research group Datamonitor estimated that in 2015 in the US, Japan and five major EU markets asthma and COPD drug sales totalled US$14.5bn and US$8.4bn respectively. The US Centers for Disease Control estimate there are 25.5m asthmatics and 6.8m people with COPD in the US.

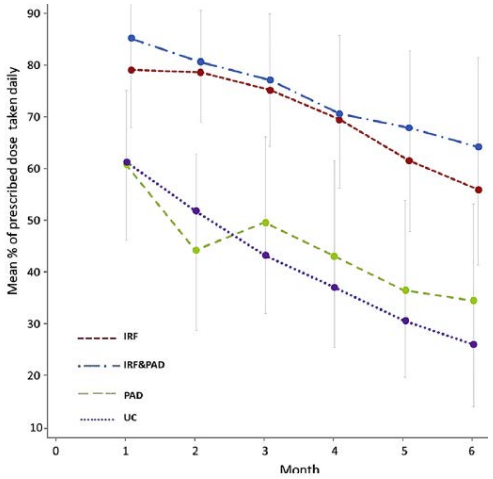
Adherium's current portfolio of Smartinhaler devices clip on to the inhaler, with different devices tailored for each pharma company's proprietary dry powder or pressurised metered dose inhaler. This allows pharma companies to supply devices to patients and be confident that they can only be used with that company's product. Adherium is developing a miniaturised device that can be integrated within the inhaler during the manufacturing process. We expect embedded devices to be a key part of the longer-term growth of the company and assume a market launch in 2020.

Exhibit 1: Smartinhaler data is transferred to patient devices and to physicians via the cloud



Source: Adherium investor presentation January 2015

Exhibit 2: Improved adherence in asthma patients is maintained for at least six months



Source: Foster et al 2014. Note: The top 2 lines show adherence in groups receiving inhaler reminders and feedback (IRF). PAD= Personalised adherence discussions; UC= Usual active care.

Poor adherence to ICS leads to poor outcomes in asthma

Inhaled corticosteroids (ICS), either as a single agent or in combination with long-acting beta agonist reliever medication (ICS/LABA), are the mainstay for long-term control of asthma. These "preventer" or maintenance medications reduce airway inflammation and prevent asthma symptoms, and minimise flare-ups or exacerbations. However adherence to these medications is often poor, with low adherence associated with excessive health care costs and an increased risk of emergency room visits and mortality (Howard et al 2014). For example, a study of children with asthma by Lasmar et al (2009) reported adherence rates of 84-90% in children whose asthma was well controlled and adherence rates of 34-48% in patients with poorly controlled asthma.

Independent clinical studies confirm adherence improved

To our knowledge Adherium's Smartinhaler platform is the only technology for which independent clinical studies published in scientific journals demonstrate that the feedback and reminders from the device lead to improved adherence to maintenance asthma medications. Two completed randomised controlled trials by Chan et al and Foster et al found that patients receiving reminders and feedback showed significantly better adherence to ICS than controls, with increases of between 59% and 180% (Exhibits 2 and 3). In addition, an interim analysis of an ongoing trial in children in Sheffield, England by Morton et al reported that adherence was 144% higher in the intervention group, although no statistical testing has been done at this stage (Exhibit 3).

Importantly, the improved adherence is long lasting. For example, at the end of the six-month study described by Foster et al the adherence of patients receiving inhaler reminders and feedback was double that in the control groups (~60% vs ~30%, Exhibit 2).

Exhibit 3: Independent clinical studies demonstrate that Smartinhalers improve adherence

Trial	Design	Outcome
Chan et al 2015; Auckland	Randomised study in children aged six to 15 years who attended hospital emergency department with an asthma exacerbation. Intervention group had adherence monitored for six months with Smartinhaler device and received feedback and reminder alarms. Control group had adherence monitored but did not receive feedback or alarms. N=220.	Median adherence 84% in the intervention group and 30% in controls (p<0.0001); adherence improved by 180%. No difference in the primary clinical endpoint, the number of days off school. Among the secondary endpoints, the intervention group showed a significantly greater improvement in asthma morbidity score (2.0 vs 1.2 point improvement, p=0.008), and significantly fewer days of reliever medication use (9.5% vs 32.8%, p=0.002) and fewer parent-reported exacerbations (p=0.015). There was no significant difference in lung function or hospital visits for asthma.
Foster et al 2014; Sydney	Cluster randomised 2x2 factorial controlled trial comparing inhaler reminders and feedback (IRF) using an Adherium device vs personalised adherence discussions with GPs vs usual care alone in adult patients. N=143 patients and 43 GPs.	Average adherence significantly higher in IRF group than non-IRF groups (73% vs 46%; p<0.0001; improved by 59%). No significant effect on asthma control scores, the primary clinical endpoint. Severe exacerbations were experienced by 11% of IRF patients vs 28% in non-IRF groups (61% reduction, p=0.013 unadjusted; p=0.06 after *post hoc* adjustment for exacerbation history). No significant difference in other secondary endpoints, ie lung function, anxiety, depression, quality of life.
Morton et al 2015; Sheffield	Randomised study in children with asthma in the UK prescribed ICS. Intervention group had adherence monitored for 12 months with Smartinhaler and received feedback and reminder alarms. Control group did not receive feedback or alarms. N=90; 25 have already completed all study visits.	Interim results after 60% of follow-up visits completed: Adherence 144% higher in the intervention arm than control (83% vs 34%); number of oral steroid courses 37% lower (1.7 vs 2.7 per 12 months), indicating fewer severe exacerbations in the intervention arm; lung function at 12 months as measured by FEV1 15% higher (100% vs 87%). No statistical testing has been done on this interim data.

Source: Edison Investment Research. Note: Adherence defined as proportion of preventer doses taken relative to doses prescribed.

The trials in Exhibit 3 provide statistical proof that Smartinhaler reminders and feedback improve medication adherence, while the evidence that this improved adherence leads to better clinical outcomes is still building. The trials summarised in Exhibit 3 paint a consistent picture of fewer asthma exacerbations in patients receiving reminders, including a 61% reduction of severe exacerbation reported by Foster et al. Reducing exacerbations is an important clinical benefit, and it was somewhat surprising to see significant improvements in these relatively small trials. However, we note that neither the trial of Foster nor Chan showed significant effects on the primary endpoints of asthma control scores or days off school, respectively, possibly due to relatively small trial sizes.

A separate trial by Pilcher et al showed that SmartTurbo devices attached to Symbicort turbuhaler dry powder inhalers were 99.9% accurate in recording inhaler actuations over a three-month period.

Empowering physicians with accurate inhaler usage data

The Smartinhaler platform for the first time gives physicians accurate information on the inhaler usage patterns of patients who are prescribed ICS medications. This is a big improvement on the current situation where physicians have to interpret patient feedback such as "yes, I take the medication most of the time".

We believe that physicians who are given access to accurate information about medication usage patterns will feel that they are better able to manage their patients' health. This would be particularly relevant for patients whose asthma is poorly controlled. We expect this sense of empowerment to build strong brand loyalty among prescribing physicians.

Inhaled respiratory drugs an enormous target market

Eight of the 10 highest-selling respiratory drugs in the US are inhaled medications, and four are ICS drugs, where we expect improved adherence to bring the greatest healthcare benefits. The ICS drugs include the top seller, GSK's Advair (2015 global sales of US$5.6bn), and the third-highest seller, AZN's Symbicort (2015 global sales US$3.4bn). Exhibit 4 shows the top ICS drugs in the US market. AZN's second biggest respiratory drug, Pulmicort, had global sales of US$1,014m in 2015.

Exhibit 4: Top inhaled corticosteroid drugs, ranked by 2015 US sales

Product	Manufacturer	US B'berg sales* (US$m)	TRx prescriptions (000s)	B'berg list price (US$)	Est. Pharma net price (US$)	Pharma global sales** (US$m)	Pharma US sales (US$m)	Pharma net US yield (%)	Drug class***
Advair Diskus	GlaxoSmithKline	5,970	13,230	451	216	5,632	2,853	48%	ICS/LABA
Fluticasone	generic	3,410	40,350	85					ICS
Symbicort	AstraZeneca	3,146	8,536	369	178	3,394	1,520	48%	ICS/LABA
Flovent	GlaxoSmithKline	1,468	5,797	253	100	953	580	39%	ICS
Budesonide	generic	1,130	2,480	456					ICS
Qvar	Teva	993	4,700	211					ICS
Dulera	Merck	868	2,420	359					ICS/LABA
Pulmicort	AstraZeneca	400	1,066	375	188	1,014	200	50%	ICS

Source: Bloomberg (B'Berg), company reports, Edison Investment Research. Note: *Bloomberg sales do not account for discounts and rebates. **Net sales reported by pharma companies. ***Abbreviations: ICS, inhaled corticosteroids; LABA, long-acting β2-agonist

Smartinhaler provides a tool to fight off generic competition

The two top-selling ICS drugs Advair and Symbicort are already facing generic competition in some markets in Europe, and both are expected to face generic competition in the US and Japan by 2019 (Exhibit 5). The generic competition is likely to be in the form of branded generics that cannot be directly substituted when the original brand is prescribed. Teva's DuoResp Spiromax, which is an analogue of Symbicort that is sold in selected countries in Europe, fits into this category.

We expect patients to be slow to switch to generics due to hesitation to switch to new inhalation devices and concerns over the dose and efficacy equivalence between the branded and generic products. AZN commented in its FY15 results presentation that it is maintaining over 90% share of prescriptions in the markets in Europe where it is facing competition from generic analogues.

In this environment manufacturers are searching for ways to differentiate their branded drugs from generic analogues and build brand loyalty among prescribers and patients. Electronic monitoring devices (EMD) such as the Smartinhaler platform seem an ideal way to achieve these goals.

Embedding the Smartinhaler technology into the drug delivery device would take this strategy to the next level, and would offer a potential way to extent market exclusivity. In this regard we note with interest that Adherium is undertaking a number of projects driven by AZN, including preparations for major clinical studies in international markets. We suspect that this could refer to a study of a drug delivery device that contains embedded Smartinhaler technology. We await further details of the proposed clinical trials to see whether our interpretation is correct.

Exhibit 5: Forecast Advair and Symbicort generic launch dates

Brand	US	EU	Japan
Advair	Q316	Launched	Q319
Symbicort	Q319	Launched	Q319

Source: DataMonitor Healthcare: Asthma Forecast report, December 2015, Edison Investment Research

We see three main market opportunities for Adherium

1. Pharma and med-tech companies supply Smartinhaler to patients

Adherium's main path to market is selling the Smartinhaler platform to pharma and medical device companies, which provide the device and app to patients via their own distribution channels. Adherium has already entered a non-exclusive commercial supply agreement with AZN, which

markets the third biggest-selling respiratory drug, Symbicort (2015 global sales US$3.4bn), a combination maintenance and reliever medication (ICS/LABA) and the ICS drug Pulmicort.

2. Sales to hospitals and managed care organisations

Supplying Smartinhalers to asthma and COPD patients should allow hospitals, managed care organisations and other healthcare systems to reduce overall healthcare costs and at the same time improve health outcomes.

3. Devices sold for use in clinical trials

The Smartinhaler platform can collect accurate data about inhaler use in clinical trials. Adherium is providing Smartinhaler devices, software and data management to 31 clinical projects and programmes around the world, which will eventually involve more than 89,000 devices. The trials are an important way of building relationships with pharma customers and are an important step towards gaining additional commercial supply contracts with pharma and med-tech companies.

AstraZeneca deal a big step towards commercial success

In July 2015 Adherium entered a 10-year global Master Supply and Development agreement with AZN, including an associated Quality Assurance Agreement. The initial Product Supply Schedule covers the SmartTurbo device for use with AZN's turbuhaler dry powder inhaler. The turbuhaler device is not approved in the US where Symbicort is sold in a pressurised metered dose inhaler (pMDI). We expect AZN-driven development projects that are currently underway to lead to a Smartinhaler suitable for AZN products in the US market being added to the supply schedule.

ROI for AstraZeneca in the US looks compelling

Exhibits 6 and 7 illustrate the potential near-term return on investment (ROI) that could flow to AZN from providing Smartinhalers to Symbicort patients in the US, from either improved adherence or increased market share. In this illustration we assume that each device costs AZN US$25, in line with our base-case valuation assumptions, and that AZN pays a further US$10 for distribution and setup assistance ("onboarding"). We assume medication adherence of 40% in estimating Symbicort patient numbers, based on the average 37% adherence in the control arms of the Smartinhaler studies in Exhibit 3 and the range of 20-73% reported in a systematic review[1] of asthma studies.

The ROI for AZN would be positive even for the smallest 5% relative improvement in adherence and after allowing US$10 per device for onboarding costs. This provides a strong incentive for AZN to extend its agreement with Adherium to include devices appropriate for the US market. It also provides a strong incentive for other pharma companies to adopt the Smartinhaler platform.

Exhibit 6: Estimated AZN ROI from additional US sales due to improved adherence if 30% of existing Symbicort patients use Smartinhaler

US patients using Symbicort[1] (m)	Smartinhaler uptake	Patients using Smartinhaler (m)	Devices @ 1 per patient per year (m)	Relative improvement in adherence[2]	Symbicort net selling price (US$)[3]	Smartinhaler device cost @ US$25 each (US$m)	Extra US Symbicort sales (US$m)	Extra AZ* gross profit[4] (US$m)	AZ ROI – no on-boarding costs	AZ ROI if onboarding costs US$10
1.78	30%	0.53	0.53	5%	178	13.3	22.8	5.5	41%	1%
1.78	30%	0.53	0.53	10%	178	13.3	45.6	24.3	182%	102%
1.78	30%	0.53	0.53	15%	178	13.3	68.4	43.2	324%	203%
1.78	30%	0.53	0.53	20%	178	13.3	91.2	62.0	465%	303%

Source: Edison Investment Research. Notes: [1]Calculated from 8.5m Symbicort prescriptions in 2015 assuming 40% adherence (4.8 prescriptions per patient per year); [2]A 10% relative improvement would see adherence increase from 40% to 44%; [3]Calculated by dividing US Symbicort revenue from AZN's 2015 annual accounts by the Bloomberg TRx prescriptions; [4]Calculated by applying AZN's 2015 core gross margin of 82.6% to the additional US Symbicort revenue. *AZ = AstraZeneca.

1 Cochrane et al 2000; Chest 117(2):542-50.

Exhibit 7: Estimated AZ ROI from additional US sales due to increased Symbicort market share

US patients using Symbicort (m)	Smartinhaler uptake	Patients using Smartinhaler (m)	Devices @ 1 per year	Relative improvement in market share	Symbicort net selling price	Smartinhaler device cost @ US$25 each (US$m)	Extra US sales (US$m)	Extra AZ* gross profit[4] (US$m)	AZ ROI – no on-boarding costs	AZ ROI if onboarding costs US$10
1.78	30%	0.53	0.53	2.5%	178	13.3	37.8	17.9	68%	30%
1.78	30%	0.53	0.53	5.0%	178	13.3	75.6	49.1	236%	160%
1.78	30%	0.53	0.53	7.5%	178	13.3	113.3	80.3	404%	290%
1.78	30%	0.53	0.53	10.0%	178	13.3	151.1	111.5	572%	420%

Source: Edison Investment Research. See notes to Exhibit 6 for explanations of terms

Commercial strategy

Adherium has indicated that it expects to sign two new commercial agreements over the next 18 months, which could potentially be with any of pharma, med-tech or managed care organisations. While we believe that this objective is achievable, at this stage we do not include additional pharma or med-tech agreements in our forecasts.

Adherium is engaged in active AZN-driven projects spanning product development, supply chain management, regulatory and quality requirements, clinical operations and product internationalisation. We would expect this to include Smartinhaler devices tailored to AZN inhalers sold in the US market, which we risk-adjust to 90% in our forecasts.

We expect Adherium to succeed in developing miniaturised smart inhaler technology that can be embedded into the drug delivery inhaler ("Smartinhaler inside"). We assume that these new drug delivery devices will require some clinical trials before they receive regulatory approval. The trials could be as simple as demonstrating that drug delivery is equivalent to existing devices, or alternatively could be designed to demonstrate efficacy in disease control. We conservatively assume the latter and allow for a commercial launch in 2020 (we risk-adjust embedded inhaler revenues to 75% in our forecasts). We would expect Adherium to supply the miniaturised Smartinhaler integrated circuit chip to AZN for use in the manufacture of the inhalation device.

A wealth of data

Adherium receives significant quantities of data daily from Smartinhaler devices that are in use, and it is establishing a dedicated data team to mine and extract value from data. Existing commercial agreements allow the company to earn additional revenue through value-added reporting. At this stage the revenue opportunity from data analysis is difficult to quantify, so we have not included it in our revenue forecasts or valuation model.

Competitive landscape

Adherium has the benefit of 14 years of experience in developing and trialling Smartinhaler devices. A number of competitors have entered the field more recently and we briefly describe the four main competitors below. None of the competitors can match the independent clinical trials showing the efficacy of the Adherium device in improving adherence.

Exhibit 8: Companies with competing smart inhaler technologies

Company	Description
Propeller Health	In December 2015 Propeller Health entered a non-exclusive development agreement and R&D collaboration with GSK to develop and manufacture a custom sensor for GSK's Ellipta dry powder inhaler for use in clinical studies in asthma and COPD. Propeller obtained US FDA 510(k) clearance in 2015 to market its platform in association with medications using GlaxoSmithKline's Diskus dry powder inhaler (DPI) device and using Boehringer Ingelheim's Respimat soft mist inhaler.
Cohero Health	Cohero offers a smart inhaler plus a mobile spirometer, which measures patients' lung function. In January 2016 Cohero Health announced a joint respiratory disease management offering in conjunction with ProCare Rx, a US pharmacy benefit manager (PBM).
Gecko Health Innovations	Smart inhaler company Gecko Health Innovations, which has developed a smart inhaler and associated software platform, was acquired by Teva, the world's largest generics drug producer, in September 2015. Deal terms were not disclosed.
Qualcomm Life	In January 2016 Novartis entered a collaboration with Qualcomm Life to develop a new version of Novartis's Breezhaler, which will incorporate smart inhaler attributes into the inhaler. Novartis plans to launch the new connected Breezhaler in 2019 following regulatory approval.

Source: Edison Investment Research

Three of the four competitors have developed EMDs that can clip onto several different brands of inhalers. In contrast, Adherium's devices are tailored to a specific drug delivery device. This gives Adherium an advantage in dealing with pharma companies, which know that the Adherium device can only be used with that company's drug. Exhibit 8 briefly describes the four main competitors.

At the time of its acquisition by Teva, Gecko was marketing the CareTRx cap which attaches to the top of pMDI inhalers and monitors inhaler use. The CareTRx cap is not suited for use with for dry powder inhaler devices such as the Symbicort turbuhaler, which is marketed outside the US.

Adherium has approvals in place

Adherium has regulatory approvals in place in the US, EU, China, Australia and New Zealand for the devices that are appropriate for those markets. It has only sought approvals in the jurisdictions that are relevant for each device, as some pharma companies sell their drugs in different delivery devices in different markets. We note that Adherium has US FDA 510(k) approval for a SmartTouch device that is compatible with the metered dose inhaler used with AZN's Symbicort in the US, but we assume that a modified device is being developed for that market.

Exhibit 9: Regulatory approvals for Adherium's Smartinhaler platform

EU	US	China	Canada	Australia/New Zealand
SmartTouch	SmartTouch	SmartTurbo2	SmartTouch	SmartTouch AV
SmartTurbo2	SmartKey		SmartTurbo2	SmartTouch
SmartDisk	Smartinhaler Live™ Connection Centre			SmartTurbo2
				SmartDisk
				SmartHandy

Source: Company data. Note: Adherium is customer-led in seeking regulatory clearances and approvals and applies for clearances in countries where there is active or expected customer activity. In some markets certain clearances may not be required under the country's regulatory framework.

Ample manufacturing capacity for near-term needs

Adherium has strong in-house capability at its ISO 13485-certified facility in Auckland for the development and prototyping of new devices and small batch manufacturing. The company engages an ISO 13485-certified third-party contract manufacturer in Asia for volume production of its products. Based on current manufacturing lines the contract manufacturer can produce 8,000 devices per week, which will be sufficient to meet demand into FY18 based on our forecasts. The contract manufacturing in place is scalable beyond these forecasts.

Intellectual property

Adherium has lodged patent applications relating to various components of its Smartinhaler technology platform, most of which have not been granted and are in the process of examination by the relevant patent offices. Several of the patents have already been granted in New Zealand and one in the US, indicating that the inventions claimed by Adherium meet the tests for patentable subject matter and have good prospects of proceeding to grant in other jurisdictions if the scope of the claims is appropriately modified to account for the prior art.

Valuation

We value Adherium at A$188m based on a discounted cash flow model, which includes our estimates of the future costs and revenue streams from sales of Smartinhaler devices and data management services to AZN; to hospitals/managed care, etc, to improve outcomes for asthma patients; and for use in clinical trials. Exhibit 10 shows our forecast assumptions for the three revenue streams and the sum-of-the-parts NPV. Our valuation is equal to A$1.31 per share (undiluted) and A$1.26 per share after diluting for the 7.0m options on issue (exercise price 8-67c).

The Product Supply Schedule under the Master Supply and Development Agreement with AZN does not yet include a Smartinhaler device suitable for the US market, but we assume a 90% likelihood that AZN will purchase Smartinhalers for use in the US market in due course..

We assume uptake of the clip-on Smartinhaler device reaches 30% of Symbicort users in Europe, Japan and the US by 2020. We further assume a 75% likelihood that in 2020 AZN will launch a version of Symbicort with Adherium's Smartinhaler technology embedded into the drug delivery device, lifting uptake to 100% of Symbicort users by 2023 and displacing clip-on sales to AZN. Exhibit 10 includes forecast revenues in FY20 and FY23, the years when we forecast peak penetration of clip-on and embedded devices, respectively, to be reached.

We assume that at volume production (eg 1.2m devices in 2020) fully-featured, connected devices sell at US$25 per device, in line with the average price so far in FY16, and earn a 50% GP margin.

In 2015 AZN reported Symbicort sales of US$1,076m in Europe and US$176m in Japan. The average ex-factory price for Symbicort in the five major European markets estimated by Datamonitor in a 2015 report was US$58 per inhaler. Using this price and assuming 40% average adherence we estimate that in 2015 there were 3.85 million Symbicort patients in Europe and 0.36 million in Japan. We estimated US Symbicort patient numbers from Bloomberg prescription data.

Datamonitor forecasts Symbicort volumes to decline by 4% per year in the period to 2024 due to competition from analogues (so called branded generics such as Teva's DuoResp Spiromax). We assume that the provision of Smartinhalers to patients will slow the decline to 2% per year.

We assume that over time Adherium enters agreements with a combination of managed care/pharmacy/hospital and disease management organisations that cover the supply of inhalers to 230,000 (1%) asthma patients in the US, and 115,000 patients outside the US.

We have extended our cash-flow forecasts for 15 years (to 2031) but do not include any terminal valuation. We assume a long-term exchange rate of US$0.76/A$ and apply a 12.5% discount rate. Under our base case assumptions we forecast Adherium to become profitable in FY19 and begin paying tax at the NZ corporate tax rate of 28% in FY21.

Exhibit 10: Adherium sum-of-the-parts DCF

	rNPV (A$m)	rNPV/ share (A$)	FY20e revenue (A$m)	FY23e revenue (A$m)	Assumptions
1. Supply of Smartinhalers to AstraZeneca in Europe and Japan	120.1	0.84	38	97	3.85m Symbicort users in Europe and 0.36m in Japan (2015 Symbicort sales of US$1,076m in Europe and US$176m for Japan; based on a price of US$58 in Europe and US$102 (75% higher) in Japan, total 20.2m scripts and 4.2m users at 40% adherence). Smartinhaler price US$25, GP margin 50% from 2019 onwards. Uptake by Symbicort patients reaches 30% by 2020. 75% likelihood embedded inhalers launched in 2020 and lift uptake to 100% by 2023 with GP remaining constant at US$12.50/patient/year (~US$2.50 per script) for embedded devices.
2. Supply of Smartinhalers to AstraZeneca in the US	47.5	0.33	14	40	1.78m patients in US use Symbicort (8.5m scripts @ 4.8 scripts/patient/year (40% adherence). Smartinhaler pricing as per Europe. 90% likelihood clip-on devices launched in US in 2017 with uptake by Symbicort patients reaching 30% by 2020. 75% likelihood embedded inhalers launched in 2020.
3. Device supply and services to hospitals, managed care etc	35.0	0.24	15	19	22.6m asthma patients in the US. Uptake by hospitals, managed care etc reaches 230,000 (1%) of asthma patients in the US and 115,000 in other markets by 2021, buying 1 Smartinhaler per patient each year at US$25 per unit, plus pays a subscription fee of US$2 per patient per month (US$49 total per patient/year).
4. Clinical trials supply & services	8.5	0.06	4	4	Clinical trial revenue A$3m in FY17 and grows at 4% pa. GP margin 50%.
5. SG&A, R&D expenses	(53.6)	(0.37)			
Portfolio total	157.4	(1.10)	71	160	
Cash as at 31 December 2015	30.8	(0.21)			
Enterprise total	188.2	(1.31)			

Source: Edison Investment Research

At this stage we do not include any revenue from 1) additional device supply agreements with pharma or med-tech companies; 2) monetising insights from analysis of the data collected; or 3) technology expansion beyond respiratory disease to the management of other chronic diseases.

Sensitivities

Adherium's business is subject to the usual risks associated with any emerging technology: slower than expected commercialisation timelines, lower rates of adoption, technology leap-frogging, patent litigation, as well as regulatory and commercial risks. While the company is at an early stage of commercialisation, its clinical trials business has a track record of revenue growth and positive gross profit margins. Adherium currently relies on a single Asian-based contract manufacturer for volume production, which increases the risk that it may not be able to guarantee supply of devices. This risk is mitigated by active supply chain management and known alternatives.

The Product Supply Schedule under the agreement with AZN does not yet include a Smartinhaler device suitable for the US market, although our analysis shows that it has a strong incentive to do so. If AZN does not sign up for a device suitable for the US market then that would be downside risk to our valuation. SmartTurbo pricing is unknown and there is no track record of patient uptake rates, so we rely on our own assumptions for these key factors in our valuation.

Exhibit 11 shows the sensitivity of our NPV model to the price at which Adherium sells Smartinhaler devices and the gross profit margins achieved. NPV ranges from A$0.58/share at US$20 per device and a 30% gross profit margin to A$2.53/share at US$40 per device and a 60% gross profit margin.

Exhibit 11: Sensitivity of NPV (A$/share) to Smartinhaler price and gross profit margin

Smartinhaler GP margin	Smartinhaler price				
	US$20	US$25	US$30	US$35	US$40
30%	0.58	0.73	0.89	1.04	1.19
40%	0.82	1.02	1.23	1.44	1.64
50%	1.06	1.31	1.57	1.83	2.09
60%	1.29	1.60	1.91	2.22	2.53

Source: Edison Investment Research

Financials

For FY15 (the 12 months ending March 2015) device sales totalled A$2.886m for 34,000 devices, at an average of A$85 per device. Gross profit margin was 53%. Total revenue in FY15 was A$3.11m including A$203k grants income and A$21k other sales. Net profit in FY15 was a loss of A$1.3m after total operating expenses of A$4.3m. The company is transitioning from a March to a June year end, so FY16 will encompass the 15 months to June 2016. The interim financial report covered the nine months to December 2015. Net loss in the period was A$3.8m on revenue of A$1.6m from the sale of 48,000 devices. The average price of A$33 per device was substantially lower than in FY15 because i) 52% of the devices sold in the period were low-cost, reminder-only devices without data connectivity for a specific customer order (we assume these devices were supplied to AZN for market testing); and ii) the commencement of commercial supply at volume-based pricing vs higher-priced clinical supply the year before.

In the period to June 2016 the company expects AZN to begin expanding the commercial roll-out of the Turbu+ programme into selected countries. We note that this programme incorporates the fully featured (and therefore higher price) Turbu+ device with data connectivity. The transfer of volume manufacturing to an Asian-based contract manufacturer reduced manufacturing costs per device by 32% in 2015, delivering a gross profit margin of 48% despite lower device prices. Adherium had A$30.8m cash on 31 December 2015 after raising A$35m (~A$32m after costs) in an IPO in August 2015. Under the use of funds outlined in the IPO prospectus, based on a 24-month programme of intensive growth and investment, Adherium projects operating funds usage of A$29.7m over the two-year period to late 2017, representing substantial growth compared to FY15. The breakdown of the proposed use of funds is R&D (40%), manufacturing support (8%), sales, clinical operations, marketing and business development (22%) and other working capital (31%).

Exhibit 12: Financial summary

A$'000s	2014	2015	2016e	2017e
Year end 30 June	AASB	AASB	AASB	AASB
PROFIT & LOSS				
Revenue	592	3,110	3,234	7,257
R&D expenses	(1,216)	(1,343)	(2,000)	(6,000)
SG&A expenses	(1,178)	(1,496)	(5,948)	(7,756)
EBITDA	(2,109)	(1,100)	(6,116)	(10,055)
Operating Profit (before GW and except.)	(2,136)	(1,174)	(6,149)	(10,281)
Intangible Amortisation	0	0	(19)	(17)
Exceptionals	0	0	0	0
Other	0	0	0	0
Operating Profit	(2,136)	(1,174)	(6,168)	(10,298)
Net Interest	72	(81)	69	553
Profit Before Tax (norm)	(2,064)	(1,255)	(6,080)	(9,728)
Profit Before Tax (IFRS)	(2,064)	(1,255)	(6,099)	(9,745)
Tax benefit	0	0	0	0
Profit After Tax (norm)	(2,064)	(1,255)	(6,080)	(9,728)
Profit After Tax (IFRS)	(2,064)	(1,255)	(6,099)	(9,745)
Average Number of Shares Outstanding (m)	65.2	65.2	127.9	143.5
EPS - normalised (c)	(3.16)	(1.92)	(4.76)	(6.78)
EPS - FRS 3 (c)	(3.16)	(0.02)	(0.07)	(0.11)
Dividend per share (A$)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	N/A	356	1,304	5,560
Intangible Assets	N/A	190	171	154
Tangible Assets	N/A	166	1,133	5,406
Investments	N/A	0	0	0
Current Assets	N/A	5,260	28,982	15,383
Stocks	N/A	969	421	1,066
Debtors	N/A	334	425	1,028
Cash	N/A	3,468	27,648	12,799
Other	N/A	489	489	489
Current Liabilities	N/A	(4,599)	(1,579)	(1,982)
Creditors	N/A	(1,329)	(283)	(686)
Short term borrowings	N/A	(1,974)	0	0
Other	N/A	(1,296)	(1,296)	(1,296)
Long Term Liabilities	N/A	0	0	0
Long term borrowings	N/A	0	0	0
Other long term liabilities	N/A	0	0	0
Net Assets	N/A	1,017	28,707	18,961
CASH FLOW				
Operating Cash Flow	(2,094)	1	(6,705)	(10,902)
Net Interest	72	22	69	553
Tax	0	0	0	0
Capex	(125)	(252)	(1,000)	(4,500)
Acquisitions/disposals	0	0	0	0
Financing	110	24	31,828	0
Dividends	0	0	0	0
Other funding	(1)	1,599	(43)	0
Net Cash Flow	(2,038)	1,394	24,150	(14,849)
Opening net debt/(cash)	(2,611)	(573)	(1,494)	(27,648)
HP finance leases initiated	0	0	0	0
Other	0	0	1,531	0
Closing net debt/(cash)	(573)	(1,967)	(27,175)	(12,799)

Source: Edison Investment Research, company accounts. Note: IPO prospectus did not provide FY14 balance sheet. *The company is transitioning from a March year end to a June year end so FY16 will encompass the 15 months ending June 2016.

Contact details	Revenue by geography
Level 2 204 Quay Street Auckland 1010 New Zealand +64 9 307 2771 www.adherium.com	N/A

Management team

Chief Executive Officer: Garth Sutherland

Garth has spent the last 20 years working for some of the world's top technology companies in Europe, North America and Australasia including Microsoft Corporation and Gallagher. Garth graduated with a master's of science in physics from the University of Waikato with first-class honours. He founded Nexus6 (now Adherium (NZ)) in 2001; having had asthma all his life he wanted a solution for automatically tracking his asthma medication use to improve his asthma management.

Chief Financial Officer: Rob Turnbull

Rob has 20 over years' corporate experience. He started his career with PricewaterhouseCoopers, where he worked in Auckland, Toronto and London, and has over 10 years' experience with technology and life-sciences companies. Most recently Rob was chief financial officer for ASX-listed biotech Neuren Pharmaceuticals, a company undertaking multiple international studies ranging from preclinical to clinical Phase III, and with operations in the US, Australia and New Zealand.

Non-Executive Chair: Dr John Douglas (Doug) Wilson

Dr Doug Wilson was senior vice president for medical and regulatory affairs for Boehringer Ingelheim Pharmaceuticals (USA) for 10 years, where he oversaw a team of 400; including a number of medical staff, and was responsible for over 50 parallel drug developments. He then became head of Boehringer's worldwide medical research group overseeing all research programmes and working on upward of 100 drugs. He later relocated to Ingelheim (Germany) as head of medicine and regulatory affairs worldwide.

Head of Commercial Development & Corporate Affairs: Bronwyn Le Grice

Bronwyn has over 12 years' executive experience in the life sciences sector including senior business and corporate development roles in Australia and as chief executive officer of NZBIO, New Zealand's national industry body representing bio-based industries. Bronwyn joined leading healthcare fund manager BioScience Managers in 2012, where she was responsible for strategic positioning, marketing and external relations and was a member of the investment team for two funds totalling A$96m under management.

Senior VP Business Development, Europe: John Tarplee

John has over 30 years' industry experience in sales and market expansion. He was previously Senior VP Europe North and International Markets for the Danish specialty allergy immunotherapy company ALK-Abello, where he was responsible for ALK's commercial operations in those regions as well as commercial leadership for its geographical expansion strategy. Prior to that he spent ten years at Sanofi-Aventis as Business Unit director UK, General Manger Sales Force Excellence Europe region, General Manger Denmark and Sales Manager UK.

Senior VP Business Development, North America: James Hattersley

James leads Adherium's partnering and market expansion in North America. He was previously Vice President of Business Development at biopharmaceutical company Nektar Therapeutics, responsible for business and corporate development, strategic alliances, identification of commercial partnership opportunities involving late stage clinical assets, and alliance management. Prior to Nektar, James was VP Business Development at Sun Pharmaceutical Industries, responsible for acquisitions and partnering transactions in North America and Japan, respectively.

Principal shareholders	(%)
Bioscience Managers	17.0
Regal Funds Management	7.2
Mr Garth Sutherland	7.1
IG Investment Management	6.8
AstraZeneca	5.8

Companies named in this report

AstraZeneca (NYSE:AZN), GlaxoSmithKline(LON:GSK), Teva (TLV:TEVA), Merck & Co (NYSE: MRK), Propeller Health, Cohero Health, Qualcomm Life

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
245 Park Avenue, 39th Floor
10167, New York
US

Sydney +61 (0)2 9258 1161
Level 25, Aurora Place
88 Phillip St, Sydney
NSW 2000, Australia

Wellington +64 (0)48 948 555
Level 15, 171 Featherston St
Wellington 6011
New Zealand