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Bioshares

26 July 2017
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Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies

Companies covered: 2017 Bioshares Biotech Summit Coverage, ACR

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - May '13)	3.1%
Year 13 (May '13 - May '14)	26.6%
Year 14 (May '14 - May '15)	23.0%
Year 15 (May '15 - May '16)	33.0%
Year 16 (May '16 - May '17)	16.8%
Year 17 (May '17 - Current)	-2.8%
Cumulative Gain	**736%**
Av. Annual gain (14 yrs)	**17.4%**

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2017 Bioshares Biotech Summit Coverage

The 13th *Bioshares* Biotech Summit was held in Queenstown, New Zealand, from July 21 to 22, with more than 170 investors, brokers and finance professionals, biotech company executives and representatives from service firms and other groups in attendance.

More than 30 speakers and panellists addressed investment topics ranging from objective medicine, fibrosis drug development, generic drug development, building and developing sales as well as delivering updates on developments following the completion of clinical trials.

In this and later editions of *Bioshares*, summaries of selected sessions and talks will be presented.

Insights into Fibrosis Drug Development Session

John Cullity from Torreya Partners opened the fibrosis drug development session by providing an overview of dealmaking in the area, which he said was an active area for deal making where fibrosis assets are sold at the earlier stage of development rather than later and with good results.

In the context of discussing NASH (liver fibrosis), Cullity said that pharmaceutical companies look to construct their portfolios by acquiring assets in at least two if not all of the four main categories or phases of NASH, from the early stage which is where NASH is more metabolically driven by the obesity phenomenon (metabolic stress and steatosis), oxidative stress and inflammation (once the free fatty acids get into the hepatocytes they set up a pro-inflammatory cycle), the fascinating intestinal story of the gut and the microbiome, and lastly fibrosis (which leads to cirrhosis).

"What we are seeing on the buyside is that they are shopping for assets which they want to bolt on to discrete elements in this continuum. They might have one asset say in fibrosis. When you talk to these groups, they are quite thoughtful and purposeful on what the next one they want is.

"We are seeing the doublets and triplets coming through. Buy-side companies are seeing that the one asset won't get the job done. They will need to have a few in the bag. The top companies know exactly what they are looking for," said Cullity.

Eli Lilly and other companies are more focused on earlier stage NASH interventions, but these companies are also diabetes companies and see a fit with their diabetes portfolios believes Cullity.

Deals Review

"What we see here is an intriguing and multi-year observation with relation to fibrosis," said Cullity "which is that large transactions have a tendency to close with Phase I data to hand". The average deal value across a survey of eight deals for Phase I assets was

Cont'd over

US$631 million compared to US$280 million for Phase II assets. Cullity said that an explanation for this was that by the time Phase II has been reached "all the good assets have been snapped up."

IPF (Idiopathic Pulmonary Fibrosis)

In IPF, the key protagonist or cell of interest is the activated myofibroblast that causes a honeycombing of the lung. What occurs is a thickening of the alveolus as the activated myofibroblasts lay down disordered collagen. This leads to a reduction in capacity for oxygen exchange in the functional units of the lung.

Once IPF gets going it is hard to slow down. What is desired is a means to slow down that decline.

Two drugs have been approved to treat IPF, Ofev (nintidinib) and Esbriet (pirfenidone), although these are not the 'gold' standard, just the standard-of-care. They are both highly priced and there is no pricing pressure on these drugs believes Cullity.

IPF drugs in development must look to demonstrate between 20%-50% improvements over these drugs to gain comparable pricing.

Cullity pointed out that based on selected IPF Phase II trials underway that such trials now require more investment to cover expanded patient number requirements. That more investment is required for an uncertain return is not going down well on Wall St and is leading to further pressure for Phase I deal making.

IPF deals tend to get done early. French company Inventiva concluded a US$170 million discovery stage, IPF deal with Boehringer Ingelheim in May 2016, and Galacto Biotech wrote a two program discovery deal, worth US$444 million, with Bristol-Myers Squibb in 2014.

Adalta – AD114 Targets Inflammation and Cell Migration

Adalta's core asset is its ibody technology, which has given rise to its lead IPF candidate AD114. It is aiming to take this candidate through to the end of Phase I (due FY2019), which CEO Sam Cobb sees as a major uplift point for the company.

Fibrosis is a complex process which progresses from (a) clotting and coagulation to (b) inflammatory cell migration to (c) fibroblast migration, proliferation and activation to (d) tissue remodelling and/or resolution.

AD114 has multiple effects across these stages: it reduces inflammatory cell migration; it blocks fibrocyte recruitment; it reduces the transition of epithelial-mesenchymal transition to myofibroblasts; it reduces fibroblast migration (into the lung); and it has also been shown to reduce collagen and extra-cellular matrix deposition.

AD114 binds to CXCR4 (the chemokine receptor 4). This receptor is traditionally involved in stem cell mobilisation. A small molecule drug, plerixafor, is on the market for that purpose so is a proven drug target in that sense.

However, and unlike every other CXCR4 antibody, AD114 does not mobilise stem cells. It binds with high affinity to CXCR4 and not to other receptors similar to it (i.e. other G-protein Coupled Receptors).

Other CXCR4 antibodies don't have any activity in lung tissue. AD114 does have activity because of its 'long loop' and its smaller size, relative to an antibody, which means that it binds in a unique way into a pocket of the CXCR4 receptor.

AD114 is very specific for diseased tissue and has no effect on normal tissue, which differentiates it from the approved drugs for IPF, nintidanib and pirfenidone, and also from plerixafor.

CXCR4 expression is increased dramatically in diseased human tissue e.g. lung, kidney.

Patients with CXCR4 positive cells (fibrocytes) have been found to be correlated with lung function and CXCR4 positive cells (fibrocytes) also appear to be an independent predictor of IPF patient mortality.

When patients have greater than 5% of CXCR4 positive fibrocytes their life expectancy is 7.5 months and 27 months if CXCR4 levels are less than 5%.

Immuron – IMM-124E Targets the Gut and the Microbiome

Immuron's oral immunotherapy, IMM-124E, targets pathogenic bacteria in the gut, the toxins they produce and stimulates the induction of regulatory T cells (CD4, CD25, FoxP3).

LPS endotoxin produced by enteric *E. coli* has been implicated in inflammation in NASH as well as in auto-immune diseases.

IMM-124E is an anti-LPS specific polyclonal antibody. It also targets the key virulence components of pathogenic bacteria, in particular the colonisation factor antigens and also the flagella. It produces an anti-inflammatory response working through the innate and the adaptive immune systems.

IMM-124E is designed to work in the gut but not be absorbed into the circulatory system.

Preclinical data generated to date has come from studies with the carbon tetrachloride model in mice, which has shown that IMM-124E delivers a significant reduction in liver fibrosis and inflammation, a marked reduction in liver enzymes (ALT and bilirubin), and a reduction in liver activated macrophages.

In an Ob-Ob model (which focuses on metabolic syndrome), IMM-124E significantly reduces ALT levels and also significantly improves metabolic markers such as triglycerides, fasting glucose and oral glucose tolerance. It also decreases TNF-alpha and increases anti-inflammatory cytokines.

In a Phase I/II proof-of-principle study in biopsy-proven NASH patients, improved metabolic status and improved liver status was observed, as well as an increase in circulatory T-Cells.

These results gave the company confidence to move into further clinical development.

IMM-124E targets the gut and the microbiome, it decreases intestinal LPS and reduces intestinal permeability (i.e. it stops leaky gut). IMM-124E activates the innate immune response to suppress the cells associated with the inflammatory response (NKTs, dendritic cells and macrophages). Its effects also translate to a decrease in insulin resistance and a decrease in LPS levels. These effects are shown in the liver where activated Kupffer cells (macrophages) also decrease.

Immuron is in the closing stages of a Phase II trial in 133 biopsy-proven NASH patients, evaluating a low dose, high dose and placebo. The endpoint is the decrease in hepatic fat fraction from baseline to week 24.

An interim analysis point was triggered when 80 patients had completed 24 weeks. A total of 69 patients had met the per protocol criteria of 24 week MRI values. The two doses were not significant from each other in effecting liver function (liver enzymes), but significantly different from placebo.

Topline results are expected by the end of the year.

Pharmaxis – Targeting the Inflammatory Stage (PXS-4728A) and the Fibrosis Stage (LOXL2 inhibitor)

Pharmaxis CEO Gary Phillips set out to show what drove the deal that the company signed with Boehringer Ingelheim in May 2015 for PXS-4728A.

He first explained how the fibrotic process begins with insults to the liver, for example from viruses and high fat diets, causing inflammation. The neutrophils adhere to the walls of the blood vessels which they then infiltrate and activate macrophages. They secrete chemokines, activating stellate cells which go from being dormant to becoming very active myelofibroblasts. The continuing production of paracrine factors from the inflammatory process causes the stellate cells to start secreting collagen, LOXL2 (lysyl oxidase-like 2) (an enzyme of interest to Pharmaxis), and matrix metalloprotineases. LOXL2 causes crosslinking in the collagen, a matrix which characterises fibrosis.

PXS-4728A inhibits SSAO which in turn prevents the adhesion of neutrophils onto the cell walls. It falls within the anti-inflammatory cascade of the disease. It slows down the inflammatory process and interferes with the signalling in the disease process and has a downstream effect on fibrosis.

PXS-4728A was sold to Boehringer Ingelheim in a deal worth up to ~$600 million. To date the company has received $39 million upfront and expects to receive $27 million when the first patient is dosed in a Phase II trial, and $15 million when a second trial is initiated (in an unnamed indication) before the end of the year.

Pharmaxis' LOXL2 inhibitors interfere with collagen cross linking, aligning it with the fibrosis end-stage. Validation for the target has come from studies conducted by Boehringer Ingelheim and Gilead Sciences, although Gilead Sciences' monoclonal antibody simtuzumab failed in clinical studies, probably because it was a poor antibody, inhibiting LOXL2 by 40%. In contrast Pharmaxis' compound inhibits LOXL2 by 100%.

Pharmaxis has commenced a licensing program for its LOXL2 asset, alongside a Phase I trial to commence this year. The company has enough cash to move the compound into Phase II. However, it has decided to license the asset at the end of Phase I because it believes a partner would be better able to decide which drug to combine it with, which patient groups to target and which fibrosis conditions to also target.

Vectus Biosystems – VB0004 Targets Salt Balance Mechanisms for Fibrosis Reversal

Vectus Biosystems CEO Karen Duggan described how vasoactive intestinal peptide (VIP) has emerged as a therapeutic target. VIP is a mediator for the gastric sodium monitor, the role of which is to maintain salt balance. Studies show an inverse relationship between VIP and myocardial fibrosis in WKY and SHR rats on varying salt diets. "Depletion of the molecule unleashes the fibrotic process," believes Duggan.

In chronic studies (18 weeks) Duggan reported that VIP reversed myocardial fibrosis in rats on a 4% salt diet and also in rats on a 4% salt plus induced fibrosis (L-NAME) when the VIP was introduced after 14 weeks. In another study of rats with induced diabetes at 26 weeks after 12 weeks of diabetes, VIP reduced after 8 weeks of diabetes with 4 weeks of treatment.

The company has developed an oral agonist of VIP for clinical development, VB0004. The company has achieved GMP manufacture of VB0004 in three synthetic steps, has improved yields at higher volumes (5kg), commenced IND enabling toxicology studies (with a 28 day study yet to be completed) and expects to start a Phase I trial in January 2018.

VB0004 has a terminal half life of 17.5 hours.

Vectus has studied the effect of VIP and VB0004 on pro-fibrotic mediators such as angiotensin 2, TGF-beta, AT1a and TNF-alpha, indicating that they both significantly decrease levels of these mediators after 4 weeks of treatment, although the natural peptide has stronger effects.

The company also has another peptide analogue, A79, which it has shown in rat models to be able to reverse pulmonary fibrosis without affecting blood pressure. Vectus believes A79 could be applied to treatment of other causes of pulmonary fibrosis including IPF, where blood pressure reduction is not required or contra-indicated.

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Objective Medicine Session – Part 1

Garth Sutherland, founder of Adherium, spoke in the opening 'Objective Medicine' session at the Summit. He said that patients with chronic diseases take only between one third to a half of their prescribed preventative medication, not just in respiratory diseases, but also in areas such as chronic cardiovascular disease.

In the G7 countries alone (US, France, Germany, Italy, Spain, the UK and Japan), there are an estimated 3.4 million patients with severe asthma or COPD who are inadequately controlled.

Adherium's technology brings together four of the greatest inventions to improve health outcomes according to Sutherland. These are pharmaceuticals, the microprocessor, wireless internet and cloud processing.

Sutherland said that Adherium has shown in over 60 peer-reviewed publications that using the company's sensor technology that is linked to a smart phone, it can significantly improve adherence to medication for respiratory diseases.

In one study in 110 children with asthma, using the company's sensor technology, the number of children achieving 80% adherence to preventative asthma treatment increased by more than threefold with a fivefold reduction in asthma related hospitalisations!

That study was conducted independent of Adherium which only supplied the technology for the trial. Sutherland said that because of the use of objective data, the relationship between the patient, caregiver and doctor was strengthened.

Adherium's initial market was to provide objective data on respiratory drug use in clinical trials. Some of its major contracts were with AstraZeneca with tens of thousands of devices sold to AstraZeneca. In 2015 the relationship moved into a global supply and development agreement.

The first application by AstraZeneca of Adherium's adherence feature was with Symbicort (used for patients over 12 years of age), a drug with annual sales for AstraZeneca of around US$4.7 billion. This relationship is non-exclusive outside of the Symbicort product area and Adherium owns the data around the use of its technology.

AstraZeneca launched the Adherium SmartInhaler for its Symbicort product last year and is currently selling the product in six countries (including Australia, Netherlands, Switzerland, Italy and the UK).

Sutherland expects the product to be on the market in 10 countries by the end of 2017 and to expand further next year. Sutherland said that the rollout is going well and is now starting to gain momentum.

To date Adherium has sold over 85,000 devices for clinical and community use. Sutherland said the commercial distributor model is straightforward; AstraZeneca places an order for the SmartInhaler devices, Adherium makes the devices in Thailand, and when AstraZeneca collects the devices from that location, Adherium invoices its partner.

Sutherland described the relationship with AstraZeneca which has got to the stage as "business as usual" with AstraZeneca rolling out country after country.

The two companies are also working on follow-on products. While work with AstraZeneca is "rate limiting", Adherium is opening up other direct channels for its SmartInhaler, including direct to hospitals and clinics (underway), and in consumer health sales direct to patients (to be launched this year).

Sutherland believes there is a large demand from hospitals to use this type of digital health technology, particularly for at-risk patients, where health costs can be reduced by 40% in patients with asthma (by US$1,500 a year) when Adherium's SmartInhaler technology is utilised.

In consumer health, Sutherland said there is a major trend in the consumerisation of healthcare, with 40% of consumers willing to pay for out-of-pocket expenses (a threefold increase from 2015) and 64% of patients willing to submit their electronic healthcare data to their doctors for more improved health outcomes.

Sutherland also pointed to the rising investment interest in digital health technologies, with US$3.8 billion invested in the sector alone in Q2 2017, which was an 81% increase over the previous corresponding period.

The new channels will give the company four distinct markets for Adherium's products, these being, in clinical trials, through distributors such as AstraZeneca, direct to the consumer, and direct to hospitals and clinics.

Bioshares

The Generics Pharmaceutical Industry

The CEO of Acrux , Michael Kotsanis, provided Summit attendees with an excellent insight into the global generics pharmaceutical industry, which started in 1984 in the US, through the Hatch-Waxman Act, which initiated the Abbreviated New Drug Application (ANDA) process.

Kotsanis said that over the 10 years ending 2015, generic pharmaceuticals had saved the US healthcare system US$1.46 trillion.

In a figure that surprised most, generic pharmaceuticals make up 89% of all pharmaceutical scripts dispensed in the US, with that figure being 0% in 1984. However on a sales basis, branded products generate 74% of the revenue, with generics capturing 26% of sales.

In Europe, the market is more fragmented, with 350 manufacturing sites and the industry employs around 160,000 people.

However, generics make up significantly less of all prescriptions than the US, with generics making up only 56% of all scrips dispensed. This figure is driven down by some of the southern countries such as Italy and Spain which do not encourage generic competition as much said Kotsanis.

Generics save around €100 billion a year and in another surprising aspect pointed out by Kotsanis, generic drug manufacturers spend up to 17% on R&D.

This figure can vary with Kotsanis previously working for a European generics group that spent around 40% of its revenue on R&D. Kotsanis' insights into the European generics industry can be well respected given he was previously on the board of the European Generics Association.

One of the obvious major differences between branded and generic drugs is the time taken to get to market. For branded drugs, it takes between 10 – 15 years, with no guarantee of regulatory approval.

For generics, the development timeline is between three to five years. Kotsanis said that generics companies will not wait until patents expire to start developing a generic drug, but will even start development on a generic copy of a potential blockbuster before approval of that product.

Generics do not promote on evidence said Kotsanis but these companies promote their products based on price advantage. Highlighting the market opportunity, between 2018 – 2021, over US$50 billion of generic drugs will come off patent in the US alone.

Kotsanis has uncovered some surprising data from the US Government Accountability Office in the US which strongly supports the Acrux business focus into the future.

Although oral blockbuster drug products will see 90% price erosion in the first week of generic competition with 50% loss in market share in that first week (from up to five to 10 generic entrants), the topical pharmaceutical pricing dynamics are somewhat an anomaly.

For topical pharmaceuticals, the intense pricing pressure does not appear to exist as seen with oral drugs, with the prices of topic drugs continuing to increase in a genericised market. Branded topical drugs still generate slightly more than 50% of the revenue of overall branded and generic topical drug sales in the US according to Kotsanis.

Kotsanis does not believe it is price collusion that is increasing drug prices in the US in the topical space, but the low generic competition and the general trend by some branded pharmaceutical companies to increase prices by 10% a year which can see prices continue to increase when only one generic competitor is present in the market.

In the US, topical drugs generate US$18 billion of annual revenue, which Kotsanis flippantly described as a 'niche' pharmaceutical market compared to oral branded and generic products which generate annual sales of US$200 million in the US and injectables that generate US$120 million in annual sales in the US.

The Acrux Opportunity

Acrux currently has seven topical generics in clinical development which have an addressable market of around US$1.05 billion.

The company expects to increase this number to 12 by the end of the current financial year. Acrux has chosen its target product markets because of the size of the market and the limited competition. Kotsanis said that most of the markets it will be competing in will not be commodity markets like the generic oral pharmaceutical space.

For competitive reasons, Acrux is not revealing the generic topical drugs it is developing. It plans to file its first ANDAs (regulatory approvals for generics) in mid 2018 with up to three dossiers to be filed next year in total.

Bioshares

An update on Acrux continues on the next page

Bioshares Model Portfolio (26 July 2017)

Company	Code	Price (current)	Price added to portfolio	Recommend-ation	Cap'n ($M)	Date added
Clinuvel Pharmaceuticals	CUV	$6.60	$4.15	Spec Hold A	$315	December 2014
Impedimed	IPD	$0.685	$0.245	Spec Hold A	$257	December 2013
Bionomics	BNO	$0.450	$0.295	Spec Buy A	$217	March 2016
Viralytics	VLA	$0.900	$0.300	Spec Buy B	$217	August 2013
AirXpanders	AXP	$0.690	$0.745	Spec Buy A	$198	September 2015
Somnomed	SOM	$3.25	$0.94	Buy	$188	January 2011
Opthea	OPT	$0.715	$0.160	Spec Buy A	$143	November 2014
Osprey Medical	OSP	$0.435	$0.695	Spec Buy B	$112	September 2015
Pharmaxis	PXS	$0.260	$0.260	Spec Buy B	$83	December 2016
Visioneering Technologies	VTI	$0.395	$0.435	Spec Buy A	$78	March 2017
Dorsavi	DVL	$0.370	$0.480	Spec Buy B	$62	December 2016
Volpara Health Technologies	VHT	$0.535	$0.375	Spec Buy B	$60	June 2017
Acrux	ACR	$0.31	$0.31	Spec Buy A	$51	July 2017
Micro-X	MX1	$0.43	$0.42	Spec Buy A	$50	May 2017
Adalta	1AD	$0.23	$0.23	Spec Buy A	$23	July 2017
Adherium	ADR	$0.130	$0.495	Spec Buy A	$22	March 2016
IDT Australia	IDT	$0.084	$0.260	Spec Buy B	$21	August 2013
Rhinomed	RNO	$0.215	$0.320	Spec Buy B	$20	December 2015

Portfolio Changes – 26 July 2017

IN:
1AD has been added with a Spec Buy Class A recommendation (see page 2)

ACR has been added with a Spec Buy Class A recommendation (see commentray below)

OUT:
No changes

Acrux – First Generic to Axiron Launched

Acrux's (ACR:0.31) licensee Eli Lilly has reported stronger Axiron sales for the June quarter, at US$36.8 million. This was higher than the March quarter of US$27.3 million, but down slightly from Q1 and Q2 of FY2017 which were both US$39 million. Axiron sales move around based on rebates, while the product volume sales remain reasonably constant. Overall, the market testosterone market continues to decline, at around 10%-15%.

The first generic to Axiron was launched earlier this month by Perrigo. Eli Lilly has reached an agreement with another generics company to sell what's called an authorised generic that will compete with other generic products. Acrux receives a royalty stream from Axiron sales and will receive royalties from the authorised generic.

Eli Lilly and Acrux are appealing an unfavourable legal decision around Acrux's axilla patent which has allowed generic competition to surface 10 years earlier than expected. An outcome from the appeal is expected in Q3 2017.

Acrux finished the half year ending December 31, 2016 with $31 million in cash after generating a pre-tax profit of $9.0 million ($6.3 million after tax) on income (mainly Acrux royalty) of $14.3 million. It has stopped paying dividends since the unfavourable patent decision that allows early generic competition to Axiron.

Acrux's cash position should be strengthened following the second half result (FY2017), with the company holding an estimated $35 million in cash. (Axiron sales in 2H were US$64.1 million compared to US$78.9 million in 1H 2017, a fall of 19%).

Acrux is currently spending $10.6 million a year on corporate and development costs for its range of generic topical pharmaceuticals. Excluding additional royalty income (which will decrease significantly from generic competition, unless the axilla patent decision appeal is successful), the company has sufficient funds to bring its first seven generic pharmaceuticals to market by 2021.

Acrux is capitalised at $51 million.

Bioshares recommendation: **Speculative Buy Class A**

(Acrux has been added to the Bioshares Model Portfolio)

Bioshares

How Bioshares Rates Stocks

For the purpose of valuation, Bioshares divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, Bioshares grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks. For both groups, the rating "Take Profits" means that investors may re-weight their holding by selling between 25%-75% of a stock.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

Speculative Buy – Class A
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C
Sell

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