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In this edition....
Coverage from the 20th Bioshares Biotech Summit continued.

Companies covered: BB1, BDX, COV, CUV, IIQ, PEB, PIQ, RHY

BIOSHARES
Australia's Independent Biotech Investment Resource, est.1999

1 September 2026
Edition 999

	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)	-35.8%
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 - May '18)	-7.1%
Year 18 (May '18 - May '19)	-2.3%
Year 19 (May '19 - May '20)	39.5%
Year 20 (May '20 - May '21)	86.8%
Year 21 (May '21 - May '22)	-15.6%
Year 22 (May '22 - Dec '22)	-2.2%
Year 23 (CY2023)	-15.4%
Year 24 (CY2024)	40.8%
Year 25 (CY2025)	20.3%
Year 26 (CY2026 - current)	-20.7%

Williams Sends Cats Flying at the Bioshares Biotech Summit

Biotech change agent and investment banker, David Williams, threw the proverbial cats in amongst the pigeons in a colorful and entertaining Mike Hirshorn Address at last month's Bioshares Biotech Summit.

Williams has built a career in finding mis-priced and mis-managed companies to effect corporate turnarounds with considerable success.

His philosophy is that if his clients don't want to buy a particular asset, then Williams and his company will buy the asset.

2003 was a big year for Williams when he bought the salmon company Tassal from receivers for $42 million, then listed it on the ASX. In 2022, that business was sold to Canadian group Cooke Inc for $1.7 billion.

Continued over

Summit Coverage: Diagnostic & Biomarkers Super Session

In what was one of the standout sessions at this year's Summit, seven diagnostic product developers were asked to present on what level of accuracy will be required to bring a commercially viable product to market, and also how large the clinical studies will need to be to certify sufficient accuracy in their tests.

Introduction into Diagnostic Measures

CEO of BlinkLab, Henk-Jan Boele stressed that what is much more important than sensitivity and specificity is NPV (Negative Predictive Value) and PPV (Positive Predictive Value). "What is the chance that I really have the disease," is what the patients (or carers) want to know. "That is the most relevant question here."

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Edition Number 999 (1 September 2026)

Clinuvel Considers ASX Delisting and Move to US Markets

Clinuvel Pharmaceuticals (CUV: $8.24) is looking to make the US more of a focus, with its first Phase III study in Vitiligo to read out later this year. One of the company's priorities is to build out its US presence with its operational headquarters to be based in the US, along with internal manufacturing.

Alongside these events, the company is currently considering a listing on the Nasdaq market, and to delist from the ASX. Underperformance of the company's share price over the last five years, falling from an all-time high of $44 in 2021, is a likely driving factor in

Continued on page 7

– MHA cont'd from page 1

In the same year (2003) Williams listed Medical Developments on the ASX to commercialise the Penthrox inhaler (the "Green Whistle") used in ambulances across Australia, New Zealand and the UK. Williams held 39% of the company at listing. Williams took that company from revenue of $1.5 million in 2003 to $32.2 million in 2023 when he stepped down from the board. In the process Williams has sold over $75 million in shares whilst retaining just under a 12% stake as of last year.

In February 2014 Williams joined the board of Polynovo (then called Calzada) and became chairman in March. In 2014, the company had revenue of just $0.3 million, reaching $150 million in 2025 before Williams left the board in October last year. Williams had bought shares in the company starting at $0.08 and then continued buying around $0.50 per share. He retains a 3% holding in the company. Polynovo is now capitalized at $694 million.

Companies Don't Need to Move Off-Shore

Williams had some strong words for biotech company executives who want to take their biotech companies off-shore, believing they will be better understood in the US market. "I don't believe in that at all," said Williams. The evidence on the outcome of a company's share price in moving to a US exchange is mixed according to Williams, particularly in smaller companies. "If one of my share prices is not performing, that is my fault." If fund managers don't understand a business, then it's because the CEO has not done their job. "My job is to dumb it down and get it understood."

No Shortage of Capital in Australia and New Zealand

On the topic of raising capital, Williams said there is no shortage of money in Australia. "You can get money any time of the day of night if you can get the story right."

Williams acknowledged that it is a particularly difficult time in the markets at the moment, but deals are still getting done. "Don't blame anybody else except yourself." Williams also believes that biotech CEOs are not looking in the right places. "There are so many high net worth (investors) who are putting money into biotech at the moment." He gave the example of Paula and Lindsay Fox contributing $100 million to establish the Paula Fox Melanoma Cancer Centre in Melbourne.

Williams said there are plenty of high net worth investors in Australia and New Zealand who are prepared to invest up to $20 million into the biotech sector. Hong Kong and Singapore also offer easily accessible capital markets, particularly in Hong Kong which has many Australian, New Zealand and British expat fund managers.

Need a "Working Board"

With respect to functional boards, Williams wants to see "working boards", not boards populated by friends and corporate associates, but directors who are opening doors. In the first month after joining the Polynovo board, Williams raised $13.7 million and hired 22 people in manufacturing and regulatory specialists, even though the company had no product on the market, and immediately set to building the appropriate board.

Another issue not just in Australia but in most countries, is that there is not enough board renewal. "Once they (directors) are on a board, people don't want to get off." And directors who are motivated by the director fees alone are "not going to cause any ripples at all. That's the last thing you want."

Boards Need to Transition

Boards also need to transition stressed Williams. "It's not forever." The skill set required from a board is very different when the company is in the development phase and approaching market compared to the board required once the products are on the market in many countries around the world and "doors need to be opened."

Williams also believes if you have a working board in place, then there is less need or reliance on a Scientific Advisory Board (SAB), which he has never used. Citing the Polynovo platform, the applications that are surfacing would never have come from a SAB said Williams. "The innovation is coming from the surgeons themselves. There are now over 500 articles by surgeons (on uses of the Polynovo technology)". As an example, Williams was recently approached by an Ophthalmologist from Yale and told she was using the Polynovo technology to reconstruct corneas.

Another application is in the potential treatment of diabetes. Williams has formed a private company, Beta Cell Technologies, with burns surgeon John Greenwood, who pioneered the application of the Polynovo product in burns treatment, and Professor Toby Coates.

In this application the Polynovo material is surgically placed under the skin, and then after a week, the foam is injected with pancreatic islet cells (from Novo Nordisk). "The cells are still alive and secreting insulin after four years," remarkably. So far three people have been injected. In pig studies, the company has also injected adrenaline cells and thyroid cells.

Postscript

Following the Summit, Williams has reached out to biotech CEOs to review company pitches, in conjunction with Bell Potter, Morgans and Elyse Shapiro (formerly with Canaccord). At least 12 biotechs are taking up the free offer so far.

Bioshares

– Diagnostics Session cont'd from page 1

With a data set, the sensitivity (proportion of positive cases picked up) can be increased, but this compromises the specificity (i.e. more false positives). Conversely the specificity can be increased but with a reduced sensitivity.

But importantly, the prevalence of the disease needs to be considered, which will directly impact the NPV or PPV (which effectively takes into account sensitivity, specificity and disease prevalence). For instance with a low prevalence, say 15%, a lower sensitivity would make sense to increase the Positive Predictive Value argued Boele.

> Sensitivity = (true positives) / (true positive + false negatives)
>
> Positive predictive value (PPV) is the probability that a person who gets a positive test result actually has the disease or condition.
>
> Negative predictive value (NPV) is the chance that a person with a negative test result truly does not have the disease.

BlinkLab (Autism & ADHD)

BlinkLab (BB1: $0.76) was founded five years ago as a Princeton University start-up focused on diagnosing autism and ADHD via a smartphone. With autism, the prevalence is increasing, which CEO Henk-Jan Boele said was a global phenomenon. The issues at the moment are the long wait lists to diagnosis and treatment.

"Keep in mind there is no brain scan, there is no blood test, there is no biomarker for autism." Autism continues to be measured subjectively. The only tools available are questionnaires. But early diagnosis leads to better clinical outcomes believes Boele as well as significantly reducing medical expenses.

BlinkLab is looking at blinking reflexes, and other facial movements, that similar to a knee stimulus response, can not be controlled. The company's data is published in peer-reviewed journals, where a sensitivity and specificity of 84% and 85% respectively has been achieved most recently.

The company is currently conducting a pivotal study in the US for 510k clearance for use as a diagnostic aid for specialists – not for self-diagnosis – where the test can be conducted in the home setting, with the data going to the prescribing doctor.

One of the challenges for BlinkLab is that the current diagnosis is subjective and clinicians can differ with their opinions in 70%-80% of cases. This means that a 100% 'accuracy' with a new technology can never be achieved.

As such the performance window for BlinkLab is 85%-100%. "We will never reach 100%" under the current reference system.

One of the key learnings for BlinkLab has been to agree with the FDA on your thresholds before you start your pivotal studies, which in autism is 65% for sensitivity and specificity. Another learning has been to install a second independent review, that requires a third reviewer if the first two can not reach consensus. Also important has been to run pilot studies that mirror the pivotal study as well as understanding where the new diagnostic will fit into the current clinical workflow.

A benefit that BlinkLab has is that it can sell its product through the specialist network without reimbursement because the pricing of the test is so low. The key initially is to drive early adoption. After that will come a wide use screening device, where the parameters of the test will need to be adjusted.

In ADHD, BlinkLab recently generated highly positive results in a study in 208 subjects, achieving a sensitivity and specificity of 82% and 83% respectively. The company will now look into adults as well. It has also been working with a pharmaceutical client, showing the impact of the drug methylphenidate in subjects with ADHD. Using the BlinkLab technology, the hyper-responsiveness was shown to fall away within two hours following treatment, and then to return as the drug's effect dissipated over the day. Monitoring drug responsiveness is a major commercial opportunity for BlinkLab.

Boele's five tips are:

1. Start with the gap in the market, not the technology
2. The real asset is the area under the curve
3. Intended use determines the threshold
4. One asset can have more than one use, such as a screening and diagnostic, depending on the threshold. Many diagnostics fail because of the wrong threshold
5. Adoption is driven by the NPV and PPV

Rhythm Biosciences (Bowel Cancer Diagnosis)

Rhythm Biosciences (RHY: $0.094) is developing a blood-based diagnostic for detecting bowel cancer, called ColoSTAT.

In Australia each year around 16,000 cases of bowel cancer are diagnosed, with over half detected as late stage disease (Stages III & IV), which CEO David Atkins said is completely avoidable. This is despite there being an active bowel cancer screening program in place. However around 60% of people over 50 who receive this test in the mail don't use it.

ColoSTAT was launched in Australia in April this year. In Australia around 800,000 colonoscopies are conducted each year. But Atkins believes many of those can be avoided by applying the ColoSTAT test.

In Australia the gatekeeper for ColoSTAT is the general practitioner. It is sold by directly marketing the test to GPs as well as through its collection partner 4Cyte Pathology.

The company is also selling its gene-based risk assessment test in the US, which includes six different types of cancers, with a risk assessment for lung cancer to be added to the product offering.

Continued over

Whilst the company now has its products on the market, a major step for the company is to gain reimbursement for its tests. Atkins said that it is a massive global market, one which the company does not need to immediately dominate but can grow in to.

BCAL Diagnostics (Breast, Pancreatic and Ovarian Cancer Diagnosis)

BCAL Diagnostics (BDX: $0.065) has developed a blood test for the early detection of breast cancer. It has a partnership with ClearNote Health, Helius and Sonic Healthcare.

The company has three tests on the market. The first is BREASTEST plus. And through the partnership with ClearNote Health, it has access to an ovarian cancer and pancreatic cancer test.

Newly appointed CEO of BCAL Diagnostics, Anne-Louise Arnett, discussed the example of the PSA test for prostate cancer which is an accepted test. Its everyday use is in the reassurance of a normal test result. However a positive test result is not a diagnosis, but means that more needs to be explored. (The PSA test has a false positive rate of around 75% and misses around 15% of prostate cancers.)

In breast, pancreatic and ovarian cancer, there is no equivalent PSA test. BCAL focuses on the benign result: "Can you trust the negative result?"

A negative result with a high sensitivity can rule out disease, such as with the PSA or FOBT in bowel cancer.

BCAL's tests in breast, pancreatic and ovarian cancers detect 90%, 82.6% and 78.2% of cancers. "(However) it is the PPV and NPV which are the performance indicators in the target population."

"A highly sensitive test with a high NPV is a strong rule-out that you can hold on to." Arnett pointed out that a negative test result is strongest when there is a high sensitivity and there is a low incidence of disease. "It's the negative result that carries the weight."

Collection of the samples for breast cancer testing in Australia is through the Sonic and Helius networks. The initial target market is for women with a high breast density over the age of 30, where mammography is less informative. The specificity of the test is being measured in a study in 613 women in Australia with dense breast tissue.

Arnett highlighted the importance of establishing a distribution channel, with 97% of GP's having access to the test and collection networks in place. It is currently use in 20 specialty clinics in Australia and supported by 90 doctors.

This infrastructure can now be leveraged with follow-on tests that will be brought to market. One of those is BREASTEST Monitor for women who have completed treatment for breast cancer, which has a sensitivity of 91% and a NPV of 95%.

At the moment the BCAL tests are referred by the doctor and paid for by the patient. Next comes the health economics case which will be based on negative predictive value (NPV) said Arnett. This will be followed by public reimbursement based around clinical utility and cost effectiveness. However Arnett stressed the company is commercial now and is not reliant on reimbursement.

BCAL is building the awareness for referrals across Australian GPs for the Avantect pancreatic and ovarian cancer tests which were launched in January this year (at an average price of $1500).

Other tests in development include BREASTESTplus 2, for all women above 30 years of age. This is being validated by Sonic Healthcare in the US with Sonic having an option to license the test for the US market, pending successful validation.

Inoviq (Ovarian Cancer Diagnosis)

Inoviq (IIQ: $0.18) is developing cancer diagnostics using exosomes from the blood. Its most advanced test is for ovarian cancer in women who are asymptomatic.

Inoviq CEO Leearne Hinch said that currently there is no test approved for ovarian cancer screening. This is because no test has been able to diagnose early stage disease with sufficiently high sensitivity and specificity. What makes it difficult is the low incidence of disease said Hinch.

Currently around 75% of women are diagnosed at a late stage (Stage III and IV). At that the point the five year survival is less than 29%. Hinch believes if it can be detected early enough, 93% of women would be alive after five years.

Inoviq is measuring six micro RNA from exosome surface markers linked to the cancer cells, in combination with CA125 for its test. The outcome is a cancer score yielding either a positive or negative test result.

The original work was conducted on 500 biobank samples from two hospitals in Australia. The training set used 372 of these samples, and the cross validation was conducted on 125 samples.

Inoviq received feedback on its test from gynecological oncologists with respect to optimizing the specificity and sensitivity requirements and the trade-offs that occur in that process. With a very high specificity of 99.6% (almost no false positives), the sensitivity was excellent (100%) for Stage I and Stage II disease, but less for stage III (79%) and Stage IV (50%).

This was not appropriate for these specialists who generally see high risk patients where picking up Stage III and Stage IV is important. By reducing the specificity to 98%, the sensitivity across stages I to IV was 89%, 100%, 100% and 78% respectively. This is now being taken into the US market as a laboratory-developed test.

Inoviq is currently taking the test through clinical validation, with single site biobank samples being sought.

The company has a dual commercial path. The first is to make the

Continued over

test available through a partner (such as Sonic, Quest or Labcorp) that has a CLIA lab and validate the test through that lab. The aim is to have the test available by the end of 2027, without reimbursement. This would provide the company with real world evidence.

Inoviq will focus on women at high-risk of developing ovarian cancer, for which reimbursement of US$1,000 is possible as a Laboratory Developed Test.

The second, longer path is to develop the test as an IVD (in vitro diagnostic), where a clinical study in all women (high and low risk) will be required, in more than 20,000 patients. This would help achieve reimbursement as a wide use screening test to allcomers.

Pacific Edge (Bladder cancer)

Pacific Edge (PEB: $0.205) is commercializing a test for bladder cancer. The company is based in Dunedin New Zealand, just south of Queenstown. The company is listed on the ASX with most of its revenue being generated from the US. The company is seeking part of a US$10.4 billion market opportunity.

Pacific Edge bases its test on Negative Predictive Value (NPV). The company's Triage Plus test to rule out bladder cancer in patients with blood in the urine has a NPV of 99.4%.

From an economic perspective, what is important for the company is the percentage of patients that can be ruled out for further testing. Termed Rule-Out Rate, the Triage Plus test rules out further testing (cystoscopies and further imaging) in 84.1% of patients.

The overall result is that from 100 at-risk patients, rather than performing an invasive cystoscopy procedure in everyone, just 15 would require a cystoscopy with imaging, with 10 being negative and five being diagnosed as positive for bladder cancer.

From studies done with Kaiser Permanente in California, around US$500 is saved per patient from adopting the Pacific Edge diagnostic work model.

CEO Peter Meintjes said that what really matters is the utility of the test, as measured by NPV and PPV, which are the predictive values that are of use to the doctor. "Payors don't reimburse for sensitivity and specificity. They reimburse for changes in management and the utility (of the test). In our case the utility is the high NPV that drives the Rule-Out Rate which underpins the clinical utility and the economic utility."

Learnings from the last four years is that a new offering needs to outperform existing technology and processes. Important also for the company is using KOLs to help design the right clinical test so that the utility of the test will be commercially adopted by payors.

The keys to success are:
1. Ensuring assay accuracy and reproducibility
2. Clinical validity (sensitivity, specificity, NPV and PPV)
3. Clinical utility (randomized controlled study to show improved patient outcomes)
4. Real world evidence (showing the diagnostic works at a scale in routine care), and
5. Economic modelling

For investors it's important to note that predictive values shift with prevalence. "You need to identify at a really early stage what you are really doing," said Meintjes.

With respect to IP, the protection is around depth of prospective, real-world data in the intended use population highlighted Meintjes, which is hard to copy.

Meintjes believes the market has moved now, with investors wanting not just clinical evidence, but have also demonstrated commercial traction. Meintjes also believes consolidation in this space is inevitable for companies that can't chart a way to positive cashflow from their businesses.

Proteomics International (Diabetic kidney disease, esophagael cancer, endometriosis)

CEO David Morris joined Proteomics International (PIQ: $0.155) six months ago, with a mandate to focus on the commercialization of three Promarker tests to aid in the diagnosis and management of diabetic kidney disease, esophageal cancer, and endometriosis.

The test for kidney disease is a prognosis, that alerts patients with diabetes about the risk of developing kidney disease up to four years in advance. "The whole treatment regime can differ if you know that in advance," said Morris.

The second test is for esophageal cancer which is not common. The triggers for this are chronic reflux and Barrett's disease.

The third test, for endometriosis, affects one in 10 women in Australia. Morris confirmed that it is not about sensitivity and specificity but about hitting the right NPV or PPV.

Proteomics International has a high NPV in detecting diabetic kidney disease (95%-97%) and esophageal cancer (99.9%), and relatively high NPV in endometriosis (75%).

In detecting diabetic kidney disease means that it can be treated earlier and significantly reduce the associated treatment costs without early detection and intervention.

In people at risk of esophageal cancer, Proteomics International is seeking to substitute the invasive endoscopy procedure where patient compliance (every two to three years) can be poor. By incorporating the Proteomics tests, a negative result can delay the need for invasive testing.

A positive test result can also change the depth of surgical analysis for some of these difficult-to-diagnose diseases.

For endometriosis, the detection process can take up to 10 years. The company could perform 50,000 tests a year at between $1,000 - $1,500 per test in Australia alone. Morris said the market in the US is eight times bigger.

Continued over

The company's path to market is via a distributor that has access to the pathology and clinical networks. In July this year the company signed a three year distribution deal with Helius in Australia for the three tests. This will give Proteomics access to 2,000 patient collection centres and its GP and specialist network. The products are expected to be rolled out starting in the current financial year. Following that the company will look to commercialise in the US.

CLEO Diagnostics (Ovarian cancer)

CXCL10 forms the backbone of CLEO Diagnostics' (COV: $0.35) diagnostic assay, which is combined with other established biomarkers CA125 and HE4. When ovarian lesions are found, in 90% of cases the tumours are benign. Ovarian cancer is highly complex with around 30 different subtypes.

Dayna Louca, Head of Corporate development at CLEO Diagnostics, said that CA125 alone is very unreliable, with even exercising causing this marker to become elevated. Louca said that CXCL10 is elevated early in the disease.

CLEO has three separate markets it is aiming to position its diagnostic assay in for ovarian cancer. The fastest pathway to FDA clearance said Louca is as a presurgical test. The second application is measurement of tumour recurrence, which occurs in around 80% of patients. And finally the company's long-term vision is to move into ovarian cancer screening.

As a triage test for surgery, the company has achieved a sensitivity and specificity of 95% measured across 350 patients. The company is now conducting a pivotal study prior to seeking FDA approval for the first test. Blood samples have been collected from 514 women. The company is targeting FDA submission for the test in early 2027.

In ovarian cancer, missing tumours has potentially life changing consequences stressed Louca so achieving high sensitivity is essential. High specificity (low false positives) is also important to avoid unnecessary intervention. Louca also highlighted that a successful diagnostic does need to change clinical practice.

CLEO will launch initially with reimbursement under a miscellaneous CPT code (81599) before building up data from real world use to achieve a dedicated reimbursement code. Currently similar tests are reimbursed for up to US$900. The triage market is estimated to be between 2-3 million women each year. The company has also conducted a health economics study to show the cost benefits as well of implementing the CLEO test.

Panel Discussion

So how may test samples are required to change clinical practice? For accuracy, a power calculation needs to be conducted. Peter Meintjes said that this number can be quite low at times, with a recent power calculation conducted by Pacific Edge indicating that just 109 samples would be required to achieve 95% confidence. There is also an optics benefit around larger sample studies.

David Atkins believes the answer is in how good or bad the current standard-of-care is and how urgent is the problem that needs to be fixed. Dayna Louca said that if the company moves into a broader screening application, then a study as large as 20,000 patients may be required.

Leearne Hinch said that Inoviq's power calculation for the high-risk group revealed that 320 samples would be required. "But in terms of what would be accepted by clinicians, it's likely to be significantly higher than that." As a population screening tool, there needs to be a minimum of 10 ovarian cancers detected, which translates to a study involving 25,000 women. For that Invoviq would need to partner.

In colorectal cancer, companies that have taken screening tests to market have involved 50,000 participants. Hinch said this is why Inoviq is focused on high-risk screening (in ovarian cancer).

Henk-Jan Boele believes that it's much harder to convince private payors than the FDA. Historically studies to convince the major medical insurers are 10 times larger for medical devices than studies for the FDA. Insurance companies want much higher than 90% confidence in a test result which results in the requirement for substantially larger studies. Boele said the mean gap for medical devices from receiving FDA approval to receiving the first reimbursement is 5.6 years.

The way to 'hack' the system is to have your device adopted rapidly at a very low price to generate the large numbers required to convince private payors believes Boele.

So what would it cost to get to that point where full coverage in the US is achieved from the government and private insurers? Boele answered by saying that getting from approval to reimbursement is much more expensive than obtaining initial FDA approval. Depending on the indication, other panelists indicted this figure could be between $10 - $50 million.

On the question of does the sensitivity and specificity requirement change for the potential severity of disease, Anne-Louise Arnett believes that it does, that the impact of the false positive or false negative needs to be considered. Morris said that for esophageal cancer the sensitivity needs to be extremely high and is, at over 99%. However for endometriosis, the sensitivity does not need to be as high if it is still changing clinical practice.

On the question of key parts to their commercialization plans, for Boele from BlinkLab it's about being able to not just diagnose, but to also monitor disease progress and assess pharmaceutical interventions. This potentially opens up a whole new stream of revenue said Boele.

– Clinuvel cont'd from page 1

light of the strong business performance over this period. Over that time, product revenue has doubled from $48 million to $94 million in 2026, and net profit before tax has increased by 86% to $47.7 million.

The company has been investing in two other key programs over this period, Vitiligo and Neuracthel, a potentially high-margin, generic ACTH product. The company's cash balance has increased by 200% from $82.7 million to $252 million at June 30 this year.

A re-rating of the stock from a US listing is an unknown outcome, with the company's shares currently trading on the Nasdaq as Level II ADS. Just one third of the stock is held by Australian investors, with the balance predominantly in the US and Europe.

2026 Financial Results

For FY2026, revenue from product sales was down 1% to $94 million from the PCP, with net profit after tax down 6% to $33.9 million. The US market was down due to competing drugs in development for the treatment of EPP being made available to patients with EPP for no charge. European sales volumes increased by 13% over the year.

One drug candidate, bitopertin from Disc Medicine has been made available to patients with EPP under an Expanded Access Program. This drug candidate was originally trialed in schizophrenia by Roche. Clinuvel CEO Philippe Wolgen remains skeptical about this therapy in EPP.

Another drug in development is dersimelagon, which was licensed to Leo Pharma last month by Tanabe Pharma for US$425 million in upfront and short term milestones, plus longer term milestone payments and royalties. The drug candidate was submitted for FDA approval in June. The compound's side effects are mild-to-moderate, including nausea and the development of freckles.

Chronic use of the therapy will be a consideration. By comparison, Clinuvel's Scenesse therapy has been delivered over 21,500 times over 16 years with a very favourable and well established safety profit. A long-term Phase III safety and tolerability study in 301 subjects across 45 sites is continuing with dersimelagon. Dersimelagon is an orally delivered melanocortin-1 receptor agonist.

Wolgen indicated that he is not overly concerned with the current competitors. "We are pretty calm."

Peptide Delivery Technology Advances

Clinuvel's drug Scenesse is a peptide that is delivered as a depot injection that lasts for two months. Over several years the company has been developing a controlled-release, liquid injectable technology to allow more flexible dosing. The company has passed the proof-of-concept stage following positive results in a preclinical model.

Clinuvel is looking at a range of melanocortin peptides. Wolgen said that outside of Vitiligo, this is the most exciting development within the company, with very little competition.

The company is doubling the footprint of its Singapore R&D facility, where the peptide delivery development work is undertaken.

Vitiligo

Results from the first Phase III study in 200 patients with Vitiligo are due to be released in December, with a second Phase III study to begin in November this year. Pricing of Scenesse in Vilitigo is expected to be similar to the current price for EPP treatment. Patients are receiving seven injections over 20 weeks with narrowband UVB treatment (twice weekly), with the potential in the future for one to two maintenance injections each year.

Neuracthel

Neuracthel, a generic version of ACTH, is due to be filed with the European regulator this year. Whilst it may take 12-16 months to gain approval, Wolgen expects rapid penetration into the market, which will be sold directly to hospitals. There are between two to four competitors in various markets around the world.

Clinuvel is capitalized at $413 million.

Bioshares recommendation: **Buy**

(Note the shares may stop trading on the ASX and list on the Nasdaq market.)

Bioshares

Bioshares Model Portfolio (1 September 2026)

Company	Code	Price (current)	Price added to portfolio	Recommendation	Cap'n ($M)	Date added
Telix Pharmaceticals	TLX	$15.29	$7.85	Spec Buy A	$5,179	December 2021
Neuren Pharmaceuticals	NEU	$19.89	$3.25	Hold	$2,516	December 2021
PYC Therapeutics	PYC	$2.29	$1.03	Spec Hold A	$2,252	April 2025
Anteris Technologies	AVR	$11.91	$21.50	Spec Buy A	$1,179	September 2022
Clarity Pharmaceuticals	CU6	$2.33	$2.48	Spec Buy A	$869	August 2026
Cogstate	CGS	$3.04	$0.24	Hold	$520	April 2019
Clinuvel Pharmaceuticals	CUV	$8.24	$20.31	Buy	$413	November 2020
Aroa Biosurgery	ARX	$0.55	$1.11	Buy	$190	November 2021
Dimerix	DXB	$0.290	$0.09	Spec Buy A	$174	December 2018
Actinogen Medical	ACW	$0.041	$0.04	Spec Buy B	$147	Feb 2026
Blinklab	BB1	$0.760	$0.855	Spec Buy A	$116	January 2026
Amplia Therapeutics	ATX	$0.135	$0.061	Spec Buy A	$69	April 2024
Cyclopharm	CYC	$0.510	$2.87	Spec Hold A	$62	October 2023
Botanix Pharmaceuticals	BOT	$0.021	$0.17	Spec Hold B	$57	July 2025
Syntara	SNT	$0.026	$0.26	Spec Buy A	$50	December 2016
Clever Culture Systems	CC5	$0.014	$0.09	Spec Buy A	$30	April 2022
Acrux	ACR	$0.011	$0.01	Spec Buy C	$6	June 2026

IN:
None

OUT:
None

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 Some 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 of 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

Corporate Subscribers: Cogstate, Syntara, Dimerix, Neuren Pharmaceuticals, Aroa Biosurgery, Clinuvel Pharmaceuticals, Clever Culture Systems, Actinogen Medical, Acrux, Vaxxas, Ceretas

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