BELL POTTER

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**Speculative**

**See key risks on Page 5 and Biotechnology Risk Warning on Page 7. Speculative securities may not be suitable for Retail Clients.**


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# Kazia Therapeutics

## New In-license deal

**Recommendation**
Buy (unchanged)
**Price**
$1.36
**Target (12 months)**
$2.50 (previously $3.60)
**Risk**
Speculative

**GICS Sector**

**Healthcare Equipment and Services**

| Expected Return | |
|---|---|
| Capital growth | **83.8%** |
| Dividend yield | **0.0%** |
| Total expected return | **83.8%** |

| Company Data & Ratios | |
|---|---|
| Enterprise value | **$210.3m** |
| Market cap | **$176.3m** |
| Issued capital | **129.6m** |
| Free float | **100%** |
| Avg. daily val. (52wk) | **$1.9m** |
| 12 month price range | **$0.35 - $1.88** |

**Price Performance**

| | (1m) | (3m) | (12m) |
|---|---|---|---|
| Price (A$) | 1.60 | 1.21 | 0.38 |
| Absolute (%) | -13.48 | 14.52 | 264.57 |
| Rel market (%) | -17.01 | 7.57 | 229.21 |

**Absolute Price**


SOURCE: IRESS

## New In-License Deal

KZA recently announced an in-license deal under which it has acquired the rights to a new VEGFR3 inhibitor from the Hamburg based drug developer Evotec. Under the agreement Kazia will develop, manufacture and commercialise EVT801 in all territories and indications. It will pay an immediate upfront of €1m (A$1.6m) and contingent milestones of up to A$480 million related to achievement of clinical, regulatory and commercial outcomes and a tiered single-digit royalty on net sales.

This in-license agreement is consistent with Kazia's strategy to expand its drug pipeline via in-license deals. Other than the modest upfront we estimate Kazia will invest a further $8m - $10m in the phase I trial treating up to 90 patients across kidney, liver and soft tissue tumours. Further trials may follow pending the outcome of the initial human study.

VEGFR inhibitors have been a mainstay of cancer treatment for more than 2 decades and have a well understood mechanism of action. EVT801 is targeted towards a specific cellular receptor known as VEGFR3 – known to inhibit growth of new lymphatic vessels. The more targeted approach may result in an improved toxicity profile leading to longer duration of treatment. The company will also investigate combinations with checkpoint inhibitors.

## Investment View: Retain Buy (Spec)

The valuation attributes no value to EVT801 at this time. Our Buy (Speculative) rating remains, however valuation is reduced by 30% to $2.50 essentially reflecting the increased risk of dilution to shareholders associated with future development cost. KZA had cash at 31 March of $19.5m which we understand includes the US$4m upfront from the out license of Cantrixil but is before the US$11m due from Simcere (for the out license of paxalisib in China). Notional cash is approximately $34m. FY22/FY23 earnings now include $5m of expense in each year related to the phase 1 clinical trial of EVT801. Excluding the impact of any future license deal in paxalisib, we estimate KZA has a cash runway of approximately 18-24 months.

**Earnings Forecast**

| June Year End | FY20 | FY21e | FY22e | FY23e |
|---|---|---|---|---|
| Revenues $m | 1.0 | 18.7 | 4.5 | 46.2 |
| EBIT $m | -12.7 | -7.4 | -17.6 | 26.1 |
| NPAT (underlying) $m | -12.4 | -7.2 | -17.7 | 26.0 |
| NPAT (reported) $m | -12.4 | -7.2 | -17.7 | 26.0 |
| EPS underlying (cps) | -17.0 | -5.6 | -13.7 | 20.0 |
| EPS growth % | nm | nm | nm | nm |
| PER (x) | nm | nm | nm | 6.8 |
| FCF yield (%) | nm | nm | nm | nm |
| EV/EBITDA (x) | nm | nm | nm | nm |
| Dividend (cps) | - | - | - | - |
| Franking | 0% | 0% | 0% | 100% |
| Yield % | 0% | 0% | 0% | 0% |
| ROE % | -88% | -19% | -89% | 57% |

SOURCE: BELL POTTER SECURITIES ESTIMATES

# Next Generation VEGFR Inhibitor

## EVT801 Overview

VEGFR inhibitors have become of mainstay of cancer treatment for selected tumours over the last 20 years. These drugs target angiogenesis (the formation of new blood vessels) and thereby starve tumours of blood flow and reduce metastasis.

The downside of this drug class is the significant toxicity profile. In clinical trials of Nexavar, 44% of patients experience either grade 3 or 4 adverse events with the most common being diarrhea, abdomen pain and fatigue. This often leads to treatment being discontinued.

EVT801 is a pre-clinical-stage, small-molecule inhibitor of the lymphatic growth receptor VEGFR3. Its primary activity is to inhibit lymphangiogenesis, (the formation of new lymphatic vessels around a growing tumour) more than the inhibition of angiogenesis. Targeting lymphangiogenesis achieves many of the same objectives (as angiogenesis) but may avoid the problems of hypoxia induced resistance as well as further minimising metastatic spread of disease.

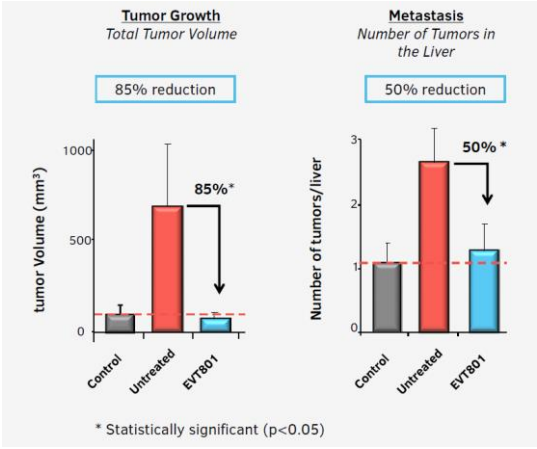
The theorised competitive advantages of EVT801 are:

- more favourable toxicity profile;
- more specific targeting to VEGFR3 compared to other marketed drugs in the class;
- less prone to development of treatment resistance; and
- greater inhibition of metastasis.

The first two bullet points are directly related with the consequence of potentially higher tolerability and therefore longer duration of treatment.

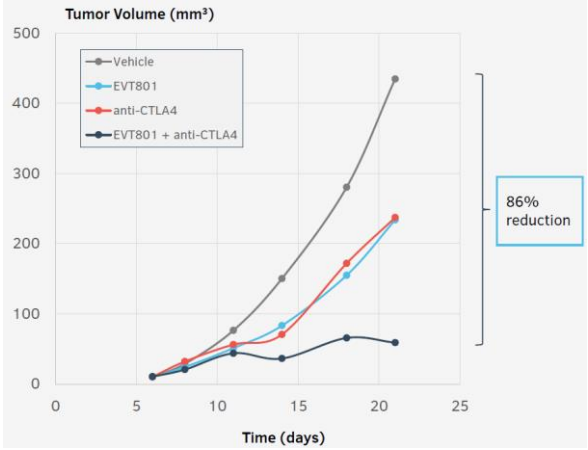
Kazia describes the data package supporting this in-license transaction as first class. Preclinical data has confirmed activity of EVT801 in the reduction in growth of primary tumours versus untreated comparator (in murine models) and appears to have a significant anti-metastatic effect.

**Figure 1 - Murine hepatocellular model**




SOURCE: COMPANY DATA

**Figure 2 – 4T1 tumour cell model, combination with Ipilimumab**




SOURCE: COMPANY DATA

The data in figure 1 is taken from an induced hepatocellular mouse model and shows a clear benefit from treatment with EVT801. Figure 2 demonstrates efficacy in a combination with Yervoy.

**PHASE I CLINICAL TRIAL**

Kazia is targeting commencement of a phase I trial in 2H CY21 in a range of advanced solid tumours in patients who have progressed on standard of care. This is normal for phase 1. The trial will take place in France (and not under an IND) under an arrangement with Evotec.

Endpoints of the trial will include safety and tolerability, mechanism of action and preliminary efficacy. Biomarkers will also be investigated to provide a deeper understanding of the EVT801 activity.

We expect the trial will include a dose escalation component. The draft protocol includes administration as both monotherapy and in combination with an IO drug (probably an anti CTLA4 inhibitor – Yervoy).

Initial targets are expected to include renal, hepatocellular and soft tissue cancers.

Kazia will initially utilise Evotec facilities for manufacturing and a range of other services.

**COMPETITIVE LANDSCAPE**

Marketed VEGFR inhibitors are listed in Figure 3. Each drug is approved in multiple indications, however, none is specifically targeted to VEGFR3.

**Figure 3 - Approved VEGFR inhibitors**

| | | Revenues A$ | | | | |
|---|---|---|---|---|---|---|
| Owner | Drug | 2019 | 20220 | Approval Date | Patent Expiry Date | Indicated Approvals |
| Bayer | Nexavar | 1,057.4 | 1,136.9 | 2005 | 2023-2028 | Hepatocellular Carcinoma<br>Renal Cell Carcinoma<br>Differentiated Thyroid Carcinoma<br>Gastrointestinal Stromal Tumor |
| Pfizer | Sutent | 1,189.5 | 1,346.7 | 2006 | 2021 | Advanced Renal Cell Carcinoma<br>Adjuvant Treatment of Renal Cell Carcinoma<br>Advanced Pancreatic Neuroendocrine Tumors |
| Novartis | Votrient | 922.3 | 1,086.3 | 2009 | 2021-2023 | Renal Cell Carcinoma<br>Soft Tissure Sarcoma |
| Pfizer | Inlyta | 1,143.1 | 686.3 | 2012 | 2025-2036 | First-Line Advanced Renal Cell Carcinoma<br>Second-Line Advanced Renal Cell Carcinoma |
| Boehringer-Ingleheim | Ofev | 2,319.2 | 3,196.5 | 2014 | 2024-2029 | Idiopathic Pulmonary Fibrosis<br>Chronic Fibrosing Interstitial Lung Diseases with a Progressive Phenotype<br>Systemic Sclerosis-Associated Interstitial Lung Disease |

SOURCE: BLOOMBERG, FDA

Figure 3 excludes Avastin (by Genentech) being a VEGF-A inhibitor which is approved in lung and certain breast cancers. It generates US$7bn in revenues annually.

**ADDRESSABLE MARKET**

Cumulative revenues from the drugs in figure 3 are approximately $7.4bn (2020) albeit these cover numerous indications some of which are relevant to EVT801. With the exception of Inlyta (Pfizer), revenues from each of the other drugs increased in CY2020. 1Q21 results from Pfizer indicate that Inlyta revenues are again increasing following an approval in combination with Keytruda in first line treatment for renal cancer.

Combination approvals (of a range of drug classes) with immune checkpoint inhibitors are very much in trend in oncology. As the range of indications for these combinations expands demand for these drugs (including VEGFR inhibitors) is expected to continue to increase.

The pre-clinical data package for EVT801 includes detailed confirmation of the mechanism of action across several tumour types together with data on combinations with immunotherapy agents. We expect a future phase 2 trial will involve a combination.

We note data in the KZA announcement regarding the potential for future revenues growth in this drug class. The research estimates the VEGFR inhibitor market to reach US$10.2 billion in annual sales by 2023, with annual growth of 8%. As the volume of combination approvals with IO drugs increases, this is probably not unreasonable. Immuno-oncology

remains the fastest growing section of the treatment market in solid tumours (excluding blood cancers).

**IP PROTECTION**

EVT801 is a new chemical entity and has strong IP protection via composition of matter patents which expire in 2032/2033 across most jurisdictions.

Upon registration, new chemical entities are subject to an immediate period of exclusivity of 5 years in the United States, irrespective of patents. Patent life extension measures may also become relevant if the drug becomes approved.

**Figure 3 - Summary of earnings changes**

| | 2021 | | | 2022 | | | 2023 | | |
|---|---|---|---|---|---|---|---|---|---|
| | New | Old | % change | New | Old | % change | New | Old | % change |
| Revenues | 18.7 | 18.7 | 0% | 4.5 | 4.5 | 0% | 46.2 | 46.2 | 0% |
| EBIT | -7.4 | -7.4 | 0% | -17.6 | -12.6 | -40% | 26.1 | 31.1 | -16% |
| NPAT | -7.2 | -7.2 | 0% | -17.7 | -12.7 | -39% | 26.0 | 31 | -16% |
| EPS | -5.6 | -5.6 | 0% | -13.7 | -9.8 | -39% | 20.0 | 23.9 | -16% |

SOURCE: BELL POTTER SECURITIES ESTIMATES

FY22/FY23 now include $5m of expense related to the development of EVT801.

Valuation is amended from $3.60 down to $2.50. The revised valuation target represents an adjustment to the discount rate in the DCF model to allow for the significant increase in clinical trial risk associated with EVT801. The risk of further dilution to shareholders is increased with this second asset in development.

The model does not include any future revenues from EVT801.

**Figure 4 - Clinical Program Overview**

| | Indication | Stage | n | Progress | Design | Sponsor | Registration |
|---|---|---|---|---|---|---|---|
| Paxalisib | Glioblastoma | Phase II | 30 | Completed recruitment | Single Arm, open label | Kazia Thereapeutics | NCT03522298 |
| | Glioblastoma GBM Agile | Phase II/III | up to 200 | Ethics approvals | Three treatment cohorts. Randomised controlled study | Alliance for clinical trials in Oncology and Genentech | NCT03970447 |
| | DIPG (childhood brain cancer) | Phase II | 27 | Active, Not Recruiting | Various treatment cohorts on paxalisib and radiation therapy | St Jude Children's Research Hospital | NCT03696355 |
| | Primary CNS Lymphoma | Phase II | 25 | Ethics approvals | Single Arm, open label | Dana Farber Cancer Institute | Not yet registered |
| | Brain Metastases | Phase II | 150 | Recruiting | Any brain metastses with clinically validated alternation in PI3K pathway | National Cancer Institute | NCT03994796 |
| | Brain metastases - breast cancer | Phase II | 47 | Recruiting | Non randomised, single arm, combination study of Paxalisib with Trastuzumab | Dana Farber Cancer Institute | NCT03765983 |
| | Brain Metastases - any source | Phase 1 | 36 | Recruiting | 3+3 dose escalation cohorts on paxalisib and radiation therapy | Memorial Sloan Kettering | NCT04192981 |
| | DIPG | Phase 1 | TBA | Ethics approvals | Paxalisib to be partnered with ONC022 | PNOC | TBA |
| EVT801 | Carious solid cancers | Phase 1 | ~90 | Planning | Dose escalating, multiple arm study including combination with Yervoy | Kazia Thereapeutics | TBA |

SOURCE: COMPANY DATA

# Key Risks

The key risks include but are not limited to the following items:

Kazia's ability to achieve profitability is dependent on a number of factors, including its ability to complete successful clinical trials, obtain regulatory approval for its products and successfully commercialise or partner Paxalisib and EVT801. There is no guarantee that the company will achieve these goals.

Kazia does not currently generate revenue from product sales and revenues are not anticipated in the short to medium term. The company is likely to continue to rely on shareholders to fund the business of the foreseeable future.

**CLINICAL TRIAL RISK**

KZA may be unable to secure necessary approvals from regulatory agencies and institutional bodies (clinics and hospitals) to conduct future clinical trials. There is also no assurance that either of the drugs under development will prove to be safe and efficacious in clinical trials, or that the regulatory approval to manufacture and market its products will be received. Clinical trials might also potentially expose the company to product liability claims in the event its products in development have unexpected effects on clinical subjects.

Paxalisib and EVT801 must undergo a comprehensive and highly regulated development and review process before receiving approval for marketing.

The company is also dependent on commercially attractive markets remaining available to it during the commercialisation phase and there is a risk that, once developed and ready for sale, commercial sales to fund sufficient revenues for continued operations and growth, may not be achieved.

**ARRANGEMENTS WITH THIRD-PARTY COLLABORATORS**

Kazia may pursue collaborative arrangements with pharmaceutical and life science companies, academic institutions or other partners to complete the development and commercialisation of its products (including for the GBM Agile study). These collaborators may be asked to assist with funding or performing clinical trials, manufacturing, regulatory approvals or product marketing. There is no assurance that Kazia will attract and retain appropriate strategic partners or that any such collaborators will perform and meet commercialisation goals. If Kazia is unable to find a partner, it would be required to develop and commercialise its products at its own expense. This may place significant demands on the Company's internal resources and potentially delay the commercialisation.

**REQUIREMENT TO RAISE ADDITIONAL FUNDS**

The company may be required to raise additional equity or debt capital in the future. There is no assurance that it will be able to raise that capital when it is required or, even if available, the terms may be unsatisfactory. If the company is unsuccessful in obtaining funds when they are required, it may need to delay or scale down its operations.

**INTELLECTUAL PROPERTY**

The company's ability to leverage its innovation and expertise depends upon its ability to protect its intellectual property and any improvements to it. The intellectual property may not be capable of being legally protected, it may be the subject of unauthorised disclosure or be unlawfully infringed, or the company may incur substantial costs in asserting or defending its intellectual property rights.

# Kazia Therapeutics
as at 10 May 2021

| | |
|---|---|
| Recommendation | Buy, Speculative |
| Price | $1.36 |
| Target (12 months) | $2.50 |

## Table 1 - Financial summary

| ` | FY19 | FY20 | FY21e | FY22e | FY23e |
|---|---|---|---|---|---|
| **Year Ending June** | | | | | |
| R&D incentive | 1.5 | 1.0 | 4.3 | 4.5 | 4.5 |
| License income - paxalisib | - | - | 9.2 | - | 41.7 |
| License income - Cantrixil | - | - | 5.2 | - | - |
| **Total Revenue** | **1.5** | **1.0** | **18.7** | **4.5** | **46.2** |
| COGS | - | - | - | - | - |
| Gross profit | 1.5 | 1.0 | 18.7 | 4.5 | 46.2 |
| | | | | | |
| R&D spend - paxalisib | -6.5 | -9.5 | -19.0 | -10.0 | -8.0 |
| R&D spend - EVT801 | 0.0 | 0.0 | 0.0 | -5.0 | -5.0 |
| Amortisation | -1.1 | -1.1 | -1.1 | -1.1 | -1.1 |
| Other expenses | -2.8 | -2.1 | -6.0 | -6.0 | -6.0 |
| Total Expenses | -12.2 | -13.7 | -26.1 | -22.1 | -20.1 |
| EBIT | -10.7 | -12.7 | -7.4 | -17.6 | 26.1 |
| Interest income | 0.0 | 0.0 | 0.2 | -0.1 | -0.1 |
| Pre tax profit | (10.6) | (12.7) | (7.2) | (17.7) | 26.0 |
| Tax expense | 0.3 | 0.3 | - | - | - |
| **NPAT- normalised** | **(10.3)** | **(12.4)** | **(7.2)** | **(17.7)** | **26.0** |
| Reported NPAT | (10.3) | (12.4) | (7.2) | (17.7) | 26.0 |

| Cashflow (A$m) | FY19 | FY20 | FY21e | FY22e | FY23e |
|---|---|---|---|---|---|
| Gross cashflow | -6.7 | -8.8 | -6.7 | -16.4 | 27.3 |
| Net interest | 0.0 | 0.0 | 0.2 | -0.1 | -0.1 |
| **Operating cash flow** | -6.7 | -8.8 | -6.5 | -16.5 | 27.2 |
| Clinical trial deposit - GBM Agile | 0.0 | 0.0 | -7.0 | 0.0 | 0.0 |
| **Free cash flow** | -6.7 | -8.8 | -13.5 | -16.5 | 27.2 |
| Other investments | 0.0 | 0.0 | -1.6 | 0.0 | 0.0 |
| Proceeds from issuance | 3.8 | 12.1 | 30.8 | 0.0 | 0.0 |
| Movement in borrowings | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Other | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Change in cash held** | -2.9 | 3.3 | 15.7 | -16.5 | 27.2 |
| Cash at beginning of period | 6.0 | 5.4 | 8.7 | 24.4 | 7.9 |
| FX adjustment | -0.1 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Cash at year end** | **5.4** | **8.7** | **24.4** | **7.9** | **35.0** |

| Balance Sheet (A$m) | FY19 | FY20 | FY21e | FY22e | FY23e |
|---|---|---|---|---|---|
| Cash | 5.4 | 8.7 | 24.4 | 7.9 | 35.0 |
| Receivables | 1.7 | 1.4 | 1.4 | 1.4 | 1.4 |
| Other current assets | 0.4 | 0.5 | 0.5 | 0.5 | 0.5 |
| Property, Plant and Equipment | - | - | - | - | - |
| Intangibles | 13.5 | 12.4 | 12.9 | 11.8 | 10.7 |
| Other non current assets | 0.2 | - | 7.0 | 7.0 | 7.0 |
| **Total assets** | 21.2 | 23.0 | 46.1 | 28.5 | 54.6 |
| Trade payables | 1.8 | 3.5 | 3.0 | 3.0 | 3.0 |
| Other liabilities | 1.4 | 1.8 | 1.9 | 2.0 | 2.1 |
| Deferred taxes | 3.7 | 3.4 | 3.4 | 3.4 | 3.4 |
| Provisions | 0.1 | 0.2 | 0.2 | 0.2 | 0.2 |
| **Total Liabilities** | 7.0 | 8.9 | 8.5 | 8.6 | 8.7 |
| **Net Assets** | 14.2 | 14.1 | 37.6 | 19.9 | 45.9 |
| Share capital | 36.6 | 48.8 | 79.6 | 79.6 | 79.6 |
| Other equity | 2.5 | 1.5 | 1.4 | 1.4 | 1.4 |
| Retained earnings | (24.9) | (36.2) | (43.4) | (61.1) | (35.1) |
| Reserves | - | - | - | - | - |
| **Shareholders Equity** | 14.2 | 14.1 | 37.6 | 19.9 | 45.9 |

| Valuation Ratios (A$m) | FY19 | FY20 | FY21e | FY22e | FY23e |
|---|---|---|---|---|---|
| Reported EPS (cps) | -16.6 | -17.0 | -5.6 | -13.7 | 20.0 |
| Normalised EPS (cps) | -16.6 | -17.0 | -5.6 | -13.7 | 20.0 |
| EPS growth (%) | nm | nm | nm | nm | nm |
| | | | | | |
| **PE(x)** | **nm** | **nm** | **nm** | **nm** | **6.8** |
| **EV/EBIT (x)** | nm | nm | nm | nm | nm |
| | | | | | |
| P/NTA (x) | 120.7 | 75.7 | 7.1 | 21.7 | - |
| Book Value Per Share (cps) | 22.9 | 14.9 | 29.0 | 15.4 | 35.4 |
| Price/Book (x) | 5.9 | 9.1 | 4.7 | 8.8 | 3.8 |
| | | | | | |
| DPS (cps) | - | - | - | - | - |
| Payout ratio % | 0% | 0% | 0% | 0% | 0% |
| Dividend Yield % | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| Franking % | 0% | 0% | 0% | 0% | 0% |
| FCF yield % | nm | nm | nm | nm | nm |
| | | | | | |
| Net debt/Equity | 0% | 0% | 0% | 0% | 0% |
| Net debt/Assets | 0% | 0% | 0% | 0% | 0% |
| Gearing | net cash | net cash | net cash | net cash | net cash |
| Net debt/EBITDA (x) | n/a | n/a | n/a | n/a | n/a |
| Interest cover (x) | n/a | n/a | n/a | n/a | n/a |

| Interim Results | 1H20 | 2H20 | 1H21 | 2H21e |
|---|---|---|---|---|
| Revenues | 0.6 | 0.4 | 0.0 | 18.7 |
| R&D Expense | -4.2 | -5.3 | -2.9 | -16.1 |
| Amortisation | -0.5 | -0.6 | -0.5 | -0.6 |
| All Other expenses | -1.9 | -0.2 | -3.0 | -3.0 |
| EBIT | -6.2 | -6.5 | -6.4 | -1.0 |

SOURCE: BELL POTTER SECURITIES ESTIMATES

**Recommendation structure**

**Buy:** Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

**Hold:** Expect total return between -5% and 15% on a 12 month view

**Sell:** Expect <-5% total return on a 12 month view

*Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.*

*Such investments may carry an exceptionally high level of capital risk and volatility of returns.*

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