



Biotech Daily

Wednesday April 1, 2020

Daily news on ASX-listed biotechnology companies

- * COVID-19 HITS ALL INDICES: MARCH BDI-40 DOWN 23%, ASX200 21%, BIG CAPS 5%
- * TODAY: ASX, BIOTECH UP: NANOSONICS UP 14.5%; ANTISENSE DOWN 6%
- * CE MARK FOR GENETIC SIGNATURES SARS-COV-2 DETECTION KIT
- * ALCIDION \$1.5m, 5-YEAR EXTENSION TO NHS FIFE PATIENTTRACK DEAL
- * US FDA ACCEPTS MESOBLAST RYONCIL GVHD APPLICATION, PRIORITY
- * OSPREY REQUESTS CAPITAL RAISING TRADING HALT
- * DORSAVI, THERANOW DEAL FOR PHYSIOTHERAPY TELEHEALTH
- * GENETIC TECHNOLOGIES: 100 BREAST, COLORECTAL CANCER KIT SALES
- * ONCOSIL PANCREATIC CANCER DEVICE CE MARK, UK 'BREAKTHROUGH'
- * PYC IN-VITRO MODELS 'EFFECTIVELY TREAT RETINITIS PIGMENTOSA'
- * MEDLAB COMPLETES DEPRESSION TRIAL, RESULTS BY JULY
- * RESAPP SLEEPCHECK AT-HOME SLEEP APNOEA TEST
- * EXOPHARM: 'COVID-19 HALTS PLEOXOVAL WOUND HEALING STUDY'
- * NOXOPHARM CLAIMS IDRONOXIL 'BLOCKS COVID-19 CYTOKINE STORMS'
- * PALLA UK BUSINESS OPTION EXPIRES, TALKS CONTINUE
- * CHINA TRADEMARK FOR TALI TRAIN, DETECT
- * BOD RECEIVES \$851k R&D TAX INCENTIVE
- * CRESO WINS \$896k UNIVO ISRAEL ORDER FOR CANADIAN MARIJUANA
- * GI DYNAMICS EXTENDS CRYSTAL AMBER NOTE
- * PERENNIAL CEASES IN RHINOMED
- * KARL PECHMANN REPLACES ONCOSIL CFO, CO SEC NICHOLAS FALZON
- * PAUL STEPHENSON REPLACES STEMCELL DIRECTOR EE TING NG

MARKET REPORT

The Australian stock market climbed 3.58 percent on Wednesday April 1, 2020, with the ASX200 up 181.8 points to 5,258.6 points. Twenty-six of the Biotech Daily Top 40 stocks were up, seven fell, three traded unchanged and four were untraded.

Nanosonics was the best, up 81 cents or 14.5 percent to \$6.41 with 1.9 million shares traded. Pharmaxis climbed 14.1 percent; Alterity, Genetic Signatures and Polynovo were up more than 12 percent; Actinogen, Compumedics and Medical Developments rose 10 percent or more; Mesoblast was up nine percent; Cynata, Orthocell and Pro Medicus were up more than eight percent; Immutep and Telix improved more than seven percent; Paradigm and Volpara were up six percent or more; Clinuvel, Imugene, Optiscan and Starpharma rose five percent or more; Cochlear, Neuren and Resonance climbed more than three percent; with Avita and Ellex up one percent or more.

Antisense led the falls, down 0.3 cents or 6.25 percent to 4.5 cents, with 791,336 shares traded. Next Science and Resmed fell more than four percent; Universal Biosensors lost 3.2 percent; with Kazia, LBT, Opthea and Uscom shedding two percent or more.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

As the Sars-Cov-2 virus spread across the planet, all investment indices were hit, but biotechnology was unexpectedly resilient.

It's not just that some companies might benefit from the production of vaccines, drugs, tests, ventilators or other equipment, but the ability to continue work remotely, with internet orders and payments, along with the re-opening of manufacturing in China, has made March a very mixed month.

While the ASX200 fell to its lowest level since March 2016, falling 21.2 percent in the month and 17.9 percent for the year, the Biotech Daily Top-40 Index (BDI-40) fell to its lowest level in just 10 months, down 23.2 percent for the month, but up 25.8 percent for the 12 months to March 31, 2020.

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) pretty much shrugged off the Covid-19 pandemic, sliding 4.8 percent in March to a collective market capitalization of \$182,223 million their lowest level since January and up 53.9 percent for the year to March 31, 2020.

In the US, the Nasdaq Biotechnology Index (NBI) lost 5.4 percent to 3,392 points, down 3.4 percent for the 12 months.

CSL shed \$9,401 million or 6.5 percent in March to \$134,707 million, its lowest market capitalization in all of 90 days and its third highest monthly market capitalization on record. Resmed was up one percent to \$35,497 million, with Cochlear tumbling during the month on news that surgeries would be cancelled, then recovering on a 10 percent over-subscribed \$880 million placement to lose just 0.5 percent in March to \$12,019 million.

Just seven of the BDI-40 companies were up, 32 fell and one was unchanged.

Genetic Signatures was the best of the few, up 56.6 percent to \$249 million on development of a test for Sars-Cov-2, the virus itself, while outside the BDI-40, Cellmid jumped 106.7 percent to \$31 million on news that it would distribute a Chinese test for Covid-19 illness antibodies.

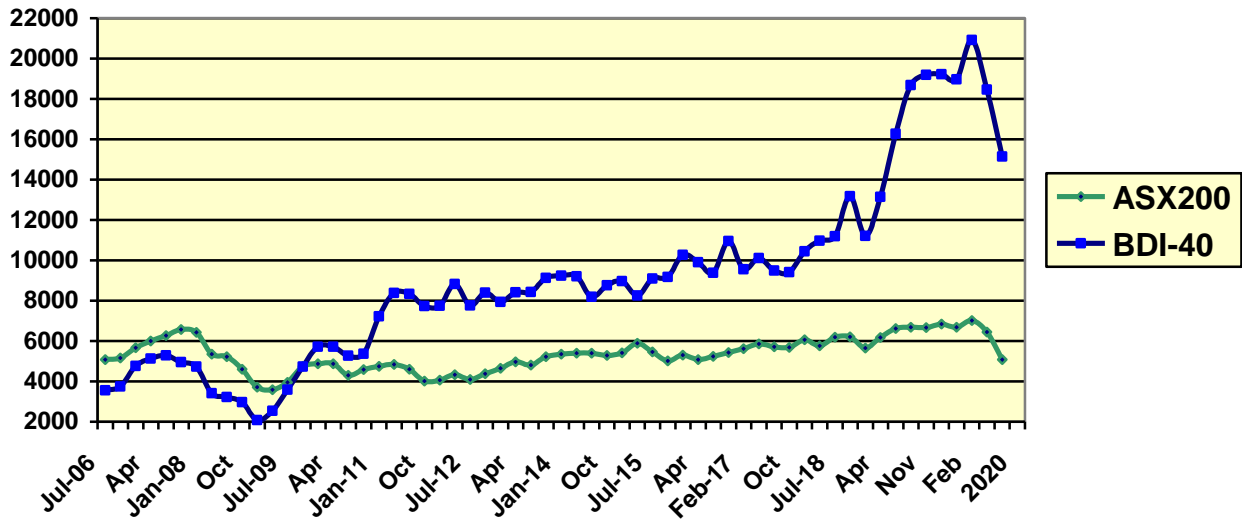
Alterity (Prana) was up 16.7 percent on what appeared to be unrelated trading, as were Dimerix (13.6%), Pharmaxis (9.1%), Oncosil (7.6%), Universal Biosensors (3.7%) and Cyclopharm (2.6%).

Outside the BDI-40, TBG jumped 883.3 percent prior to an announcement of Conformité Européenne (CE) mark approval for its Taiwan sister company's Sars-Cov-2 test, but has been suspended "pending further enquiries by ASX".

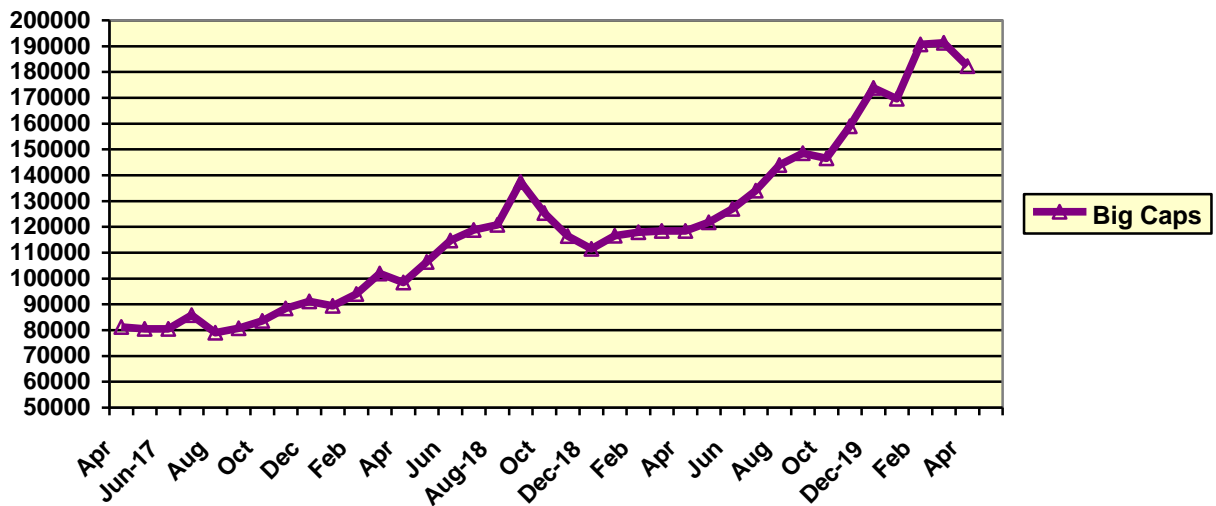
Allegra was up 50 percent to \$15 million, followed by Resapp (22.4%), Respiri (7.9%) and Medadvisor (2.8%)

All the marijuana companies fell, except for Lifespot Health which claimed a fever tracking device and climbed 66.7 percent from \$3 million to \$5 million. The 20 companies collectively fell a further 24.2 percent to \$578 million, down 62.3 percent in 12 months.

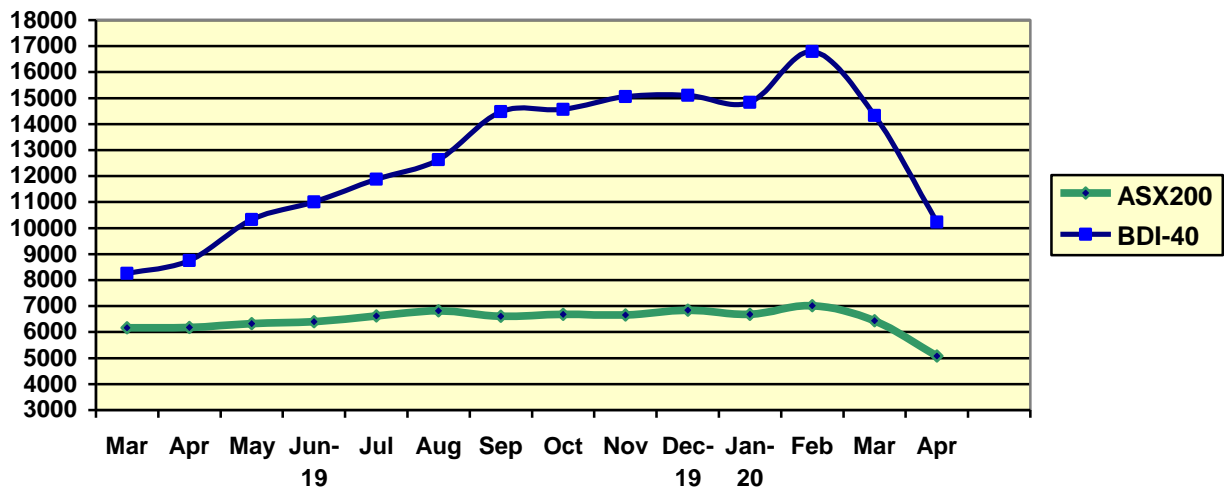
BDI-40 v ASX200 Jun 30, 2006 to Mar 31, 2020 - Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) Mar 31, 2017 – Mar 31, 2020



BDI-40 (\$m) v S&P ASX 200 – Mar 31, 2019 – Mar 31, 2020 (current, raw data)



GENETIC SIGNATURES

Genetic Signatures says it has received Conformité Européenne mark approval for its severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) detection kit.

In February, Genetic Signatures said its Easyscreen respiratory pathogen targeted an assay for all known coronaviruses, including Sars-Cov-2 (BD: Feb 26, 2020).

On Monday, the company said it had applied for approval in Europe and with the Australian Therapeutic Goods Administration for its real-time polymerase chain reaction (PCR) assay that identified the presence of Sars-Cov-2, and planned to apply for US Food and Drug Administration emergency use authorization (BD: Mar 30, 2020).

Genetic Signatures chief executive officer Dr John Melki said that the Covid-19 pandemic was “being fought on multiple fronts and our new molecular test will give healthcare workers in Europe a high throughput and accurate diagnostic solution to help combat this virus”.

“It is a significant achievement to attain registration so quickly, and our team should be proud of what they have done,” Dr Melki said.

The company said the Sars-Cov-2 detection kit could be used on Genetic Signatures highest throughput instrument, the GS-1000, which could process about 1,500 samples in a 24-hour period in a fully staffed laboratory in batches of 188 samples per run.

Genetic Signatures was up 21.5 cents or 12.3 percent to \$1.965 with 1.8 million shares traded.

ALCIDION GROUP

Alcidion says it has a \$1,470,000, five-year extension to UK National Health Service (NHS) Fife Patientrack agreement.

Alcidion said that under the extension, it would deploy Patientrack across the whole NHS Fife estate, including a minimum of 10 hospitals, two main acute hospitals and a network of community and day hospitals, amounting to about 1,342 beds.

Alcidion was up 1.5 cents or 11.5 percent to 14.5 cents with 5.7 million shares traded.

MESOBLAST

Mesoblast says the US Food and Drug Administration has accepted its Ryoncil or remstemcel-L biologics licence application for priority review.

Mesoblast said priority review would direct attention and resources to the evaluation of applications that significantly improved safety or effectiveness for a serious condition compared to standard applications.

The company said the FDA had set a September 30, 2020 Prescription Drug User Fee Act (PDUFA) action date and if approved, Ryoncil would become immediately available in the US for paediatric steroid-refractory acute graft versus host disease (GvHD).

Mesoblast chief executive officer Dr Silviu Itescu said the acceptance of the application was “an important milestone for the company”.

Mesoblast was up 12.5 cents or 9.0 percent to \$1.51 with 6.1 million shares traded.

OSPREY MEDICAL

Osprey has requested a trading halt “pending an announcement by Osprey in relation to a proposed capital raising”.

Trading will resume on April 3, 2020 or on an earlier announcement.

Osprey last traded at 1.5 cents.

DORSAVI

Dorsavi says it has a 12-month distribution agreement with US company Therainc, or Theranow, for virtual clinic telehealth for physiotherapists in Australia and the US. Dorsavi said it signed the Theranow agreement due to Covid-19 challenges, but it was too early to predict the impact of the agreement which would promote Theranow's telehealth platform to Dorsavi's wearable sensor technology customers. Dorsavi was up 0.4 cents or 40.0 percent to 1.4 cents with 1.3 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says that in the three months to March 21, 2020 it has sold 100 Genetype 'generation three' breast cancer and colorectal cancer test kits. Genetic Technologies said four patients who were not eligible for hereditary mutation testing and not identified as high risk during routine health checks, were identified by the Genetype test as potentially high risk of developing breast cancer. Genetic Tech was up 0.1 cents or 20 percent to 0.6 cents with 23.2 million shares traded.

ONCOSIL MEDICAL

Oncosil says it has received Conformité Européenne (CE) mark approval for its pancreatic cancer device and breakthrough designation from its EU reference body. Oncosil chief executive officer Daniel Kenny said the British Standards Institute "designation ... as a breakthrough device is a validation of our platform technology which can be used to treat solid tumor types such as liver, biliary duct and ... pancreatic cancer". "Having secured CE marking approval, our focus is now on multiple registration filings in jurisdictions which recognize CE marking certification," Mr Kenny said. Mr Kenny said the Covid-19 pandemic would not impact its CE mark approval, but it would "impact our launch preparedness and delay our European launch". Oncosil was up half a cent or 3.7 percent to 14 cents with 36.3 million shares traded.

PYC THERAPEUTICS (FORMERLY PHYLOGICA)

PYC says its lead drug candidate has effectively treated retinitis pigmentosa type 11 using its cell penetrating peptide-antisense oligonucleotide technology, in-vitro. PYC said it used retinal pigment epithelium (RPE) cells to assess the likely effectiveness of the drug for first-in-human testing, which it expected to begin next year. The company said it found that the drug mediated restoration of the scavenger function or self-repair process lost in retinitis pigmentosa type 11. PYC was up 0.9 cents or 15 percent to 6.9 cents with 18.4 million shares traded.

MEDLAB CLINICAL

Medlab says it has completed its Queensland University of Technology 150-patient trial of its probiotic NRGBiotic for depression, with results expected by July 2020. Medlab said it closed the trial early with 120 patients rather than the full 150 patients, after it found "a distinct trend line in the blinded trial data". The company said the trial investigated the use of NRGBiotic versus a placebo as an adjuvant with a selective serotonin reuptake inhibitor (SSRI) or a serotonin-norepinephrine reuptake inhibitor (SNRI) for depression. Medlab was up three cents or 15.8 percent to 22 cents.

RESAPP HEALTH

Resapp says it has developed an at-home obstructive sleep apnoea screening smartphone application, Sleepcheck, for use directly by consumers.

Resapp said the application used “clinically accurate algorithms to assess person’s risk of [obstructive sleep apnoea], by analyzing their breathing and snoring sounds during sleep”. Resapp was up half a cent or 2.6 percent to 20 cents with 11.6 million shares traded.

EXOPHARM

Exopharm says its Plexoval I exosome wound healing study has been disrupted by the Covid-19 outbreak and it is not clear if the study will be completed.

Exopharm said it would reduce recruitment numbers and it would instead focus on preparations and approval of the proposed off-the-shelf Plexaris allogeneic study.

Exopharm fell 1.5 cents or 8.8 percent to 15.5 cents.

NOXOPHARM

Noxopharm claims its idronoxil can block cytokine storms, believed to be responsible for most Covid-19 deaths.

Noxopharm said that Melbourne’s Hudson Institute of Medical Research identified that idronoxil inhibited “a key inflammatory pathway involved in a process known as a cytokine storm ... associated with an abnormally excessive inflammatory response and is believed to be responsible for most deaths in patients with Covid-19”.

In 2016, Noxopharm said that NOX66 delivered “high levels of the experimental anti-cancer drug idronoxil to the brain in rats and in 2018 said it had registered the trademark name ‘Veyonda’ for its anti-cancer compound NOX66 (BD: Nov 23, 2016; Aug 20, 2018).

Today, the company said it sought non-dilutive funding for a trial of idronoxil, for patients at risk of acute respiratory distress syndrome and Covid-19-related multi-organ failure.

Noxopharm climbed 13 cents or 92.9 percent to 27 cents with 7.7 million shares traded.

PALLA PHARMA

Palla Pharma says it has elected not to exercise an option to acquire an unnamed major UK customer but is still in negotiations and hopeful it will reach an agreement.

Palla said that in February, it entered into an option agreement with a UK customer to acquire its business and the option would expire on March 31, 2020.

The company said it expected negotiations to conclude “imminently”.

Palla was up one cent or 1.8 percent to 56 cents.

TALI DIGITAL (FORMERLY NOVITA HEALTH, AVEXA)

Tali says the China Trademark Office has issued a trademark for Tali, covering its Tali Train and Tali Detect products for autism spectrum and attention disorders.

Tali said Tali Train was classed as a class 41 service for education, tutoring, training and entertainment and its Tali Detect was classed as a class 44 medical analysis product for the diagnosis and treatment of persons.

The company said that about one percent of China’s 249 million children had autism spectrum disorder.

Tali was up 1.4 cents or 70 percent to 3.4 cents with 125.1 million shares traded.

[BOD AUSTRALIA](#)

Bod says it has received \$851,000 from the Australian Tax Officer under the Federal Government Research and Development Tax Incentive program.

Bod said the rebate related to research and development for the year to June 30, 2019.

Bod was up one cent or 5.1 percent to 20.5 cents.

[CRESO PHARMA](#)

Creso says its subsidiary Mernova Medicinal has received a \$C775,000 (\$A896,191) order to ship two strains of its Canadian marijuana to Israel's Univo Pharmaceuticals.

Creso said half would be paid within 10 business days of signing the order and half would be paid following delivery, which was expected within one month, subject to an export permit by Health Canada.

Creso was unchanged at 5.9 cents with 3.5 million shares traded.

[GI DYNAMICS](#)

GI Dynamics says it has extended the maturity date of its Crystal Amber Fund 2017 convertible notes from March 31 to May 1, 2020.

In 2017, GI Dynamics said it had a \$US5,000,000 (\$A6,595,767) convertible note financing with Crystal Amber to fund its 2017 working capital (BD: Jun 16, 2017).

Today, the company said Crystal Amber most recently extended the date from October 1, 2019 to March 30, 2020.

GI Dynamics was untraded at 0.3 cents.

[RHINOMED](#)

Perennial Value Management says it has ceased its substantial holding in Rhinomed.

Last October, IOOF Holdings, formerly the Independent Order of Oddfellows, with subsidiary Perennial, said it had become substantial in Rhinomed with 9,090,910 shares or 5.373 percent and later ceased in the company, but did not disclose how many shares it had sold (BD: Oct 8, 2019).

Today, the Sydney-based Perennial said that between March 24 and 27, 2020 it sold 633,000 shares for \$44,652 or 7.05 cents a share.

Rhinomed fell 0.2 cents or 2.7 percent to 7.1 cents.

[ONCOSIL MEDICAL](#)

Oncosil says it has appointed Karl Pechmann as chief financial officer and company secretary, replacing Nicholas Falzon.

Oncosil said Mr Pechmann was previously the chief financial officer and company secretary of regulatory technology company Kyckr and the finance director of Immutep.

[STEMCELL UNITED](#)

Stemcell says it has appointed Paul Stephenson as a director, replacing Ee Ting Ng.

Stemcell United said Mr Stephenson was a lawyer with Israeli law firm Efik & Co and was previously a partner of the Sydney-based HWL Ebsworth Lawyers for 13 years but retired in 2017 and continued as a consultant.

Stemcell was up 0.1 cents or 11.1 percent to one cent.

Biotech Daily Top 40 with Market Capitalization At March 31, 2020

Company \$Am	Apr-19	Mar-20	Apr-20
Cochlear	9,959	12,078	12,019
CSL	87,719	144,108	134,707
Resmed	20,704	35,152	35,497
BDI-40			
Avita	522	1,387	1,088
Clinuvel	1,217	985	944
Compumedics	80	120	58
Cyclopharm	75	76	78
Cynata	125	97	71
Ellex	85	101	75
Genetic Signatures	117	159	249
Immutep	112	129	51
Medical Developments	317	548	349
Mesoblast	691	1,311	744
Nanosonics	1,293	2,043	1,683
Neuren	118	182	99
Opthea	175	781	528
Paradigm	267	564	316
Pharmaxis	103	33	36
Polynovo	486	1,633	1,061
Pro Medicus	1,537	2,159	2,020
Starpharma	357	414	287
Telix	183	332	252
Volpara	224	301	236
Second 20			
Actinogen	59	27	22
Alterity (Prana)	25	12	14
Amplia (Innate)	5	5	4
Antisense	16	29	23
Dimerix	14	22	25
Impedimed	82	41	20
Imugene	69	99	86
Kazia	29	43	29
LBT Innovations	16	26	25
Next Science	179	330	231
Oncosil	25	79	85
Optiscan	19	13	10
Orthocell	12	55	46
Osprey	56	7	6
Patrys	27	14	14
Prescient	12	17	11
Proteomics	24	24	23
Resonance	37	65	49
Universal Biosensors	35	27	28
Uscom	25	46	37

* Biotech Daily editor, David Langsam, owns shares in Acrux, Alcidion, Alterity, Amplia, Cochlear, Cynata, Mesoblast, Nanosonics, Neuren, Patrys, Polynovo, Telix, Volpara and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in other biotech companies: <http://www.australianethical.com.au/who-we-invest-in>. These holdings are liable to change.

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