

Biotech Daily

Thursday March 28, 2024

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.99 percent on Thursday March 28, 2024, with the ASX200 up 77.3 points to 7,896.9 points. Twenty-six of the Biotech Daily Top 40 were up, eight fell and six traded unchanged. All three Big Caps were up.

Mesoblast was the best, up six cents or 12.1 percent to 55.5 cents, with 42.3 million shares traded. Prescient improved 10 percent; Cynata climbed 8.6 percent; Resonance rose 7.7 percent; Actinogen and Proteomics were up more than six percent; 4D Medical, Impedimed, Syntara (Pharmaxis) and Universal Biosensors were up five percent or more; Micro-X was up 4.35 percent; Atomo, Genetic Signatures and Medical Developments were up three percent or more; Alcidion, Curvebeam, Immutep, Neuren, Percheron (Antisense) and Polynovo rose two percent or more; Clinuvel, Orthocell and Pro Medicus were up more than one percent; with Avita, Cochlear, CSL, Nanosonics, Resmed and Telix up by less than one percent.

Compumedics led the falls, down 1.5 cents or 5.3 percent to 27 cents, with 5,894 shares traded. Clarity, Next Science and Starpharma lost three percent or more; Cyclopharm shed 2.2 percent; Dimerix and Emvision were down more than one percent; with SDI down by 0.6 percent.

DR BOREHAM'S CRUCIBLE: UNIVERSAL BIOSENSORS

By TIM BOREHAM

ASX code: UBI (Chess Depositary Instruments)

Share price: 20 cents; Market cap: \$46.2 million

Shares on issue: 231,400,768 (298,067,435 after completion of the \$12.5m capital raise)

Financials (calendar 2023): revenue \$6.63 million (up 47%), reported net loss after tax \$6.74 million (previous loss of \$26.85 million), cash of \$10.24 million (down 61%)

Chief executive: John Sharman

Board: Graham McLean (chair), Craig Coleman, David Hoey, Judith Smith

Identifiable major shareholders: Viburnum Funds (Craig Coleman) 24.8%, Richmond Hill Capital 10.65%, Jencay Capital 8.4%, Hancock & Gore 7.2%

When your columnist caught up with Universal Biosensors chief John Sharman early last Tuesday, he was exasperated about investor indifference towards the company.

Indeed. In the spirit of Easter, one could say the stock indeed had been crucified.

"It's a frustrating time but our key message is our sales are growing and we are investing heavily in sales infrastructure," Mr Sharman said. "Revenue is up, costs are down, the balance sheet is strong and we have world class opportunities, both in terms of rolling out the products and new opportunities."

A couple of hours later, Mr Sharman was much perkier after the US Food and Drug Administration (FDA) said it had approved its coagulation blood-testing tool, Xprecia Prime as a class-two device.

UBI shares shot up 50 percent - an impressive resurrection.

Xprecia Prime is the second-generation iteration of UBI's foundation blood glucose and coagulation testing platform, originally developed for Johnson & Johnson's Lifescan and Siemens Healthcare, respectively.

Mr Sharman dubs the FDA assent as an "historic moment", representing "more than 10 years of research and development work and many millions of dollars in investment."

Now, the company is applying its electro-mechanical testing platform to other pursuits including winery quality control (Sentia), diabetes monitoring for dogs and cats and water testing.

Currently the company has 11 revenue-generating products, which in December produced monthly revenue of \$1 million for the first time.

The evolution of UBI

Similar to the cartridge-and-printer model, UBI derived annuity revenue from its hand-held devices (the 'printers') and the single-use disposable strips (the 'cartridges').

The products are based on its proprietary electro-chemical sensing system, devised by a team led by CSIRO electro-chemist Dr Alistair Hodges.

UBI listed in December 2006 after raising \$22 million at 50 cents apiece.

For reasons lost in the mists of time, the company is incorporated in Joe Biden's home state of Delaware but is not listed in the US.

Mr Sharman was CEO of Medical Developments for 10 years, having previously run the nuclear imaging company Cyclopharm.

When he started, UBI derived most of its (modest) revenue from providing its Xprecia Stride blood coagulation monitoring strips to Siemens (for users of blood-thinning drugs, like warfarin). Siemens launched Xprecia Stride in 2015, but UBI bought back the rights in 2019.

In September 2018, US diagnostics giant Johnson & Johnson's Lifescan exercised its option to buy the rights to Universal's Xprecia Prime blood-glucose monitoring platform for \$44.6 million - a disappointing deal that trashed the share price - despite being clearly flagged in the original prospectus.

Xprecia Prime, was approved in Europe in February last year.

A CLIA advantage for Xprecia

The FDA approval for Xprecia Prime was accompanied by a Clinical Laboratory Improvement Amendment (CLIA) waiver, which is more momentous than its sounds.

As Mr Sharman explains, the waiver means the tests can be used by laboratories that are not necessarily medical facilities and administered by non-doctors (nurses).

The majority of US tests are done at such labs. "Because [coagulation] is more life-threatening than glucose, the FDA is very reluctant to allow [testing] outside of the hospitals," he says. "So, the agency did not take the decision lightly."

Technically, the tests are prothrombotic time (PT) and international normalised ratio (INR) assays.

In short, PT/INR tests check the dosage of vitamin K antagonists (such as warfarin). Too much efficacy means there's a risk of dangerous bleeding; too little means there's a risk of thrombosis.

At the end of 2023, 6,072 Xprecia devices had been sold in 36 countries, a year-on-year increase of 60 percent. Test strip sales grew 130 percent.

No need to wine about testing

Until now, busy vignerons have had to test their fermenting brews in separate procedures involving beakers and lots of fuss. The Sentia device enables instant hand-held testing of free sulphur dioxide, malic acid, glucose, fructose, acetic acid and titratable acidity. The company hopes to fill the obvious missing element - alcohol level testing.

The Sentia devices sell for just over \$2,000, with a per-strip cost of \$3.50 - a fraction of the cost of the current tests.

With more 100 million tests carried out each year, the wine market turns over \$US850 million (\$A1.1 billion) annually. Mr Sharman says 20 percent of Australian wineries have bought a Sentia device, as have seven percent of New Zealand and US wineries.

Elsewhere the take-up has been minimal, notably in Europe where only about 300 of the region's 100,000 wineries have come on board.

"We see [adoption by wineries in Australia] getting close to 40 percent and we see no reason why the US and the rest of the world won't get to those numbers in due course," Mr Sharman says.

The truth about cats and dogs

The company expects its Petrackr (sic) glucose testing device to be a howling success because owners will spend anything - or almost anything - to keep their treasured fluffballs healthy. At the same time, canine and feline obesity and diabetes levels are proliferating.

Currently, UBI sells Petrackr in the US, Canada, the UK, New Zealand and Australia and cites a \$300 million-a-year market, growing at 12 percent a year.

However, sales have been slower than expected since the product hit distributors' shelves in the September quarter last year.

"We thought we would do a couple of million of sales in the second [December] half, but we did just north of \$500,000," Mr Sharman says.

The key reason is that pet owners have about a year's supply of 50-70 strips for the incumbent product, sold by Zoetis.

UBI's opportunity arises because Zoetis is discontinuing its current product and is forcing customers to upgrade.

"We expect a large proportion of that market to move to Petrackr," Mr Sharman says.

Why?

"Our device is easily the best and significantly cheaper."

Need we have asked?

Oncology not forgotten

UBI has been developing an early warning test for the TN antigen which is expressed in at least 10 carcinomas including breast, lung, prostate, bladder and colorectal.

Apart from early diagnosis, the simple test could help physicians to test cancer progression from stage one to stage three. The trouble is, the test is only about 70 percent effective, when 90 percent efficacy is needed. UBI would need to spend \$10 million to \$20 million over the next three to five years to perfect a test – a time span the market is not willing to support.

Still, a reliable hand-held blood-based assay for a disease such as prostate cancer would be the Holy Grail of diagnosis.

Water good idea

With apologies to Danny Boy, the pipes, the pipes are calling for UBI by way of detecting heavy metal impurities in water.

UBI's initial focus is on copper and lead, while arsenic and cadmium are also problematic.

The company says about 180 million tests worth \$US5.4 billion are done each year, with about 100 million properties in Western countries serviced by lead water pipes.

Mr Sharman says these pipes are removed routinely when sites are redeveloped. That's fine, in theory: damaged, leaching lead pipes are dangerous. But many of these conduits are working fine and will do so for decades more.

"The quicker the [housing] development, the more the pipes are cut and the faster the contamination," Mr Sharman says.

UBI's device would enable house-to-house testing from the tap, enabling an accurate profile of where the problems lie. The company estimates one sample would cost around \$5, compared with \$60 for the current tests.

Mr Sharman says water test is a low-cost, near-term opportunity that could help the company progress to break-even.

Finances and performance

UBI pre-empted the March 19 FDA news by announcing a \$2.5 million institutional placement and a \$10 million non-renounceable rights issue. The raising, which requires shareholder assent, is struck at the then market rate of 15 cents.

The rights offer is underwritten by major shareholder Viburnum, which is represented on the UBI board by Craig Coleman.

The offer also included a one-for-one option, exercisable at 20 cents within three years.

In late February, UBI reported revenue of \$6.63 million for the calendar 2023 year, 47 percent higher and narrowed its net loss to \$6.74 million from \$26.85 million previously.

Product sales increased 66 percent to \$5.64 million, while services revenue declined 14 percent to \$990,000. The former is attributable to largely to Xprecia and Sentia sales and the latter to the company's legacy laboratory testing arm, HRL.

Over the last year, UBI shares have ranged between 31 cents (mid-August last year) and 14 cents (mid-March this year). They peaked at around \$2 in January 2010.

Wielding the scythe

Management has excised at least \$4 million from the company's cost base – items such as rent and power – and invested it in sales and marketing.

"Two years ago, we had one sales and marketing person; today we have 18," Mr Sharman says.

Given the testing platform is mature, the company needs to spend little on ongoing research and development. UBI's key challenge is to improve utilisation of its production facility, at rented premises at Rowville in eastern Melbourne.

While the factory spat out about two million strips last year, it can manage up to 70 million on a single shift, with no extra investment required.

Dr Boreham's diagnosis:

Mr Sharman likens the company to Roadshow Antiques, the multi-country TV franchise which appraises folks' trinkets in the hope of finding long-lost treasures.

"If everyone dusted off what Universal Biosensors had - especially around its technology - they would go 'wow'," he says.

Given its slew of opportunities, UBI indeed has the potential to become the next Ming dynasty vase of the sector, rather than a mass-produced ceramic pot. Within 14 to 18 months, sales from UBI's new and expanded products should flow in earnest - and it would not be a stretch for the company to double its revenue in 2024.

While investors have required oodles of patience, Mr Sharman promises that "greatness" is around the corner.

"Patience and persistence are not the same thing," he says. "You can patiently wait for things that are never going to come, but persistence requires you to put effort in to stay on the right path."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is yet to discover a Ming dynasty vase among the chipped and crazed op-shop Carlton Ware but will never relinquish the hunt

TELIX PHARMACEUTICALS

Telix says a Spanish hospital has conducted the first bladder cancer sentinel lymph node procedure using its Sensei miniature robotic-assisted gamma probe.

In an email to investors not released to the ASX, Telix said that the first use of the Sensei probe to detect radiation in patients and guide surgery was conducted at Hospital del Mar in Barcelona.

The company said that Sensei was "smaller than an AA battery and designed specifically for robotic-assisted and minimally invasive surgery ... [in] tight surgical spaces such as around the bladder".

Telix said that Sensei was indicated for use during sentinel lymph node biopsy in prostate, endometrial and cervical cancers.

The company said that as part of an investigator-initiated clinical trial, Sensei was used by the Hospital del Mar head of urology Dr Lluís Cecchini, with the da Vinci Xi surgical robotic platform in a patient scheduled for radical cystectomy and Bricker urinary diversion with sentinel lymph node biopsy.

"Lymph nodes around the bladder have a high chance of being cancerous and are therefore important to excise," Dr Cecchini said.

"Radio-guided surgery has historically been limited by the fact that gamma probes are generally only suitable for open surgery," Dr Cecchini said.

"The size and flexibility of Sensei meant it was easy to manipulate within the surgical cavity, see the gamma signal within the robotic console, and quickly locate the [sentinel lymph node], where I might otherwise not have known it was present," Dr Cecchini said. "Being able to perform the procedure with minimal impact on surrounding healthy tissue is a high surgical priority," Dr Cecchini said.

Telix said that its subsidiary Lightpoint Surgical developed the Sensei miniaturized surgical gamma probe for minimally invasive and robot-assisted surgery.

The company said that the device was approved for sale in the US, European Union, UK and Australia and was in clinical use in the US, UK, Germany, France, Netherlands, Belgium and Spain.

Telix said that Lightpoint was its medical technologies division.

Last year, Telix said it would buy the Chesham, England-based Lightpoint Medical and its Sensei radio-guided surgery business for up to \$US45 million (\$A51.6 million) in a combination of scrip or cash, later confirming the purchase (BD: Jun 22, Nov 2, 2023). Telix was up three cents or 0.2 percent to \$12.89 with 602,228 shares traded.

FISHER & PAYKEL HEALTHCARE CORPORATION

Fisher & Paykel says it has begun a voluntary limited recall of batches of its Airvo 2 and Myairvo 2 devices built before August 14, 2017, at an estimated cost of about \$12 million. Fisher & Paykel said the recall was due to a speaker issue that might have resulted in "distorted, intermittent or inaudible alarm sound levels" in its continuous positive airway sleep apnoea masks, and that the issue did not impact the device's therapeutic effect. The company said it expected costs for the recall to be about \$12 million, which it would include in its financial statements for the year to March 31, 2024.

Fisher & Paykel said it was "consulting with the various international regulatory authorities to initiate appropriate action in each country".

The company said it would contact distributors, dealers and hospitals that may have products subject to the recall and would replace any affected devices.

Fisher & Paykel said there were about 9,000 affected devices in use.

Fisher & Paykel fell 67 cents or 2.75 percent to \$23.66 with 976,991 shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has raised \$110 million at \$2.55 a sharein a \$101 million placement and a \$9 million institutional rights offer, with an \$11 million retail offer to follow.

On Tuesday, Clarity said it expected to raise \$121 million at \$2.55 a share, a 12.5 percent discount to its five-day volume weighted average price, in a fully-underwritten \$101 million placement and \$20 million, one-for-33 rights offer (BD: Mar 26, 2024).

Today, the company said the raise had "strong support from a broad range of new and existing institutional investors".

Clarity said Bell Potter was the sole underwriter and was joint lead manager with Wilsons Corporate Finance.

Clarity executive chair Dr Alan Taylor said it was "the first capital raising after the completion of the company's record \$92 million [initial public offer] capital raising on the ASX in August 2021".

"We are now very well positioned to maximize the value of our company in what has become one of the most exciting areas of the pharmaceutical industry, radiopharmaceuticals," Dr Taylor said.

Clarity fell 10 cents or 3.5 percent to \$2.75 with 1.4 million shares traded.

RESONANCE HEALTH

Resonance says Tokyo's medical imaging provider Micron Inc will sell Resonance imaging analysis products and services in Japan.

Resonance said Micron was a molecular imaging contract research organization that provided medical imaging and clinical trial support services to other organizations and companies.

The company said Micron would sell its magnetic resonance imaging (MRI)-based Ferriscan, Ferrismart, Hepafatscan, Hefafatsmart and Liversmart products through its 'Indicate' online platform and through "introductions to Micron's customers including its clinical trial partners".

Resonance did not disclose the commercial terms of the deal.

Resonance chief executive officer Andrew Harrison said Micron had "service provision to over 250 customers and our collaboration with them represents a great opportunity to deliver products and services into the large and lucrative Japanese market".

Resonance requested a trading halt until April 3, 2024 for an "acquisition" and last traded up half a cent or 7.7 percent at seven cents.

INHALERX

Inhalerx says it has taken a \$500,000 convertible loan facility with Melbourne's Peak Asset Management at 10 percent a year on the amounts drawn down.

Inhalerx said \$250,000 would be drawn-down on the execution of the agreement, with the remaining \$250,000 to be drawn-down six months after, and that the loan term was two years from the initial drawdown.

The company said the loan was convertible into shares by Peak at the lower of five cents or the 30-day volume weighted average price, and Peak would receive one option exercisable at five cents for every share converted.

Inhalerx said it would pay one percent in fees to Peak following the initial drawdown.

The company said the funds would be used for working capital and to prepare its phase II clinical trial of IRX211.

Inhalerx was untraded at five cents.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says the World Health Organization will publish standardized anaemia diagnosis guidelines based on its research of the disease. The Institute said that, in 2014, the World Health Organization requested its researchers to formally review its anaemia guidelines, which were last updated in 1968 and did not include children in the dataset.

WEHI said anaemia could be diagnosed by measuring haemoglobin in the blood, but there was no consensus on the thresholds that should be used to define the condition. The Institute said the revised guidelines would help alleviate the challenge of diagnosing anaemia by providing "a clear set of haemoglobin thresholds that could, for the first time, be uniformly used to harmonize the diagnosis and treatment of anaemia".

WEHI said it analyzed data from hundreds of thousands of healthy individuals, from multiple countries and found the haemoglobin threshold for diagnosing anaemia in children should be "slightly reduced".

The Institute said it conducted a genetic study on the correlation between ethnicity and haemoglobin thresholds, but found "no solid evidence to support changing the current recommendation based on ancestral background".

WEHI said the World Health Organization hoped to halve the prevalence of anaemia by 2025, and that the revised guidelines would "be a critical step towards achieving this". WEHI said the research article, titled 'Haemoglobin thresholds to define aneamia from 6 months to 65 years', was published in The Lancet Haematology, and was available at: https://www.thelancet.com/journals/lanhae/article/PIIS2352-3026(24)00030-9/fulltext.

WEHI's head of anaemia research Prof Sant-Rayn Pasricha said "a patient can be diagnosed with anaemia at one clinic but not the other, even within the same city". "As people living with anaemia often need ongoing treatment, every anaemia misdiagnosis causes unnecessary costs and pain," Prof Pasricha said.

"While the WHO guidelines are a key resource for health professionals in treating anaemia, experts also depend on other sources like medical textbooks and leading medical societies to guide patient treatment, but these resources can have varying information," Prof Pasricha said. "We hope these new guidelines will be adopted as the new global advice and help to reduce the health burden that continues to be inflicted by anaemia across the world."

ARGENICA THERAPEUTICS

Argenica says it has dosed the first of up-to 92-patients in its blinded, phase II trial of ARG-007 neuroprotective peptide compared to placebo for acute ischaemic stroke. In 2023, Argenica said Melbourne's St Vincent Hospital approved the trial, with a primary objective the safety of a single, intravenous dose of ARG-007, and a secondary objective to show the effect on reducing the volume of brain cell death (BD: Sep 12, 2023).

Today, Argenica said the patient was dosed at the Royal Melbourne Hospital, following a diagnosis of an acute ischaemic stroke cause by a large vessel occlusion.

Argenica said its data safety monitoring board would review patient safety following the dosing of the first five patients, with additional reviews following dosing of 23 patients, 46 patients, 69 patients and all 92 patients.

Argenica managing-director Dr Liz Dallimore said the company was "absolutely delighted to have officially commenced our phase II clinical trial by dosing our first stroke patient". "We will be carefully monitoring the recruitment of patients in this trial, and report progress as we go," Dr Dallimore said.

Argenica was up eight cents or 13.6 percent to 67 cents.

NYRADA INC

Nyrada says it has begun "good laboratory practice" pre-clinical studies of its NYR-BI03 for brain injury, in rats and dogs, to be completed this year.

Nyrada said the study would confirm a safe dose range for NYR-BI03, identify possible side effects, and include cardiac safety, pharmacology and toxicology tests.

The company said that it would use the study to begin a human phase I trial, expected by the end of this year, subject to positive outcomes.

Nyrada chief executive officer James Bonnar said "NYR-BI03 is a first-in-class therapy with a novel mechanism of action targeting significant market opportunity".

"Given the strong efficacy and positive safety signals from our pre-clinical stroke study, we have now commenced the necessary [good laboratory practice] studies that will lead to human trials for NYR-BI03," Mr Bonnar said.

In February, Nyrada says its NYR-BI03 "showed a significant neuro-protective signal providing strong evidence of efficacy" in mice (BD: Feb 28, 2024).

Nyrada was up 0.9 cents or 10 percent to 9.9 cents with 5.9 million shares traded.

WOKE PHARMACEUTICALS

Woke says it hopes to screen the final 80 of 160 patients and begin its phase IIb trial of the psilocybin-based WP002 for treatment-resistant depression by July 2024. In 2022, Woke said that with Melbourne's Swinburne University of Technology it would conduct a 150-patient phase IIb trial of its WP002 tablet, containing 25mg of psilocybin, with psychotherapy, for treatment-resistant depression and begin enrolment in "early 2023" (BD: Aug 16, 2022).

Today, the company said results were expected "around June next year". Woke is a private company.

REGENEUS

Regeneus says its extraordinary general meeting voted 98.5 percent in favor of its acquisition of Cambium Medical Technologies and its 'Cambium Bio' name change. Last month, Regeneus said it would acquire the Atlanta, Georgia-based Cambium Medical Technologies LLC for its Elate Ocular for dry eye disease in exchange for shares and 5.5 percent of future royalties, and become 'Cambium Bio' (BD: Feb 14, 2024).

At that time, the company said it had 306,436,915 shares on issue and would issue a further 306,436,915 shares to Cambium shareholders, and pay 5.5 percent of future revenue royalties, so long as the development costs did not exceed an aggregate of \$US20.5 million (\$A31.7 million).

In a separate announcement today, Regeneus said it was "currently working to finalize the last of the conditions to closing occurring, pursuant to the merger agreement" which it expected would be satisfied in the coming days.

Regeneus was unchanged at half a cent.

OSTEOPORE

Osteopore has requested a suspension "due to unexpected delays in completing the December 31, 2023 annual report".

Osteopore said the delay was "due to compiling information requested by [its] ... auditors". Trading will resume on April 30, 2024, or on the earlier announcement. Osteopore last traded at 30 cents.

AUDEARA

Audeara says its shareholders will vote to issue 5,000,000 options to chief executive officer Dr James Fielding, director Hsin-Chieh Peng and chair David Trimboli. Audeara said the extraordinary general meeting would vote to issue 1,750,000 options to Dr Fielding, 1,750,000 options to Mr Peng and 1,500,000 options to Mr Trimboli, exercisable at a 43 percent premium to the 30-day volume-weighted average price, within three years of issue.

The company said shareholders would vote to issue 592,332 shares, at 5.4 cents a share, to Mr Trimboli in lieu of director's fees.

The meeting will be held at Grant Thornton, King George Central, Level 18, 145 Ann Street, Brisbane on April 30, 2024 at 9am (AEST).

Audeara fell 0.2 cents or 3.9 percent to 4.9 cents.

NEUROTECH INTERNATIONAL

percent opposition (BD: Dec 22, 2023).

Merchant Funds Management says it has increased its substantial shareholding in Neurotech from 53,424,419 shares (6.03%) to 65,344,330 shares (7.12%). Perth's Merchant Funds said that between December 2023 and March 2024 it bought and sold shares, with the single largest purchase of 2,000,000 shares off-market in March for \$120,000, or 6.0 cents a share, and exercised 7,500,000 options for \$450,000 or 6.0 cents each.

According to data from Commsec, throughout March, Neurotech traded between 9.0 and 11.0 cents a share

Neurotech was up half a cent or 4.8 percent to 11 cents with 2.3 million shares traded.

MEDLAB CLINICAL

Medlab says chair Dr Sean Hall and director Michael Carter have resigned, with Edmond Tan and Tim Walker appointed non-executive directors, effective from today. Last year, Medlab said its extraordinary general meeting approved the sale of its subsidiary Medlab Pty Ltd and intellectual property to director Dr Hall, but with 32.4

Today, the company thanked Dr Hall and Mr Carter "for their time and diligent efforts in managing the company on a care-taker mode, since [it] entered [a] trading suspension". Medlab said Mr Tan was a director of Regenerate Pty Ltd and was Obsidian Global Partner's Australian representative.

The company said Mr Tan held a Bachelor of Commerce from Perth's Curtin University. Medlab said Mr Walker had experience in mergers and acquisitions in both Canada and Australia and had been a director at "various commodity groups".

The company said Mr Walker held a Bachelor of Commerce from Perth's University of Western Australia.

Medlab was in a suspension and last traded at a post-consolidation \$6.60.