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In this edition...

More and more, Mesoblast is shaping up as one of the most exciting biotech stocks on the market, with an expanding pipeline of products in development and a well articulated multi-pronged approach to commercialisation. Similarly, Universal Biosensors has the potential to generate returns from multiple product applications. We also update readers on problems faced by Acrux's competitors and a very positive endorsement of Cogstate's cognition test.

Readers should take the time to peruse Lester Crawford's contribution, titled 'Myths and Realities of the FDA'. Lester, a former head of the FDA, points out among other things that appealing an FDA regulatory decision is not a terminal mistake.

The Editors

Companies Covered: ACR, CGS, CXS, MSB, UBI

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.3%
Year 9 (May '09 - Current)	81.5%
Cumulative Gain	**253%**
Av Annual Gain (9 yrs)	**22.1%**

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Bioshares

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Mesoblast AGM Report

At the Mesoblast (MSB: $1.43) AGM, held in Melbourne on November 30, Chairman Brian Jamieson said that five years after listing, the company was ready commercialise its adult stem cell technology and was "poised to make a significant difference to millions of people by creating new treatment paradigms for massive diseases and disorders with clearly defined clinical requirements".

Jamieson said that significant de-risking had occurred. The manufacturing of Mesoblast's adult stem cell products was now industrialised, scalable and cheap. Furthermore, IP had been broadened and strengthened.

Mesoblast CEO, Silviu Itescu, said that it was a pivotal time for the company, which had now become a mid-staged clinical organisation with as many as eight different products moving towards registration.

Since listing, the company had raised $65.8 million, which had been applied to pre-clinical and clinical development and also invested in Angioblast Systems, in which it holds a 38.4% stake.

The company holds $15.8 million in cash, and with a cash burn of $8.2 million, has funds at hand that should enable the company to support two years of development activity.

Mesoblast has developed allogeneic stem products from mesenchymal pre-cursor stem cells that can potentially be applied to treat bone, cartilage, eye disease, bone marrow related diseases and cardiovascular conditions. A batch of Mesoblast's allogeneic stem cells can treat as many 20,000 unrelated people.

In discussing Mesoblast's adult stem cell products, Itescu said that "batch-to-batch consistency is the most important criteria", a feature that makes the products attractive to pharmaceutical companies.

Mesoblast has two Phase II trials underway for spinal fusion, one that is directed at lumber fusion, the other at cervical fusion. A Phase II trial that will evaluate the MPCs as a means to repair intervertebral discs will commence in 2010. It is possible that this new clinical indication could overtake the development of the spinal fusion products, with a primary end point from invertebral disc repair occurring at six months, compared to 12-24 months for the spinal fusion indications.

A Phase II trial in knee osteo-arthritis is also ongoing.

Cont'd over

Subscription Changes

Please note, from January 1, 2010, the price of an individual subscription to Bioshares will increase to $350 per 48 issues.

In the cardiovascular area, Mesoblast's investee company, Angioblast Systems, is conducting a Phase II trial for the use of MPCs to treat congestive heart failure patients, and is managing another Phase II trial to treat patients who have experienced heart attacks. A Phase I/II trial is ongoing in the area of bone marrow transplantation, for expanding umbilical cord blood. A Phase I trial in Age-related Macular Degeneration will commence in early 2010.

Interim data from the Phase II congestive heart failure trial showed that MPC treatment delivered a 9.6 point relative increase in ejection fraction at the six month mark. Although heart function data at 12 months will be the final endpoint, the impact of the treatment on mortality will be an outcome that many observers will pay close attention to.

Commercial Strategy

Itescu mapped out the company's commercial strategy, which comprises of four different approaches to getting the product to market or in generating income.

Broad-based licensing

For some products, Mesoblast will license its technology for pharmaceutical indications to drug firms, essentially where large and expensive Phase III trials are required. However, another consideration is that because it is broad-based licensing, then simultaneous development of multiple applications should be achievable. Mesoblast will be seeking one or more partners for lead programs as well as partners for second generation and non-core programs

Specific product licensing

A second approach will be to license specific applications, e.g. spinal indications, to medical device firms. However, Mesoblast is considering that in such instances it could write more favourable distribution deals because Phase III trial costs could be lower than for pharmaceutical indications. The emphasis in this strategy would be on working with a company with strength in distribution.

Company managed programs

The company also intends, as a third element of commercialisation, to take some products to market, using its own sales force. Such products would be niche in nature and not require expensive Phase III trials. Typically these niche indications would qualify as Orphan Drug Indications. The task would be to build an in-house sales and marketing team.

The Bone Marrow Transplantation (BMT) market is an area which Mesoblast (Angioblast) could potentially penetrate on its own efforts. According to Mesoblast (Angioblast), 17,000 bone marrow transplants were conducted in the USA in 2008, with another 39,000 performed in Europe. BMTs are used as a treatment for patients with blood-based cancers. The company believes that the introduction of an allogeneic BMT approach could triple the BMT market if an alternative to adult bone marrow existed that did not cause graft-versus host disease (GVHD). Umbilical cord blood offers a much lower risk of GVHD bust it less effective than bone marrow because not enough of the right kind of blood cells (hematopoietic stem cells- HSCs) are contained in the cord blood. Mesoblast (Angioblast) has observed that the application of MPCs can induce a 40-fold expansion of HSCs in co-culture. The company has obtained an Orphan Drug Designation for increasing HSCs in cancer patients needing an allogeneic BMT. The US national Institutes of Health has also funded a pilot trial for up to 30 patients who will receive MPC expanded cord blood HSCs.

Eighteen patients have been transplanted to date, with the median time to engraftment of neutrophil (a type of white blood cell) cells being 16.5 days (historic controls ~30 days) and the median time to platelet engraftment being 38.5 days (historic controls >90 days). One patient was recorded as experiencing Grade III GVHD, which can be compared to approximately 7 occurrences that would be expected to have occurred based on historic controls.

Mesoblast (Angioblast) intends to move this program to a Phase III trial on an accelerated basis.

Manufacturing

Mesoblast's fourth commercialisation strategy will be to control manufacturing and capture revenues from manufacturing and supply agreements.

Commentary

As Mesoblast has matured into a clinical stage biotech, managing a large pipeline of products in development (albeit across two intertwined corporate structures), it faces a not unwelcome problem of how best to fund these numerous opportunities yet maximise returns to shareholders. With such a deep pipeline, an argument exists for an additional and large capital raising to occur so that the company can put as many of its programs on a very secure footing going forward.

However, by setting out a commercialisation plan that includes broad-based partnering, specific product licensing activities and internally managed niche products program, the company is obviously looking to strike a balance in managing its funding requirements by sourcing partnering income as well as accessing capital markets for follow-on funding.

The company may also generate revenues if it is successful in achieving approval from the Australian TGA for a manufacturing process (as opposed to one or more indication based products), thus enabling MPC therapies to be administered under the Special Access Scheme.

We expect Mesoblast/Angioblast in 2010 will generate clinical data of a headline nature from at least three different trials, including data from the congestive heart failure trial, a disc degeneration trial, and with more data from the MPC/HSC trial in bone marrow transplant patients to also follow.

Mesoblast is capitalised at $198 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Universal Biosensors Update

Last month Universal Biosensors (UBI: $1.90) announced that its marketing partner **Lifescan (Johnson & Johnson**) received marketing clearance for the glucose monitoring system developed by UBI. This triggered a US$16 million milestone payment to UBI.

It is unclear for which region Lifescan received approval for at this stage. UBI expects to received revenue of at least $25 million for the 12 months from the first approval, which means that it expects to generate at least another $8 million of revenue over the next 11 months. This should come from manufacturing payment from Lifescan, and a 1 cent per glucose test strip that is made (by UBI or other manufacturers for Lifescan).

Current Capacity

At the moment UBI can make 750 million strips a year, and this could be increased to 1.5 billion strips a year without too much difficulty. Lifescan makes and sells around 4 billion glucose strips a year. We estimate in the first year UBI will make between 300-400 million strips (generating about $4 million in strip royalty and $4 million in manufacturing revenue).

It will take some time for Lifescan to convert its existing customer base from the old glucose system to the new UBI developed meters and strips. The money for UBI and Lifescan is not in the meters but in the strips, which sell for around 50 cents each. The UBI technology allows the strips to be made at a considerable cost savings to existing methods used by Lifescan and other strip manufacturers.

The ramping up of users for the new technology should allow UBI to build consistency in its revenue and profit growth. Revenue will also come from iterative improvements by UBI to what is now the second enhanced product. Such is the secrecy in this field that the improvements of the second improved model over the first model which was scrapped earlier this year will not be known until product launch.

The Long-Term Objective: A Steady Growth Curve for Sales and Profits

For UBI's board, it is crucial that the company becomes and maintains a profitable business from now, where profits from the glucose products are not simply reinvested into other diagnostic products. This means that commercialization of other diagnostics are likely be conducted through partnerships, similar to the Lifescan arrangement. For UBI, the aim is to deliver solid sales and profit growth similar to that which was achieved by **Resmed** and **Cochlear** after the J-curve of product sales has been passed.

UBI says it has achieved prototype development of the next generation of products of which it owns outright, which are all point-of-care tests. These are immunoassays called Prothrombin Time test (conducted currently in the lab to adjust correct chronic warfarin dosage) and C-reactive Protein (a lab-based test that measures broadly inflammation in the body). A D-dimer test (currently a lab-based blood clot test) is still in development.

The Holy Grail

All three of these tests at the moment need to be processed by pathology. The UBI technology offers arguable the Holy Grail of diagnostics, that being a point-of-care, quantitative, whole blood, finger prick biosensor test that gives a lab-like answer in seconds that can be conducted simply and easily by almost any user. The difference between these tests and the glucose monitor is that the immunoassay is more complicated, involving the reaction with an antibody, compared to the more straightforward standard electrochemical cell-type reaction used in the glucose meter.

Many companies have tried and failed in developing an immunoassay biosensor. These include **Oxford Biosensors** and locally **Ambri**. UBI believes it can do just that, having successfully completed prototype development of the first two tests. In the year ahead, UBI will be seeking to convince a major partner to co-invest in commercialization of these programs. The company has started or will start negotiating with potential partners this year. The Prothrombin Time test is scheduled for market launch in 2010 and the two other tests for market launch in 2011. While these goals are ambitious, the company has always operated such that any forward predictions have been made with justified confidence.

UBI has shown that it can completely re-engineer a complex diagnostic technology successfully with its first product due for market launch. The first product has validated the technology and the management and scientific teams' ability to deliver. It is also on track to be the first company to commercialise the first true, companion, immunoassay, biosensor test that has the potential to revolutionise the way that healthcare is practised.

UBI is capitalised at $299 million with an estimated $32 million in cash (including most recent Lifescan milestone).

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Contributed Commentary

Myths and Realities of the FDA

by Lester M. Crawford

Misperceptions abound, particularly in countries outside the US, about the operating style, management and culture of the Food and Drug Administration (FDA). Most of these misperceptions stem from distance, culture and lack of familiarity. Nonetheless, the slightest of these can pose a serious barrier to the almost universal goal of legitimizing international products by gaining FDA approval. Perhaps this essay will demythologize some of the more troublesome misperceptions.

A myth that is as enduring as it is fallacious goes something like this, "FDA may forgive, but they never forget." Coexistent with this old saw is a similar myth, "Appealing a regulatory decision to the next level is a terminal mistake for a company to make." In other words, your company is doomed for all time if you are not meek and mild in all your dealings with the Agency. As ludicrous as this sounds, I personally know many pharmaceutical executives who thoroughly believe this. First of all, to penalize a company for bad conduct by delaying or not approving an application would not be allowed in an agency that specializes in compliance with rules and procedures. Secondly, an FDA staffer caught doing so would be severely disciplined and perhaps prosecuted. FDA's darkest moments came when bribery was uncovered in the late 1980s. Since that time, tampering with the approval process out of spite or for personal gain has been anathema to the Agency. Finally, I worked in the Agency over a 34 year period and I never saw evidence of this kind of retribution.

Another pernicious myth gives rise to misconceptions such as these: "FDA is like a university or a research institute." Well, FDA is neither an academic nor a research organization. Some applied research is done and it is generally targeted towards a compliance or legal problem. And, most FDA professional staff have earned a master's or a doctoral level degree. But they do not go about contemplating the eternal verities or teaching the gifted. They go about meeting drug approval deadlines or prosecuting cases of malfeasances of various kinds. So, their mentality is the intelligent use of science in arriving at regulatory decisions.

Still another time-honored myth is, "FDA is not a litigious organization." Litigious may be too strong a word but a battalion of lawyers roil the FDA waters 24/7. All transactions with FDA must be pursued with legal counsel as serious members of your regulatory team. As sobering as this is to many industry personnel, it is as it should be. The relevant laws are the bases for regulations. Therefore, one cannot manage the regulations without an expert understanding of the antecedent laws. This does not mean that one goes before the FDA in fear and in trembling. It means that the "language" of FDA is a form of "law-speak" and that virtually every FDA function is consonant with the Federal Food Drug and Cosmetic Law. But it is always well to remember that since 2002, a number of companies, including the American Red Cross, have been fined over $500M for various infractions.

The last two myths are more like preconceived notions or defective hard-wiring. The first is, "If it is logical and scientifically sound, FDA will approve it." Let me assure all, it is possible to screw up the application process of the finest drug. And it is possible for FDA, in its rigor, to kill even the finest drug by inadvertently ordering questionable tests and trials, by shifting the requirements in the middle of the application process and by delay (the worst form of denial). And sometimes FDA is snared in its own trap by Draconian standards for certain classes of drugs such as those for cancer vaccines and for antibiotics. Whilst it is perfectly logical that certain cancer vaccines and antibiotics should be allowed on the market, it is not happening. Standards that require cancer vaccines to be tested in a manner that is only marginally ethical doom these projects before they begin. Similarly, antibiotics must meet such rigid requirements for assessment of resistogenic potential that none are being approved.

The final myth is, "FDA is like an advisory committee for industry." The illogic of this maxim is proved by a few essential truths. FDA has repeatedly announced over the past 20 years that it does not have the resources to constantly meet or be otherwise available to drug sponsors. FDA is not placed in the entrepreneurial position; the sponsor must do this and must have confidence in the promise of his discovery. FDAers have little experience in most cases in designing drug utility protocols. The clear intent of the FDA law is that the sponsor, not the Agency, must bear the responsibility for establishing the safety and efficacy of the candidate compound.

Dick Crout, the archetypal FDA leader who led CDER for over a decade, once said that FDAers are special people that are not especially motivated by the financial aspects of the drugs they regulate. Rather, they are motivated by the societal good that they are able to achieve. This makes them essential in the capitalistic, free enterprise system that characterizes the US. Not approving a bad drug, approving a good drug,uncovering a miscreant and writing an essential regulation are all things that fuel the altruistic spirit that has made the US FDA the world leader for 103 years. Thus, in a world desperately in need of myths, most are rather easily debunked. Myths do occasionally provide convenient excuses for a job not well done.

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Bioshares

Acrux Testosterone Competitor Stumbles, Again

Endo Pharmaceuticals, a testosterone product competitor to Acrux (ACR: $2.19) is having no luck with US regulators. In October the FDA asked for more questions relating to its testosterone gel, to be named Fortesta, believed to be a washing study, where men need to wash their hands to show the drug is not transferred to others. Endo licensed US rights to the gel from **Prostraken Group**, for US$10 million up front, a further US$40 million by the end of 2010, and up to US$160 million more if sales targets are met.

This week, another testosterone product in development called Aveed, a testosterone injection, also ran into problems with the FDA with concerns relating to the injection technique. The FDA rejected the company's marketing application and puts the program now in some doubt. Aveed was one of the key products accessed through the US$370 million acquisition this year of **Indevis Pharmaceuticals**. Aveed was estimated by analysts to reach sales of US$94 million by 2012.

Acrux's testosterone product has no such concerns. The product is applied with an applicator, therefore not coming into contact with the hands, and it is a transdermal lotion, so there will not be any injection-related concerns. The setback of Endo on two products highlights the potential value of the Axiron product from Acrux, which is due to be submitted for FDA approval.

Acrux has hired **Credit Suisse** to assist with negotiations in forming a commercial relationship for the product. Whilst a licensing and royalty arrangement is the expectation, the installation of Credit Suisse as a corporate Advisor suggests an acquisition may be more likely. However the problem is that Axiron has not been approved by the FDA so some risk will be retained by the acquiror. A licensing deal would allow for that risk to be apportioned through an upfront payment and the majority on approval and achievement of sales targets. An outright acquisition of the company would not provide for these safeguards for the acquiring company.

Another option is that the product alone could be acquired outright (for the US or global rights), allowing for a staggered payment based on signing then FDA approval.

Acrux is capitalised at $351 million.

Bioshares recommendation: **Speculative Hold Class A**

Bioshares

Cogstate Gets Positive Endorsement From GSK

Cogstate (CGS: $0.32) received a very positive endorsement from a **GlaxoSmithKline** representative (Nicola Scott), at a recent CNS (central nervous system) conference held in London last month. GSK has become a regular user of the Cogstate cognitive testing system in its Alzheimer's disease trials.

The appeal of the Costate product/service is that allows real time data analysis, where its competitors do not. This allows statistical analysis (through a Bayesian statistical system framework) to be conducted in proof-of-concept trials (not pivotal) as the trial is progressing, to predict chances of whether the trial will show efficacy or not.

Cogstate has developed a high level of expertise in cognitive monitoring in the Alzheimer's disease setting, hiring Dr John Harrison in 2007, who pioneered the Neuropsychological Test Battery, which was used by **Elan** and **Wyeth** in their recent Phase III Alzheimer's disease trial. This NTB system is a more sensitive system suitable for detecting smaller changes in cognitive function. According to Scott, the existing ADAS-cog system is no longer considered ideal, having limited sensitivity to drug effects and does not catch all cognitive domains. The preferred system is one that a broad battery of neuropsychological tests.

The problem remains that the Alzheimer's drugs that have been approved to date have been on this ADAS-cog measure as a primary endpoint. Whilst the FDA is prepared to accept other measures in pivotal studies, some uncertainty remains for companies proposing new cognitive testing systems.

This has restricted Cogstate (and its competitors) from having their systems used as primary endpoints in Phase III trials, although this market is still showing strong growth. In the future, a more useful cognitive testing system in pivotal studies would involve a combination of the ADAS-cog, the NTB and a cognitive testing software such as the Cogstate system.

Cogstate is capitalised at $21 million.

Bioshares recommendation: **Buy**

Bioshares

ChemGenex Pharmaceuticals AGM Report

ChemGenex Pharmaceuticals (CXS: $0.97) held its eighth AGM on November 30, 2009. Major achievements in the year gone by included submission of a New Drug Application for Omapro (to treat chronic myeloid leukemia patients who test positive for T315I and have failed therapy with first-line treatment) with the FDA and a Marketing Authorisation Application with the EMEA, in addition to the appointment of Tom DeZao as Chief Commercial Officer in the US and the conclusion of an $18.4 million capital raising. DeZao is tasked with the roll-out of Omapro in the US.

In the course of the year, the company also de-listed from Nasdaq, and de-registered with the SEC, citing significant costs imposed by these obligations as the deciding factor. Consequently, the board was reduced in size from 10 to seven members.

A Paradigm Shift

ChemGenex believes Omapro can be part of a paradigm shift in the treatment of CML. The pool of patients with CML has increased due to the successful treatment with a first-line therapy (imatinib) and second line drugs (dasatinib and nilotinib). However, resistance issues necessitate the need for a third line therapy, which is the opportunity Omapro is directed at, although it may also serve as a second line therapy as well. While the number of patients that Omapro will be available to treat initially will be in the low thousands, the accessible market is expected to increase as the number of patients who fail first and second line therapy increase.

The revenue possibilities for Omapro in the US may be quite lucrative on a per course of treatment basis, if the price of current drugs can be used as a guide. Annual courses of treatment with imatinib, dasatinib or nilotinib, range from US$49,304 (nilotinib 400mg) to US$105,601 (imatinib 800mg), on an annual average warehouse price basis.

Commercial Strategy

The company's strategy is to retain US rights for Omapro but outlicense the compound for European territories. The company expects that income generated from an EU licensing deal will help support the US roll-out of Omapro. The company believes that an initial sales force covering six geographic areas and targeting 37 major hematology hospitals (or centres of excellence) would be needed for an initial phase of marketing.

Chemgenex intends to finalise a European licensing arrangement before the end of the calendar year 2009. Our expectation is that such the announcement of such a deal will coincide with the annual meeting of the American Society of Hematology, being held in New Orleans from December 5-8.

Investigators associated with the clinical development of Omapro will present three papers at ASH. Chemgenex regards these presentations as valuable opportunities to further educate and inform oncologists prior to the expected launch of Omapro in H2 2010.

ChemGenex is capitalised at $274 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares Model Portfolio (4 December 2009)

Company	Price (current)	Price added to portfolio	Date added
Biodiem	$0.20	$0.15	October 2009
QRxPharma	$0.86	$0.25	December 2008
Hexima	$0.50	$0.60	October 2008
Atcor Medical	$0.20	$0.10	October 2008
CathRx	$0.66	$0.70	October 2008
Impedimed	$0.80	$0.70	August 2008
Mesoblast	$1.43	$1.25	August 2008
Circadian Technologies	$0.70	$1.03	February 2008
Patrys	$0.14	$0.50	December 2007
Bionomics	$0.35	$0.42	December 2007
Cogstate	$0.32	$0.13	November 2007
Sirtex Medical	$7.11	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.31	$0.66	September 2007
Starpharma Holdings	$0.57	$0.37	August 2007
Pharmaxis	$2.86	$3.15	August 2007
Universal Biosensors	$1.90	$1.23	June 2007
Probiotec	$2.53	$1.12	February 2007
Chemgenex Pharma.	$0.97	$0.38	June 2006
Acrux	$2.20	$0.83	November 2004
Alchemia	$0.75	$0.67	May 2004

Portfolio Changes – 4 December 2009

IN:
No changes.

OUT:
No changes.

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.

Group A

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

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

(CMP–Current Market Price)

Group B

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

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

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

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

Speculative Hold – Class A or B or C

Sell

Corporate Subscribers: Pharmaxis, Cytopia, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Peplin, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, CathRx, BioMd

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	$950	6-10 email addresses

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