

Nevada Doctor Reports Cherie Thibodeau to Attorney General's Office

Cherie Thibodeau, a fraudulent study broker, may not be working her scam much longer.

For the past few months, she has been trying to solicit Las Vegas area doctors for business, using a business card that says, "Cherie Thibodeau, M.D., PhD., Chief Medical Officer/Clinical Operations." As far as can be determined, Cherie Thibodeau does not have a license to practice medicine, and posing as someone with a medical license is an offense that is under the jurisdiction of the Attorney General's Office in Nevada.

One Nevada doctor, whose confidence Thibodeau gained, reported her to the

Attorney General's office last week.

Off and on between stints in California State Prison, Thibodeau has operated under several aliases, including Cherie Casio and Cherie Rivard, and last year, started claiming to have a medical degree. During the six years that CenterWatch has been reporting on her activities, Thibodeau has bilked numerous investigative sites across the U.S. out of potentially hundreds of thousands of dollars.

Recently, a doctor interested in working with Thibodeau to conduct clinical research in the Las Vegas area introduced Thibodeau to an informal gathering of primary care doctors also

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Three Clinical Trial Companies Form Cardiac Safety Network

Cardiac Technologies, Spacelabs Healthcare and Charles River Laboratories—three companies helping sponsors determine the effects of new drugs on the heart—have joined together to form a collaborative called The Cardiac Safety Network.

The network combines each vendor's core competencies dealing with clinical cardiac safety trials to offer sponsor clients a single point of contact for recruiting healthy volunteers, running studies and analyzing cardiac testing data.

"We believe there is a lot more that can be done to improve the rigor of cardiac safety testing and improve the scientific basis of that

testing. That is the major objective of our trying to work together, to bring the next level of technology to cardiac safety clinical trials," said Sasha Latypova, executive vice president of iCardiac Technologies.

Wilmington, Mass.-based Charles River Services, the clinical pharmacology division of Charles River Laboratories, has more than 300 phase I beds and dedicated wards for cardiac testing.

Rochester, N.Y.-based iCardiac has developed analytical techniques and biomarkers that address issues in cardiac safety today.

And Seattle, Wash.-based Spacelabs has

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Industry Briefs**CROs**

- Pennsylvania-based CRO **Encorium Group** reported mixed results for its third quarter of 2007. The company's net revenue more than doubled from \$3.7 million in 2007 to \$7.2 million during its third quarter. European operations constituted the bulk of the CRO's revenue at \$4.8 million with its North American business generating \$2.3 million. Encorium attributed the growth to the addition of Espoo, Finland-based CRO Remedium, acquired in November 2006. However, the company reported a net loss of \$1.28 million, double last year's \$643,000 for the comparable quarter. The company expects full year revenues of approximately \$31 million compared with \$15.3 million for the year ended Dec. 31, 2006. Encorium also appointed Linda Nardone, Ph.D. chief operating officer, a newly created position for the company. Prior to Encorium, Nardone was general manager for Zila Biotechnology where she oversaw a phase III drug product for oral cancer.
- **Parexel** is expanding its late phase research services and has appointed Dr. Victor Kiri, formerly with **GlaxoSmithKline**, as director of pharmacoepidemiology within the company's Clinical Research Services business. Kiri's responsibilities include advising clients on the design and conduct of comparative observational studies, offering epidemiological analysis for compounds in development, and guiding strategic decisions regarding future areas

of research and product development.

"Regulatory pressures are increasing client demand for pharmacoepidemiological assessments and related studies as part of late phase clinical development" said Mark A. Goldberg, M.D., president of Clinical Research Services and Perceptive Informatics at Parexel. "One of Parexel's strengths is our late phase development service offering that we call Peri-Approval Clinical Excellence or PACE. Dr. Kiri's in-depth experience in late phase study design and safety-related issues further expands our capabilities."

- San Diego, Calif.-based CRO **Syneract** has established an East Coast office in the U.S. in Research Triangle Park, N.C. The office will be used to drive the company's East Coast expansion plans and help with the difficulties associated with time-zone differences for both the U.S. and overseas. The office will initially be staffed with clinical operations personnel and will support projects in the region. Syneract will be hiring CRAs, project managers and sales management.

Technology

- Ottawa-based eClinical company **TrialStat** has launched a new version of Clinical-Analytics 4.0, the firm's EDC platform solution. ClinicalAnalytics 4.0 a more user-friendly front end and more advanced graphical reporting tools. It now can automate data entry validation and incorporates a secure browser interface.

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Features (continued from page 1)

Thibodeau

interested in conducting clinical research. One of the doctors present at this meeting spoke to *CWWeekly*. "Internists in this part of town are starting to do drug research clinical trials, and we had a meeting. One of the physicians was approached by Cherie with all kinds of organizational promises not only for drug studies, but she has a company to run your office and she has a computer tech guide to save you money on computers," said Howard J. Mason, M.D. "We filled out a lot of paperwork for Cherie, and we were going to pursue it. Cherie was emailing us a lot of forms on confidentiality and it looked on the up and up. To have somebody who's involved with connections who knows all the ins and outs is not a bad thing."

But Mason became suspicious. "Then it started to smell fishy when just last week she

asked if she could borrow one of our staff members to help Dr. [X]. That didn't sound right because we're a small office and we need everybody we have. It sounded like she was trying to hurry up Dr. [X] before [X] could do it right." Mason has broken all business ties with Thibodeau.

CenterWatch obtained a copy of a solicitation letter from an alert reader who recognized Thibodeau's name from previous articles in *CWWeekly* and *The CenterWatch Monthly*. That letter was sent by "Cherie Thibodeau, M.D." and "Dr. X" to Las Vegas area doctors on Oct. 3, 2007. The letter states that "Doctor X" has been selected to participate as a principal investigator in a phase IIa post-herpetic neuralgia clinical trial and is looking for "consulting physicians who are interested in referring patients who meet criteria for the study and enroll as possible participants." Thibodeau

promises compensation to doctors for patient referrals, which is unethical according to Good Clinical Practice.

Dr. X became suspicious of Thibodeau during the site review when she gave the monitor a different name than the doctor knew her by—Cherie Casio. When Dr. X asked her about it, Thibodeau claimed that Casio was her maiden name and that she preferred to use it.

Thibodeau's typical scam is to promise doctors that she will get them studies and handle administrative tasks for a percentage of the study budget. All payments go through her. Thibodeau starts off paying sites their fair share or enough of it for the first one or two studies and then pays them nothing and can't be reached. Lately, she's paid sites nothing at all, defrauding them of funds due them. Most recently, she bilked a site in Ohio out of \$5,000.

Cardiac Safety Network

one of the largest electrocardiogram (ECG) core labs in the industry and has the ability to bring iCardiac's new technologies to clinical trials by using them in the testing services it offers to sponsors.

A big component of the network revolves around the improvement of standard cardiac safety trials. Sponsors seek more advanced methods to test for safety issues. One of the challenges sponsors face when conducting

safety trials is analyzing the QT interval in a precise and cost effective way. This is the interval between heart beats and a sustained prolonging of that interval, as short as 500 milliseconds, could mean a patient is about to experience a life threatening arrhythmia.

In 2005, the FDA issued its ICH-H14 guidance, mandating that all new drugs to be tested for a prolongation of the QT interval. These are the kinds of early safety studies that can reveal serious cardiovascular issues with a drug or ultimately may clear it for its next stage of

testing. But these tests are not precise enough to catch all problems and can also produce false-positive results, killing potential drugs that may be safe.

"What our large pharmaceutical companies tell us is that they terminate inherently safe drugs because of the imprecision of this measurement," said Latypova.

iCardiac has developed software algorithms, biomarker development and testing methodologies.



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Profile: Investigative Site

NeuroTrials Research Atlanta, Ga.

An interview with Russell Rosenberg, Ph.D., president

How and why was NeuroTrials Research founded?

I have 20 years experience in sleep disorders medicine and research. Working within a very busy clinical setting in the Atlanta area, it became clear that there was a lot going on in sleep research and central nervous system (CNS) clinical trials but not much in our geographic area. Two of my colleagues, who are neurologists, and I decided to form NeuroTrials Research because there was increasing demand for us to do so. We were often approached to conduct studies because of our published articles about our extensive clinical work in the field. At first, research seemed to dovetail well with our clinical work but eventually we found that doing both together was not as advantageous as we thought it might be. We found that we needed to make NeuroTrials Research a separate entity.

What differentiates NeuroTrials Research from other sites?

Even though we are a dedicated site, the largest neurology practices and sleep medicine practices in Atlanta refer their patients to our studies. Some of the physicians from those practices also act as sub-investigators for our studies.

We are also involved in a fair number of investigator-initiated studies. We've done our own studies on products that already have FDA approval and expanded their science base. All of the principal investigators have been involved in advisory boards

for product development in terms of the science and development of protocols. That has given us a springboard for presenting our own protocols and making our own proposals to sponsors in areas which we have particular interest in.

One of the other things that differentiates us is that we are interested in the advancement and continuing education of our employees. Our internal mentoring program for coordinators has produced some excellent coordinators. We're looking to retain the best because that's important to our growth and to maintaining quality. Our turnover rate is very low.

What challenges do you face?

Given that we do sleep research, we have 24-hour operations almost every day of the year. That poses a particular challenge for us. We have to have evening teams, round-the-clock teams and round-the-clock physician availability to make decisions about various aspects of the protocol. That makes us unique and also allows us to easily handle the other kinds of CNS studies that we do, for example, Alzheimer's disease or multiple sclerosis, headache or other pain or epilepsy.

How has clinical research conduct changed in the past 10, 20 years?

We've seen a lot more sites trying to develop in the field. I think there's a misconception about how easy or lucrative it is to conduct clinical trials and that it's just something you add onto your practice as another

Year founded: 1997

Employees: 30

Therapeutic areas: Central nervous system and sleep, phase II to IV

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Web site: www.neurotrials.com

er revenue source. I've seen some of those sites come and go fairly quickly. I think there's more variability now in terms of the quality of sites based on how serious or how well-trained they are in the research field. There are some great physicians who want to be doing clinical trials in certain areas, but they don't have the training or the staff expertise to conduct clinical research, especially as complex as sleep research where you need a 24-hour team.

How have you grown and how will you grow?

We've just moved into a larger, 14,000-square-foot facility, which is a state-of-the-art clinical research center with a sleep laboratory attached. We also have The Atlanta School of Sleep Medicine and Technology in the same building where we provide education and training for physicians and technologists in the sleep field. Over the last five years, we've had an average of 20% growth each year in our personnel, our space and the numbers of studies we're doing. I attribute that to two things. First, there are more products in the pipeline in the CNS and sleep areas. Second, we have a tremendous amount of repeat business. In fact, CROs and sponsors that place a study with us typically use our site for the multiple studies needed throughout the development cycle of the investigational product.



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Drug & Device Pipeline News

Company	Drug/Device	Therapeutic Area	Status	Sponsor Info
Athersys	MultiStem	bone marrow transplantation	IND approved, phase I trials planned	(216) 431-9900 www.athersys.com
AVANT Immunotherapeutics	EPEC and cholera vaccine	enterotoxigenic <i>Escherichia coli</i> /cholera	Phase I trials planned enrolling 64 subjects in the US	(781) 433-0771 www.avantimmune.com
Quark Pharmaceuticals	AKli-5	Acute Renal Failure	Phase I trials initiated in the US, Europe and Israel	(510) 402-4020 www.quarkpharma.com
Cytochroma	CTAP101 Capsules	vitamin D insufficiency	Phase I/II trials initiated	(905) 479-5306 www.cytochroma.com
Peregrine Pharmaceuticals	bavituximab	breast cancer	Phase II trials planned enrolling 46 subjects in the Republic of Georgia	(714) 508-6000 www.peregrineinc.com
BioXell	Elocalcitol	male infertility	Phase IIa trials initiated enrolling 234 subjects in Italy	+39 02 21049 51 www.bioxell.com
Aradigm	inhaled ciprofloxacin	cystic fibrosis	Phase II trials initiated enrolling 24 subjects in Australia and New Zealand	(510) 265-9000 www.aradigm.com
Array BioPharma	ARRY-797	dental pain	Phase II trials initiated enrolling 150 subjects in the US	(303) 381-6600 www.arraybiopharma.com
BiPar Sciences	BSI-201	breast cancer	Phase II trials initiated enrolling 120 subjects	(650) 635-6050 www.biparsciences.com
Hana Biosciences	Marqibo	malignant uveal melanoma	Phase II trials initiated enrolling 30 subjects in the US	(650) 588-6404 www.hanabiosciences.com
Innovive	Tamibarotene	acute promyelocytic leukemia	Phase II trials initiated enrolling 50 subjects internationally	(212) 716 1810 www.innovivepharma.com
Novartis	QVA149	chronic obstructive pulmonary disease	Phase II trials initiated www.novartis.com	+41 61 324 11 11
Novoxel	NXL-103	community-acquired pneumonia	Phase II trials initiated enrolling 300 subjects internationally	+33 1 5714 0777 www.novoxel.com
Topigen	TPI 1020	chronic obstructive pulmonary disease	Phase II trials initiated enrolling 50 subjects	(514) 868-0077 www.topigen.com
Cogentus	CGT-2168	bleeding due to antiplatelet therapy	Phase III trials initiated enrolling 4,000 subjects internationally	(650) 543-4730 www.cogentus.net
Genmab/ GlaxoSmithKline	ofatumumab	rheumatoid arthritis	Phase III trials initiated enrolling 500 subjects	(888) 825-5249 www.gsk.com
Vivus	Qnexa	obesity	Phase III trials initiated enrolling 2,500 subjects	(650) 934-5200 www.vivus.com



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Trial Results

Endocrinology

- Novo Nordisk** released positive results from a phase II trial of **liraglutide** for the treatment of obesity. This trial enrolled 564 subjects with an average baseline weight of just below 100 kg. Following a two-week run-in period, the subjects were randomized to receive placebo, increasing doses of liraglutide or to an open-labeled control arm with orlistat, for a treatment period of twenty weeks. Results showed that liraglutide given once daily at the highest dose led to a weight loss from baseline of just above 7 kg, compared to a weight loss of just above 4 kg in the orlistat arm and a weight loss of just below 3 kg in the placebo arm. All tested doses of liraglutide reduced body weight; more than 75% of those treated with the highest dose experienced a weight loss larger than 5%, and more than 25% experienced a weight loss larger than 10% relative to their baseline body weight. In addition, pre-diabetes symptoms were observed in approximately 30% of all the subjects at baseline. After 20 weeks of treatment with any dose of liraglutide, between 80% and 90% of these subjects no longer showed signs of pre-diabetes, compared to 40% in the placebo- and orlistat-treated groups. Based on the results Novo Nordisk plans to move forward with the development of liraglutide for the treatment of obesity.

Immunology/ Infectious Disease

- Novartis** reported positive results from a phase II trial of **Menveo**, a vaccine for the prevention of meningitis in infants. This trial enrolled 175 infants who were randomized to receive either two doses of Menveo at both six and 12 months of age, one dose of Menveo at 12 months or a currently approved meningococcal meningitis serogroup C vaccine also at 12 months and then followed by Menveo at 18 months. Following vaccination, the infants were measured for immune response to antigens via the hSBA, or the human serum bactericidal antibody assay. One month after vaccination, infants receiving Menveo achieved protective antibody levels >1:4 for all four meningococcal serogroups (A, C, W-135 and Y). After two doses of Menveo, the percentage of infants achieving hSBA titer >1:4 was 100% for the serogroups C, W-135 and Y35 and 86% for serogroup A. After a single dose of Menveo at 12 months, the percentages were > 93% for serogroups C and W-135 and > 75% for serogroups A and Y. Of the infants who received the Menveo booster at 18 months following a single dose at 12 months, 100% achieved hSBA titers > 1:4 for serogroup C, 62% for A, 84% for W-135 and 81% for Y. Treatment was well tolerated in this population. Treatment was well tolerated. Phase III trials are underway and regulatory submissions are expected in 2008.
- Advanced Life Sciences** reported positive results from a phase III trial of **cethromycin** for the treatment of communi-

ty-acquired pneumonia. This double-blind, randomized, comparator study, dubbed CL-05, enrolled 584 adult subjects in the U.S., Canada and South Africa. The subjects received cethromycin 300 mg once daily or Biaxin 250 mg twice-daily, the current standard of care, for seven days. The primary efficacy endpoint was statistical non-inferiority in the clinical cure rate at the test-of-cure visit between the two treatment arms. This endpoint was achieved, with a clinical cure rate in the cethromycin group of 94.0% compared to Biaxin with a cure rate of 93.8%. In the bacteriologically evaluable population, cethromycin had a clinical cure rate of 95.9% compared to Biaxin with a cure rate of 97.1%. Treatment was well tolerated. Based on the results, Advanced Life Sciences plans to move towards the filing of an NDA with the FDA.

Oncology

- Genentech** reported positive results from a phase II trial of **Avastin** for the treatment of glioblastoma multiforme (GBM). This open-label, multicenter, randomized, non-comparative study enrolled 167 subjects with GBM whose cancer had relapsed after first- or second-line therapy, all of whom had received prior temozolimide. The subjects were randomized to receive Avastin alone or in combination with irinotecan every other week for up to 104 weeks. The primary endpoints were six-month progression-free survival

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[from paper to people]

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Trial Results (continued from page 6)

(PFS) and objective response rate. The PFS rates were 36% and 51% in the Avastin-alone and Avastin plus chemotherapy arms, respectively. Preliminary tumor responses were observed in 21% of the Avastin alone arm and in 34% of the Avastin plus chemotherapy arm. Treatment was generally well tolerated. Based on the data Genentech plans to meet with the FDA in order to determine the next step of action towards regulatory filing.

- **Thallion** reported positive results from a phase I/II trial of **ECO-4601** for the treatment of advanced cancers. The trial enrolled 26 subjects who were refractory to their respective standard of care therapy. ECO-4601 was administered in 21 day cycles consisting of a two week continuous intravenous infusion followed by a one-week rest period. The trial was conducted in two portions. In the first portion, 14 subjects received escalating doses ranging from 30 to 480mg/m²/day to assess safety, pharmacokinetics and maximum tolerated dose. In the second portion of the trial, 12 subjects were treated at the highest dose, 480mg/m²/day. Treatment was well tolerated and the maximum target dose was attained before the maximum tolerated dose was reached. Pharmacokinetic data demonstrated that estimated therapeutic plasma concentrations of ECO-4601 were reached at the higher doses and that ECO-4601 was rapidly eliminated from the bloodstream following infusion. In addition, six of seven subjects with refractory cancer who

had completed six cycles of treatment achieved stable disease. Based on the results, phase II trials were expected to be initiated in early 2008.

Rheumatology

- **Cypress and Forest** issued positive composite responder results from two phase III trials of **milnacipran** for the treatment of fibromyalgia. Study MLN-MD-02 was a double-blind, placebo-controlled design and enrolled 1,196 subjects who were randomized to receive either milnacipran 100 mg/day, 200 mg/day or placebo over a three-month period. Study FMS-031 was a double-blind, placebo-controlled trial and enrolled 888 subjects who were randomized to receive either milnacipran 100 mg/day, 200 mg/day or placebo for six months. To be considered a responder for the composite "pain of fibromyalgia" endpoint, each subject had to demonstrate concurrent and clinically meaningful improvements in two validated measures: pain and global impression of disease status. Pain composite responders were defined as individuals who achieved both a greater than or equal to 30% reduction in pain from baseline and who rated themselves as "very much improved" or "much improved" on a Patient Global Impression of Change (PGIC) scale. To be considered a composite responder for the "treatment of the fibromyalgia syndrome" endpoint subjects had to demonstrate improvement in a third validated measure: physical function.

Fibromyalgia syndrome composite responders needed to satisfy the pain composite criteria as well as demonstrate at least a 6-point improvement in their SF-36 physical component summary (SF-36 PCS) score. In study MLN-MD-02 there were 713 evaluable subjects for the fibromyalgia syndrome and pain analyses. In study FMS-031 there were 488 evaluable subjects for the fibromyalgia syndrome analysis and 491 evaluable subjects for the fibromyalgia pain analysis. A statistically significant number of subjects treated with milnacipran during Study MLN-MD-02 met the composite syndrome responder criteria: 25% and 26% for the milnacipran 100 mg and 200 mg groups compared to 13% for placebo. A statistically significant number of subjects treated with milnacipran during Study FMS-031 met the composite syndrome responder criteria at six months: 33% and 32% for the milnacipran 100 mg and 200 mg groups, respectively, compared to 19% for placebo. The composite pain responder criteria for fibromyalgia pain also reached statistical significance during Study MLN-MD-02: 39% and 46% in the milnacipran 100 mg and 200 mg groups, respectively compared to 25% for placebo. A statistically significant number of subjects treated with milnacipran during Study FMS-031 also met these criteria at six months: 44% and 45% of subjects in the milnacipran 100 mg and 200 mg groups, respectively, compared to 28% for placebo. Based on positive phase III results, Cypress and Forest planned to file an NDA around the end of 2007.

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Biotech Review

From *BioWorld Today*

- **Advanced Life Sciences Holdings**, of Woodridge, Ill., is proceeding with its new drug application for cethromycin in community-acquired pneumonia (CAP) after results of the second of two pivotal clinical trials showed that the ketolide antibiotic met its primary endpoint of statistical noninferiority cure rates. In a double-blind, randomized, multicenter, multinational phase III clinical trial of 584 adults in the U.S., Canada and South Africa, cethromycin cured 94% of patients with CAP, compared with 93.8% of patients cured with Biaxin (clarithromycin), the company said Nov. 15. Biaxin, an FDA-approved antibiotic made by Abbott Park, Ill.-based Abbott, is considered the standard of care for the treatment of CAP.
- A month after signing a billion-dollar deal with **GlaxoSmithKline**, of London, for elesclomol (formerly STA-4783), **Synta Pharmaceuticals**, of Lexington, Mass., kicked off a pivotal phase III trial of the drug in metastatic melanoma. The trial is designed to support a label in first-line treatment of melanoma, the company said. Enrollment will include about 630 Stage IV metastatic melanoma patients who have not received chemotherapy previously, although they might have received prior treatment with biologics or surgery. Those patients will be randomized to receive elesclomol plus paclitax-

el paclitaxel alone until their disease progresses. The primary endpoint of progression-free survival will be evaluated twice: first in an interim analysis designed to assess safety and nonfutility, which Synta estimated will occur in the second quarter of 2008; and again sometime around the completion of enrollment, which is targeted for late 2008.

- Having started the year with a \$70 million initial public offering, **Molecular Insight Pharmaceuticals**, of Cambridge, Mass., priced \$150 million in bonds due in 2012. The MI deal, with a syndicate of institutional investors, involves warrants to buy about 6 million shares of stock, representing an 18 percent dilution of common shares on a fully diluted, post-money basis, and provides funding to reach the launch of MI's first product, the company said. The firm had cash, cash equivalents and short-term investments of \$38.7 million as of Sept. 30. When the firm priced its IPO in February, officials pointed out that the money raised would finance operations into secondquarter 2008. Along with the five-year maturity date, the bonds bear a coupon equivalent to the London Bank Inter-Bank Offer Rate plus 8%, determined quarterly. The warrants' exercise price is \$5.87, equivalent to the closing bid price of MI common stock as of the close of trading Nov. 8. The bonds are redeemable by MI, at its option, starting Nov. 16, 2008.

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- With one kinase inhibitor in the clinic and two more in the queue, **Ambit Biosciences**, of San Diego, raised \$49.3 million in a Series D financing round. CEO Scott Salka said the company had "more funds interested in investing than we could possibly accommodate," a situation he characterized as "very different" from 2004, when Ambit was last out raising money. Salka attributed the difference both to a better fundraising environment and the company's progress. The Series D round brings Ambit's equity fundraising total to almost \$106 million, including a \$36 million Series C closed in 2005, an \$18.8 million Series B closed in 2000 and an earlier \$1.8 million Series A that Salka said was "more of a seed round." The new money should last Ambit through 2009, but Salka declined to speculate on what the company's next financing move might be. In addition to equity fundraising, Ambit has generated more than \$45 million in cash since 2004 through partnerships for its KinomeScan kinase profiling technology.



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