CAPRIUS INC
Form 10KSB
January 14, 2003

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-KSB

(Mark one)

X ----- Annual Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934
FOR THE FISCAL YEAR ENDED SEPTEMBER 30, 2002

----- Transition Report Pursuant to Section 13 or 15 (d) of the of the Securities Exchange Act of 1934

Commission File Number: 0-11914

CAPRIUS, INC.
(Name of Small Business Issuer in its charter)

| Delaware | 22-2457487 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

One Parker Plaza, Fort Lee, NJ 07024
(Address of principal executive offices) (Zip Code)

Issuer's telephone number: (201) 592-8838

Securities to be registered under Section 12 (b) of the Exchange Act:
None

Securities to be registered under Section 12 (g) of the Exchange Act:
Common Stock, par value $ .01 per share
(Title of Class)

Check whether the issuer (1) filed all reports required to be filed under Section 13 or 15 (d) of the Exchange Act during the past 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB [X].

Revenues for the fiscal year ended September 30, 2002: $1,549,794

The aggregate market value of the voting stock held by non-affiliates of the Registrant computed by reference to the price at which the stock was sold, or the average bid and ask prices of such stock as of December 31, 2002: $803,595

The number of shares outstanding of Registrant's Common Stock, $.01 par value, outstanding on December 31, 2002: 20,396,562 shares

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Documents Incorporated by Reference: None
Transitional Small Business Disclosure Format: Yes No X

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## PART I

### ITEM I. DESCRIPTION OF BUSINESS

GENERAL

Caprius, Inc. ("Caprius" or the "Company") was founded in 1983 and through June 1999 essentially operated in the business of medical imaging systems as well as healthcare imaging and rehabilitation services. On June 28, 1999, the Company acquired Opus Diagnostics Inc. ("Opus") and began manufacturing and selling medical diagnostic assays constituting the Therapeutic Drug Monitoring ("TDM") Business. The Company continues to own and operate a

comprehensive imaging center located in Lauderhill, Florida. After the close of the 2002 fiscal year, the Company made major changes in its business through the sale of the TDM Business and the purchase of a majority interest in M.C.M. Environmental Technologies, Inc. ("MCM").

The Opus acquisition was consummated coincident with the closing of an Asset Purchase Agreement (the "Oxis Purchase Agreement") between Opus and Oxis Health Products Inc. ("Oxis") at which time George Aaron and Jonathan Joels became executive officers, directors, and principal stockholders of the Company. The purchase price consisted of $500,000 in cash, a secured promissory note (the "Oxis Note") in the principal amount of $586,389, which was repaid as of December 8, 1999, and a warrant granting Oxis the right to acquire 617,898 shares of the Company's Common Stock. Additionally, pursuant to a Services Agreement, Oxis had manufactured the products of the TDM Business through December 31, 2000. On October 9, 2002, Opus sold the assets of the TDM Business to Seradyn, Inc., a Delaware corporation ("Seradyn"), pursuant to a Purchase and Sale Agreement among Opus, Caprius, and Seradyn for a purchase price of $6,000,000, subject to adjustment, and entered into a Royalty Agreement and a Consulting Agreement.

On December 17, 2002, the Company closed the acquisition of 57.53% of the capital stock of MCM, which is engaged in the medical infectious waste disposal business, for a purchase price of $2.4 million. Upon closing, Caprius designees were elected to three of the five seats on MCM's Board of Directors, with George Aaron, President and CEO, and Jonathan Joels, CFO, filling two seats. Additionally, as part of the transaction, certain debt of MCM to its existing stockholders and to certain third parties was converted to equity or restructured.

On June 12, 2002, the Company and MCM had signed a Letter of Intent to enter into an agreement whereby the Company would have the right to acquire 51% of the outstanding stock on a fully diluted basis of MCM. Concurrent with the signing of the Letter of Intent, Caprius provided MCM with a loan totaling $245,000. The Company obtained the monies to make the loan to MCM through funds provided by a short-term loan from officers and employees of the Company as well as related family members in the amount of $250,000. At the time of the acquisition of MCM, the Company's outstanding loans to MCM aggregated $565,000 which were paid by reducing the cash portion of the purchase price. For a six month period commencing 19 months and ending 25 months from December 17, 2002, pursuant to a Stockholders Agreement, the stockholders of MCM (other than the Company) shall have the right to put all of their MCM shares to MCM, and MCM shall have the right to call all of such shares, at a price based upon a pre-set determination calculated at such time. At the Company's option, the purchase price for the remaining MCM shares may be paid in cash or the Company's common stock.

On September 25, 2002, warrant holders representing 3,297,700 shares of Common Stock took the opportunity to exercise their warrants in the Company's warrant price reduction program. The Company had offered warrant holders of 4,319,750 shares of Common Stock the opportunity to exercise their warrants at a reduced exercise price for a period of 14 days during September 2002. The purpose of this program was to give the Company a quick and inexpensive means to obtain funds for short-term working capital requirements. The reduced exercise price for each of the outstanding warrants was equal to 20% of its present exercise price, but not less than $0.11 per share. As a result, the Company raised an aggregate of $409,668 and also substantially reduced the number of its outstanding warrants.

In July 1998, the Company acquired The Strax Institute ("Strax"), a comprehensive breast imaging center, located in Lauderhill, Florida. Strax is a

multi-modality breast care center that performs approximately 24,000 procedures per year comprising of x-ray mammography, ultrasound, stereotactic biopsy and bone densitometry. The Company continues to evaluate the possible sale of Strax.

THERAPEUTIC DRUG MONITORING BUSINESS

Prior to October 9, 2002, Opus was engaged in the development, distribution and sale of diagnostic assays, controls and calibrators for therapeutic drug monitoring ("TDM") which were sold under the trademark INNOFLUOR(R) in kit form for use on the Abbott TDx and TDxFLx instruments. Opus received and accepted an unsolicited offer from Seradyn to purchase its TDM Business. Seradyn had been a contract manufacturer of the Opus TDM kits. Pursuant to a Consulting Agreement, Opus will consult with Seradyn on ongoing projects for a $50,000 annual fee for a two-year period. The purchased assets included three diagnostic assays still in development, for which Opus will receive royalty payments upon the commercialization of any of these assays based upon varying percentages of net sales. Caprius, Opus and its three executive officers entered into non-compete agreements with Seradyn restricting them for five years from competing in the TDM business.

MCM ENVIRONMENTAL TECHNOLOGIES INC.

DESCRIPTION OF MCM ENVIRONMENTAL TECHNOLOGIES INC. (MCM) BUSINESS

BACKGROUND OF THE REGULATED MEDICAL WASTE INDUSTRY

UNITED STATES

In response to environmental issues including medical waste washing-up along the eastern coast of the United States, the federal government adopted the Medical Waste Tracking Act ("MWTA") in 1988. The MWTA defined medical waste and those wastes to be regulated, - establishing a "cradle to grave" tracking system mandating a waste generator initiated tracking form; required management standards for segregation, packaging, labeling and marking, as well as storage of the medical waste. MWTA introduced record keeping requirements and penalties that could be imposed for mismanagement. The MWTA, a two-year demonstration program that has since expired, triggered the development and implementation of state regulations concerning medical waste, many of which incorporate parts of the MWTA. The state legislatures promulgated their own laws and regulations to define regulated medical waste ("RMW") and to establish guidelines for its treatment and disposal. Oversight of the legislation is often the responsibility of a state environmental protection and/or health agency.

Therefore, it became more critical in the disposal of medical waste to have adequate means to either transport from the facility and destroy it off site, or to obtain systems to destroy the waste on site.

The US medical waste disposal market has been estimated to be $1.7 billion annually with an annual growth rate of 10% (Frost and Sullivan, 1998). According to an Environmental Protection Agency ("EPA") report in 1994, approximately 500,000 tons of biohazardous waste was generated in the US. Hospitals, which comprise only 2% of the total number of waste generators, produce about 71% of biohazardous waste, with the remainder generated by clinics, laboratories and other alternative site facilities. To remove the waste about 80% of the hospitals use waste management firms which both transport and treat the waste; 8% use on site incinerators and 11% use other onsite technology coupled with waste haulers which transport the residual to landfills.

The medical waste disposal market has changed dramatically over the past several years. The passage of the Clean Air Act Amendments of 1997, has forced hospitals either to refit their incinerators with expensive pollution control devices or close them (final implementation date was September 2002). The environmental problem generated by the medical waste incinerators is that hydrogen chloride and heavy metals were being emitted into the atmosphere. Concurrently, medical waste haulers are also subject to increased regulatory oversight from the US Department of Transportation. The consolidation of the medical waste industry to one large provider and several small local/regional



players has contributed to increased disposal costs for the producers of medical waste. In addition, medical waste generators are coming under increasing pressures to reduce expenses as a result of decreasing reimbursement from managed care companies and Medicare. The combination of these pressures is forcing medical waste generators to reconsider their current waste disposal methods. The Company believes these factors provide MCM with an excellent marketing opportunity.

EUROPE

Members of the European Union are implementing laws to mirror the US regulations on medical waste disposal. In 1994, the European Commission implemented a Directive where member states had to adhere to the provisions of the United Nations Economic Commission for Europe ("UNECE") European Agreement on the International Carriage of Dangerous Goods by Road. This requires that clinical or medical waste would be packed, marked, labeled, and documented according to defined specifications. Drivers are also required to be trained as to check and monitor waste upon collection. MCM is considering the opportunity in Europe as part of its marketing strategy as the SteriMed(R) system is CE Mark compliant.

THE MCM STERIMED(R) SYSTEM

The proprietary MCM SteriMed(R) system treats contaminated waste of all kinds including syringes, dialysis filters and kits, scalpels, cloth, test tubes, organic materials, and other hazardous bio-medical waste. A dedicated closed system designed for on-site simultaneous shredding and chemical treatment, the SteriMed(R) units destroys biomedical waste into tiny pieces reducing its volume by approximately 90%, and exposes it to a disinfecting solution called Ster-Cid(R). The diluted chemical solution, which is 94% biodegradable, is separated from the solid waste and goes into the sewage system. The now solid waste product can be disposed at a landfill as ordinary waste. The SteriMed(R) system's chemical process kills biological contaminants. The SteriMed(R) system is designed to process approximately 750 pounds of medical waste per day. Through a highly controlled process, approximately 9 gal (35 liters) of water and 175 ml of Ster-Cid(R) are automatically released into the treatment chamber. The shredding, grinding and mixing of the waste is then initiated to expose all surfaces of the medical waste to the chemical solution during the processing cycle. At the end of each cycle, a valve in the treatment chamber automatically opens, allowing the entire contents to be released into the centrifuge or separator, which separates the solid from the liquid components. The centrifuge traps the solids in a filter sack and discharges the liquids into the sewage system. The dimensions of the SteriMed(R) unit are height-50 inches, width-48 inches, depth-27 1/2 inches, and the weight is 1,044 pounds.

To meet the needs of smaller facilities, MCM developed the

SteriMed-Junior(R), This system provides the same functionality but due to its more compact size and smaller capacity, it is marketable to dialysis centers, clinics and physicians' offices. The SteriMed-Junior(R), similar in its basic capabilities to the larger SteriMed(R), is designed to be the most cost-effective medical waste treatment system available today for smaller facilities. The SteriMed-Junior(R) can process a large variety of medical waste; chemically treating approximately 150 pounds per day of bagged waste. The dimensions of the SteriMed-Junior(R) are height- 42 inches, width-33 inches-depth-20 inches and the weight is 645 pounds.

MCM has received applicable state and federal regulatory approvals, as described below.

REGULATORY ISSUES IN THE UNITED STATES

The U.S. Environmental Protection Agency has federal jurisdiction over medical waste treatment technologies that claim to reduce the infectivity of the waste (i.e. that claim any microbiological activity) by use of a chemical. Specifically, this jurisdiction applies to the Federal Insecticide, Fungicide and Rodencide Act of 1972 ("FIFRA").

States have differing requirements for processing, treating and disposing medical waste. As a result, approval process and review methods for Alternative Technologies are different and varies from state to state and may be handled by contrasting departments. In addition, states require that the chemicals are registered. To date, 49 states have finalized the registration process of the chemicals (Ster-Cid(R)), of which 43 states allow the marketing of the SteriMed(R). To date, the SteriMed-Junior(R) has been approved for use in 37 states. Approvals are pending in the other states.



On the local and county level, many local authorities (especially in urban areas) require that discharge permits will be obtained from Publicly Owned Treatment Works ("POTW") by all facilities discharging substantial amount of liquids to the sewer system. Usually General Discharge Permits are obtained by health facilities, such as hospitals, as part of their License to Operate. The effluent discharge of the SteriMed(R) systems has been characterized and found to be within the lower range of the general requirements as set by the National Pollutant Discharge Elimination System (NPDES) Permitting Program used as the basis by states to establish their discharge limits.

These approvals allow medical waste treated by the MCM technology to be considered as disinfected. The residual waste is permitted to be placed in normal municipal waste.

Medical waste treated by MCM technology allows for it to be later disposed as regular municipal "black Bag" waste. To be permitted to do this, MCM had to demonstrate that it could reduce the level of the Bacillus subtilis spores by a 6Log10, or by one-millionth (0.000001).

The SteriMed(R) process, unlike other waste medical disposal technologies, does not have to contend with the Clean Air Act Amendments of 1990 (since there is no incineration or generation of toxic fumes), and the Hazardous Materials Transportation Authorization Act of 1994 (as there is no transportation of hazardous waste).

COMPETITION

Medical waste had routinely been disposed through incineration. Due to the pollution generated by medical waste incinerators, novel technologies have been developed for the disposal of medical waste. Some of the issues confronting these are energy requirements, space requirements, unpleasant odor, radiation exposure, excessive heat, volume capacity and reduction, steam and vapor containment, and chemical pollution. The following are the various technologies and the competitors.

Autoclave (steam under pressure): Autoclaves and retort systems are the most common alternative method to incineration used to treat medical waste. Autoclaves are widely accepted because they have historically been used to sterilize medical instruments. However, there are drawbacks as autoclaves may have limitations on the type of waste they can treat, the ability to achieve volume reduction, and odor problems.

Microwave Technology: Microwave technology is essentially a steam-based low-heat thermal process as disinfection occurs through the action of moist heat /steam and microwaves. This is usually achieved at temperatures in the range of 95-100oC or 203-212oF ,2450 MHz and wavelength 12.24. Competitors have developed both large and small units. These systems tend to have high capital costs. Processing of metal objects in some systems may cause problems such as fire.

Thermal Processes: Thermal processes are dry heat processes and do not use water or steam, but forced convection, circulating heated air around the waste or using radiant heaters. Companies have developed both large and small dry-heat systems, operating at temperatures between 350oF-700oF. Use of dry heat requires longer treatment times.

High Heat Thermal Processes: High heat thermal processes operate at or above incineration temperatures, from 1,000oF to 15,000oF. Pyrolysis, which does not include combustion or burning, contains chemical reactions that create gaseous and residual waste products. The emissions are lower than that created by incineration, but the pyrolysis demands heat generation by resistance heating such as with bio-oxidation, induction heating, natural gas or a combination of plasma, resistance hearing and superheated steam.

Radiation: Electron beam technology creates ionized radiation, damaging cells of microorganisms. Workers must be protected with shields and remain in areas secured from the radiation.

Chemical Technologies: Disinfecting chemical agents that integrate shredding and mixing to ensure adequate exposure are used by a variety of competitors. Chlorine based chemicals, using sodium hypochlorite and chlorine



dioxide, are somewhat controversial as to their environmental effects and its impact on wastewater. Non-chloride technologies are varied and include peracetic acid, ozone gas, lime based dry powder, acid and metal catalysts as well as alkaline hydrolysis technology used for tissue and animal waste.

Among the competitors of MCM are Stericycle, Inc. Steris Corporation, Mark-Costello Co., and Sanitec, Inc.

MCM'S STRATEGY

Seizing the opportunity afforded by the regulatory changes and pricing pressures in the healthcare industry, MCM is positioning its products as viable alternatives to the traditional medical waste disposal methods. The SteriMed(R)

system seeks to offer medical waste generators a true on-site option that is less risky, less expensive, and more environmentally friendly than the alternatives. The main advantages of the SteriMed(R) System are:

Improves Safety:
---
Renders infectious waste benign
Reduces pathogens to meet or exceed federal, state and local standards
Minimizes exposure of patients, visitors, and staff by reduced handling and transportation
Eliminates storage at site of medical waste generator
Processes automatically so operator does not come in contact with contaminated waste

Reduces Costs:
---
Costs are typically substantially lower per pound of medical waste compared to other systems

Complies with Federal and States regulations
---
Enables infectious medical waste generating facilities to replace existing systems while meeting federal, state and local environmental as well as health regulations

Environmentally friendly
---
Uses chemicals which are approximately 94% biodegradable
Produces no smoke, smell, steams, or any other emissions into the air
Reduces waste volume by approximately 90%
Low energy consumption

Handles large volumes quickly
---
Takes approximately 15 minutes per cycle
Can handle over 200 tons of waste per year

Easy to install, operate and maintain
---
Requires only one operator and once the cycle has started, the operator can walk away
Requires small operating floor space due to its compact size
No special ventilation or lighting
Generates very low noise

These features are intended to make the SteriMed(R) System a very attractive solution to health care organizations, especially those that are forced to reconsider their current medical waste management programs because of federal and state regulations or because of pressures to reduce operating costs.

MARKET SIZE

Estimated US Facilities and Annual Biomedical Waste Generated

| FACILITY TYPE | NUMBER OF US FACILITIES | ANNUAL BIOMEDICAL WASTE GENERATED (TONS) | % OF TOTA W |
|---|---|---|---|
| Hospitals | 7,000 | 360,000 | |
| Physicians offices | 180,000 | 35,200 | |
| Nursing homes | 18,800 | 29,700 | |
| Clinics (Outpatient) | 41,300 | 26,300 | |
| Laboratories | 7,200 | 25,900 | |
| Dentist's offices | 98,000 | 8,700 | |
| Free standing blood banks | 900 | 4,900 | |
| Veterinarians | 38,000 | 4,600 | |
| Corrections | 4,300 | 3,300 | |
| Health units in industry | 221,700 | 1,400 | |
| Fire and Rescue | 7,200 | 1,600 | |
| Residential Care | 23,900 | 1,400 | |
| Funeral homes | 21,000 | 900 | |
| Police | 13,100 | | |

THE HOSPITAL MARKET

Because of their sheer size and limited number of facilities in comparison to the numbers by other user categories, hospitals are a very important market for MCM. At present, hospitals have had three options for the disposal of their biomedical waste: to outsource to a waste management company; to process it on-site using an incinerator or to process it on-site using other alternative technology. The following chart depicts the estimated distribution of methods used by US hospitals.

| | OUTSOURCE | ON-SITE INCINERATION | ON-SITE ALTERNATIVE |
|---|---|---|---|
| PERCENTAGE OF HOSPITALS UTILIZING DISPOSAL METHOD | 80% | 8.4% | 11.6% |

OUTSOURCED - WASTE MANAGEMENT COMPANIES

A majority of healthcare facilities contract with third-party waste

management companies for the removal of their solid waste for disposal. The 80% figure, however, reflects hospitals that contract with these third-party waste management companies for both the removal and the treatment / disposal of their medical waste. This is a changing industry. Recently, the top four waste management companies have consolidated into two. This consolidation is expected to increase prices. Presently, the regulators are adding new restrictions to transport medical waste across state lines, which are likely to increase the costs to hospitals.

ON-SITE - INCINERATION

Hospitals with on-site incinerators have been impacted by new Environmental Protection Agency emissions standards requiring the reduction of the release of dioxin, mercury and other potentially carcinogenic materials into the atmosphere. These hospitals will have to either retrofit their existing incinerators at a projected cost of $300,000 - $400,000 along with legal fees and other permit requirements (Healthcare Purchasing News, August 1997, Vol. 21, No. 8) or shut down their incinerators and dispose of their waste through other methods. The following is an estimate of the number of incinerators and those



projected to close:

| TYPE | # OF FACILITIES | BURNING LBS./HOUR | % ESTIMATED TO CLOSE |
|---|---|---|---|
| Small | 1,100 | | |