PATIENT INFOSYSTEMS INC
Form 10KSB
March 31, 2005

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-KSB

(Mark One)

[X] x **Annual Report Pursuant to Section 13 or 15(d)**
of the Securities Exchange Act of 1934

For the Fiscal Year Ended December 31, 2004

[X] o **Transition Report Pursuant to Section 13 or 15(d)**
of the Securities Exchange Act of 1934

For the transition period from ___ to ___

Commission File Number: 0-22319

Patient Infosystems, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	16-1476509
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
46 Prince Street	
Rochester, New York	14607
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code (585) 242-7200

Securities registered pursuant to Section 12(b) of the Act:

None.

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $.01 per share

(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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] x No [X]o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulations S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in a definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]x

Issuer's revenue for the year ended December 31, 2004: $15.7 million.

As of March 30, 2005, the aggregate market value of the voting and nonvoting common stock held by nonaffiliates of the registrant was $34 million and 6,328,019 shares of common stock were outstanding.

As of March 30, 2005, there were 9,743,600 shares of the issuer's common stock outstanding.

PART I

Item 1. Description of Business.

General

Patient Infosystems, Inc. (Patient Infosystems) was incorporated in the State of Delaware on February 22, 1995 under the name DSMI Corp., changed its name to Disease State Management, Inc. on October 13, 1995, and then changed its name to Patient Infosystems, Inc. on June 28, 1996. Patient Infosystems principal executive offices are located at 46 Prince Street, Rochester, New York 14607 and its telephone number is 585-242-7200. Patient Infosystems' Internet address is www.ptisys.com.

Patient Infosystems is a health management solutions company that integrates clinical expertise with advanced Internet, call center and data management capabilities. Founded in 1995 as a disease management company, Patient Infosystems has evolved to offer a comprehensive portfolio of products and services designed to improve patient clinical outcomes and quality of life, reduce healthcare costs and facilitate patient-provider-payor communication. These products are now marketed under the label Care Team Connect for Health.

Patient Infosystems expects to distribute approximately 10,000,000 shares of ACS common stock and retain 1,000,000 shares. The distribution will occur as soon as practicable following the effectiveness of a registration statement and will be in the form of a dividend to the stockholders of Patient Infosystems. Patient Infosystems intends to distribute one share of common stock of ACS for every two shares of Patient Infosystems stock owned as of the record date. The record date for stockholders eligible to receive the distribution has not yet been established. Following the spin-off, ACS will be a new independent public company with its own management and board of directors.

Patient Infosystems has historically marketed its services to a broad range of clients, including self-insured employers and trust funds, insurance companies, pharmaceutical and medical equipment and device manufacturers, pharmacy benefit managers (PBMs), other healthcare payors, such as managed care organizations (MCOs) and healthcare providers, including integrated delivery networks (IDN s). Current marketing efforts are targeted to self-insured employers, employer groups, union health and welfare funds, and others who pay for the health care of defined populations.

During its first two years of operations, Patient Infosystems emphasized the development of pure disease management programs, which accounted for a substantial portion of its revenue through 1997. However, beginning in 1998, Patient Infosystems devoted resources to the development of broader applications of its technology platform, and its additional products grew to account for nearly 45% of the total revenue of Patient Infosystems during the fiscal year ended December 31, 2002. During 2003, Patient Infosystems further expanded its product mix to include services that support providers' clinical improvement efforts. These services include support for development, training and maintenance of clinical registry software, consultative services in improvement methodologies and support of web-based informational and reporting resources. On December 31, 2003, Patient Infosystems acquired the assets of American Caresource Corporation and formed American Caresource Holdings, Inc. (ACS) to operate those assets. ACS provides ancillary benefits management services, including a network of ancillary specialty providers and value-added services that assist our clients in controlling the cost of a range of ancillary medical services. On September 22, 2004, Patient Infosystems acquired 100% of CBCA Care Management, Inc. ("CMI"), a New York corporation. CMI provides utilization management and case management services which are part of the Care Team Connect for Health product.

The Patient Infosystems and its subsidiaries (the"Company") operates in two segments. One segment includes the operating results of the ACS subsidiary (the "American Caresource Segment") and the other includes the operating results of Patient Infosystems and its CMI subsidiary (the "Patient Infosystems Segment"). Patient Infosystems expects to distribute to its shareholders approximately 10,000,000 shares of ACS common stock to Patient Infosystems shareholders and retain 1,000,000 shares. The distribution will occur as soon as practicable following the effectiveness of a registration statement filed by ACS with the Securities and Exchange Commission and will be in the form of a dividend to the stockholders of Patient Infosystems. Patient Infosystems intends to distribute one share of common stock of ACS for every two shares of Patient Infosystems common stock owned as of the record date and one share for every two shares of common stock issuable upon the conversion of the preferred stock owned as of the record date.. The record date for stockholders eligible to receive the distribution has not yet

been established. Following the spin-off, ACS will be a new independent public company with its own management and board of directors.

In the year ended December 31, 2004, the Care Team Connect portfolio represented 46% of the Patient Infosystems Segment's revenue; innovation and improvement services for providers represented 54% of the Patient Infosystems Segment's revenue. Primarily due to the addition of CMI, Care Team Connect portion of revenue increased to 68% of Patient Infosystems' revenue during the three month period ended December 31, 2004.

Products and Capabilities

Care Team Connect for Health

Care Team Connect for Health, which is Patient Infosystems principal product line, provides a complete solution for population health management that can be marketed as a comprehensive solution or a set of discrete services that complement a client s existing operations. Care Team Connect integrates a number of components that had historically been marketed by Patient Infosystems as stand alone products. During 2002, the clinical content of these components was revised and all components were migrated to an updated technology platform. During 2003, the Care Team Connect product was expanded to include certain wellness services, as well as utilization management and case management services, provided through subcontract relationships with partner organizations. During 2004, Patient Infosystems acquired CMI and now can provide utilization management and case management services without the need for a subcontractor. Care Team Connect includes the following:

1) 24-hour nurse help/triage line,
2) Population analysis and identification,
3) Disease management services,
4) Care management,
5) Smoking cessation program,

Nurse help line

The Care Team Connect for Health nurse help line is a triage, advice, referral and health-counseling service that provides employees and members with round-the-clock access to registered nurses who use algorithm-based assessment tools and have access to provider and/or network information. The help line can provide users with information about a specific health problems or answers to their health-related questions. Use of nationally recognized clinical algorithms assist callers in determining the most cost-effective options for acute care treatment and has effectively been able to reduce the use of emergency rooms and after hours physician contact. Through the Nurse Help Line, individuals may also be identified for referral into disease management or case management intervention. The nurse help line is operated from Patient Infosystems Utilization Review Accreditation Commission (URAC) accredited call center.

Population analysis and identification

As part of its disease management services, Patient Infosystems provides comprehensive medical and pharmaceutical claims analysis that includes the administration of proprietary algorithms to identify patients with chronic disease and then stratifies them by level of risk for high

resource utilization.

The stratification algorithm employed is categorical in nature as patients are classified into low, moderate, high and critical groupings. The data employed in the algorithm are both nominal (using claim codes known as ICD9 and procedure codes known as CPT) and ratio (usage of resources). The nominal data determines the presence of a particular chronic condition and thus identifies patients with a specific condition. A combination of the nominal and ratio data, as defined in the algorithm for each condition, determines the risk level for the individual patient.

Following identification and stratification, patients/employees can be enrolled into the appropriate (low, moderate or high) disease management intervention program.

The first time the claims analysis is completed on the client s historical claims data, the client will be provided with a summary report that profiles its population as related to health care dollars spent, prevalence of disease, and the numbers of identified at-risk members by risk level. Claims data is used on a retrospective

basis to assess the financial impact of the Care Team Connect programs and calculate savings and return on investment.

Disease management services

Patient Infosystems disease management services are provided for individuals with a diagnosis of asthma, diabetes, hypertension, or congestive heart failure. These services are comprehensive in approach and focus on both the medical and behavioral aspects of chronic health care management. The programs involve clinical assessments and the delivery of messages on self-care, medication compliance and treatment adherence. Through monitoring and on-going assistance, they empower the participants to become more proficient and proactive in managing their disease or condition. By including 24-hour access to the nurse help line, participants always have a place to turn for questions or issues that arise with their disease. The long-term goal of Patient Infosystems disease management services is a judicious use of health care resources through health care education, as well as reinforcement of the provider s treatment plan.

The disease management programs are based on nationally recognized treatment guidelines for each disease state. The programs provide condition-specific assessment, support and education with behavior-based interventions according to the patient s identified risk level. Each of Patient Infosystems' chronic condition management programs is reviewed and updated as needed on an annual basis to assure that these programs reflect current knowledge and practices in clinical management.

Disease management interventions include various components according to the risk level of the target individual. These components are as follows:

Low risk:	Quality of life surveys
	Reminders
	Static educational mailings
	24-hour nurse help line
Moderate risk:	Nurse engagement
	Quality of life surveys
	Chronic condition management program
	Reminders
	Static educational mailings
	24-hour nurse help line
High risk:	Nurse engagement

	Quality of life surveys
	Gold chronic condition management program
	Telemonitoring signs and symptoms assessment
	Reminders
	Static educational mailings
	24-hour nurse help line
Critical risk:	Dedicated registered nurse as disease care manager
	Baseline clinical assessment and treatment action plan
	Regularly scheduled on-going clinical patient assessments

Disease management program components

Nurse engagement call

Moderate, high and critical risk disease management programs generally begin with a nurse engagement call. The nurse care counselor explains the specific program for which the member is targeted and the benefits of the program, while starting to build a relationship with the member. The nurse care counselor confirms the patient s acceptance to participate and obtains pertinent member information.

The nurse intervention assesses specific areas of clinical management based on national clinical practice guidelines. Specific to each disease, these include the following types of information:

- Healthcare utilization.
- Disease status.
- Functional status.
- Quality of care.
- Treatment adherence and self-care practices.
- Education/knowledge.
- Motivation and program evaluation.

The assessment focuses on the most important health behaviors the patient must manage in order to effectively control symptoms of their disease.

Chronic condition management program

Moderate risk patients are generally enrolled in our chronic condition management programs. Each of the chronic condition management programs utilize a combination of telephone and mail interventions to monitor patients while providing educational information about disease-specific treatment guidelines.

By providing unique, individually tailored intervention strategies, Patient Infosystems provides each patient with personalized, educational feedback and positive reinforcement, both verbally and through written communication. Each telephonic intervention also generates an on-demand published report for the patient s physician/case manager.

High risk patients are enrolled in our gold chronic condition management program. The gold program includes all of the components of the chronic condition management programs described previously, ***plus*** the incorporation of symptom assessment and monitoring throughout the duration of the contract.

Disease care management for critical risk patients

Disease care management is a specialized clinical intervention. The highly specialized clinical support by a registered nurse may provide the management and coordination of patient care services for critical-risk individuals in a population.

The program s key functions are the following:

1. One-on-one support by a dedicated registered nurse.
2. Establishing an extensive baseline clinical assessment and treatment action plan.
3. Regularly scheduled on-going clinical patient assessments that include extensive disease monitoring and surveillance.

Care management services

Care management programs include the components of utilization management and case management and are designed to ensure that participants receive quality medical care at the best possible price, while maximizing plan benefits. The programs assist in avoiding unnecessary expenditures with an objective, information-intensive approach that combines clinical judgment with accepted practice patterns.

Care management services are to comply with URAC standards and are further developed to ensure compliance with the legislative requirements of the states in which utilization review functions are performed.

The data collected from the Care Team Connect for Health interventions is stored in an integrated information warehouse which links the numerous programs and services. This integrated data warehouse allows our clients, the patient s providers and other associated service providers access to program data as necessary in order to best manage the member s health.

Smoking Cessation Services

During 2003, Patient Infosystems began providing the call center operations for a smoking cessation program which is owned by and marketed by Behavioral Solutions. Patient Infosystems has the right to independently market this program for direct sales.

Provider innovation and improvement support

In 2003, Patient Infosystems expanded its role in services to certain federally funded health centers that are sponsored by the Bureau of Primary Healthcare through the Institute for Healthcare Improvement that promote disease management programs directly to the providers in the health centers.

Population Health Disease Management Systems and Strategies

Patient Infosystems provides technical assistance to the health centers relative to management of chronic disease. This includes organizations such as the federal government, health plans, state primary care associations, and the National Association of Community Health Centers.

Learning Organization Services

Patient Infosystems serves as a teaching organization promoting improvement in care delivery systems. This includes logistics support for learning sessions, training; recruitment, development and support of faculty, subject matter experts in key topics; training in improvement methods and knowledge management of best practices. Topics include chronic disease management, idealized clinical practice design and the business case for planned care. Patient Infosystems collaborates with the Institute for Healthcare Improvement on such initiatives.

Technical assistance

Patient Infosystems assists with the development of clinical registries used to more effectively manage patients with chronic disease. Patient Infosystems services include (i) project management and Implementation of a patient registry for federally qualified health centers through a national initiative known as the Health Disparities Collaboratives and (ii) Patient Infosystems provides technical assistance in web based reporting applications for clinical outcomes. This project is administered as a subcontract through the Institute for Healthcare Improvement.

Outcome Assessment, Data Collection and Reporting

Patient Infosystems collects data about clinical, financial, quality of life and satisfaction. This data is analyzed and outcomes are reported.

Ancillary benefits management

Ancillary healthcare services include a broad array of services that supplement or support the care provided by hospitals and physicians, including the non-hospital, non-physician services associated with surgery centers, free-standing diagnostic imaging centers, home health and infusion, durable medical equipment, orthotics and prosthetics, laboratory and many other services. These ancillary services are provided to patients as benefits under Group Health plans and Workers Compensation plans.

Ancillary services include but are not limited to the following categories: Outpatient Therapy/Rehab	Orthotics and Prosthetics
Home Health Services	Pain Management
Surgical Centers	Pharmacy
Laboratory Services	Physical Therapy
Home Infusion therapy	Respiratory Services
Chiropractic Services	Sleep Studies
Diagnostic Imaging/Radiology	Sub-Acute and Skilled Nursing facilities
Dialysis Services	Hospice Services

Durable Medical Equipment Bone Growth Stimulators

ACS manages the administration of these non-hospital, non-physician services.

Through its contracts with over 3500 ancillary service providers (with over 17,500 sites nationwide), ACS is able to offer its clients direct cost savings in the form of discounted rates for contracted services and administrative cost savings by functioning as a single point of contact for managing a comprehensive array of ancillary benefits. ACS benefits management services include processing the claims submitted by its covered providers, re-pricing the claims, submitting the claims for payment, receiving and disbursing claims payments and performing customer service functions for its clients and contracted providers. For preferred provider organization (PPO), third party administrator (TPA) and similar clients, contracting with ACS also allows the clients to market comprehensive, efficient and affordable ancillary service benefits to their payor customers.

As part of its ancillary benefits management services, ancillary providers submit claims for services performed for covered members. ACS re-prices these claims under the relevant payor fee schedules, performs electronic conversion and HIPAA formatting services, and submits the re-priced claims to the appropriate payors. After adjudication of the claims by the Payor, the Payor issues an Explanation of Benefits and check for each claim. In most cases, these checks are sent to ACS. ACS then pays the providers under the relevant provider fee schedules. The difference between the amounts received by ACS from its clients and the amounts paid by ACS to its contracted providers represents ACS gross margin on its benefits management services.

Value-added services that ACS provides to its clients include the following:

Ancillary network analysis. ACS analyzes the available claims history from each client and develops a specific plan to meet their needs. This analysis identifies high-volume providers that are not already in ACS network. ACS attempts to contract with such providers to maximize discount levels and capture rates.

Ancillary out-of-network negotiations. For services performed by providers outside of the ACS network, ACS negotiates a discounted rate for the client on a case specific basis.

Ancillary custom network. ACS customizes its network to meet the needs of each client. In particular, ACS reviews the out-of-network claims history through its network analysis service and develops a strategy to create a network that efficiently serves the client s needs. This may involve adding additional providers for a client and removing providers the client wants excluded from their network.

Ancillary reimbursement. ACS uses its network analysis to develop a single reimbursement level for all ancillary providers. ACS also processes denials and appeals for its clients and for its contracted providers.

Ancillary network management. ACS manages ancillary service provider contracts, reimbursement and credentialing for its clients. This provides administrative benefits to ACS clients and reduces the burden on providers who typically must supply credentialing documentation and engage in contract negotiation with separate payors.

Ancillary utilization management support. ACS provides support for utilization and case management efforts used by each payor. ACS facilitates preauthorization at the point of referral based on pre-established criteria. ACS also flags cases for follow-up, review, and concurrent reviews to ensure all the payor guidelines are followed by each service provider and the efficacy of services and progress of the patient is satisfactory. There are a large number of high demand cases that are subject to case management efforts. For those cases, ACS helps coordinate the supporting documentation and preparation of reports to manage and monitor progress and establishment of reserves for specific claims.

Ancillary systems integration. ACS has created a proprietary software system that enables it to manage many different customized accounts and includes the following modules:

Provider network management

Credentialing

Eligibility management and card printing

Claims and case referral management

Data transfer management/EDI

Repricing and auto-adjudication

Multi-level reimbursement management

Posting, EOB, check, and e-funds processes

Customer service management

Directory management

Claim repricing / adjudication

Advanced data reporting

Ancillary reporting. ACS provides a complete suite of reports to each client monthly. The reports cover contracting efforts and capture rates, discount levels, referral volumes by service category and complete claims and utilization reports.

Ancillary claims management. ACS can manage ancillary claims flow, both electronic and paper, and integrate into the client s process electronically or through repriced paper claims. ACS can also perform a number of customized processes that add additional value for each client. As part of the claims management process, ACS manages the documentation requirements specific to each payor. When claims are submitted from the service provider without required documentation, ACS works with the provider to get the documentation so that the claim is not denied by the payor. This also saves labor costs for the payors.

ACS estimates that at least 80% of all claims in ACS ancillary categories are submitted by paper. ACS is able to provide a conversion of these paper claims into the HIPAA-compliant Electronic Data Interchange (EDI) form through its scanning operations.

Sales and Marketing

Through 1997, Patient Infosystems efforts focused primarily on the development of disease management programs. Beginning in 1998, Patient Infosystems began aggressively marketing the other services that its technology platform can provide, including demand management, patient surveys, pharmaceutical support programs and outcomes analysis. During 2003 and 2004, Patient Infosystems marketed its integrated Care Team Connect for Health product. Its target market is the organization that pays for health care services on behalf of its members, employees or beneficiaries. These industry organizations include several groups: insurance companies, managed care organizations, third party administrators (TPA s), health and welfare funds organized under the Taft-Hartley Labor Act, purchasing coalitions, and self-funded employer groups.

Sales and marketing efforts for the ACS product line are currently focused on healthcare payor organizations as well as TPA S, large self funded organizations and Taft-Hartley groups that self-administrate. ACS spent several years developing its business model, know-how, infrastructure, client base and provider base and until 2001, ACS focused on managing ancillary benefits in the Workers Compensation market. In early 2001, ACS expanded and refocused its business to address the management of ancillary benefits in the Group Health market. It launched its Group Health initiatives by marketing to healthcare networks such as TPAs and PPOs. As of the end of 2003, ACS began to focus its marketing efforts on the direct payor community. This is in alignment with the marketing focus for the Care Team Connect product line.

Patient Infosystems currently employs a sales and marketing staff of five persons to market its services. The Ancillary Network of ACS is marketed through one full time sales person and independent contractors providing additional commission salespersons. In addition, the senior members of Patient Infosystems management are actively engaged in marketing Patient Infosystems programs.

Patient Infosystems has agreements in place with several organizations to co-market Patient Infosystems products and services. These agreements are in place with Loge Group, LLC, formerly CBCA, Gilsbar, CHA Health and POMCO. All of these organizations provide third-party administrator services. These agreements permit either company to co-market and sub-contract for the services of the other company.

Competition

The market for health care information products and services is intensely competitive. Competitors vary in size and in scope and breadth of products and services offered, and Patient Infosystems competes with various companies in each of its disease target markets. Patient Infosystems competitors include specialty health care companies, health care information system and software vendors, health care management organizations, pharmaceutical companies and other service companies within the health care industry. Many of these competitors have substantial installed customer bases in the health care industry and the ability to fund significant product development and acquisition efforts. Patient Infosystems also competes against other companies that provide statistical and data management services, including clinical trial services to pharmaceutical companies.

Research and Development

Research and development expenses consist primarily of salaries, related benefits and administrative costs allocated to Patient Infosystems research and development personnel. These personnel are actively involved in the conversion of Patient Infosystems technology platform to a fully web-enabled design. Patient Infosystems research and development expenses were $130,332 or 0.8% of total revenues for the fiscal year ended December 31, 2004, $131,782, or 2.3% of total revenues and for the fiscal year ended December 31, 2003. Patient Infosystems anticipates that the amount spent on research and development will remain relatively constant in future periods as it continues its internal process to update its products.

Government Regulation

The health care industry is subject to extensive regulation by both the Federal and state governments. A number of states have extensive licensing and other regulatory requirements applicable to companies that provide health care services. Additionally, services provided to health benefit plans in certain cases are subject to the provisions of the Employee Retirement Income Security Act of 1974, as amended ("ERISA").

Furthermore, state laws govern the confidentiality of patient information through statutes and regulations that safeguard privacy rights. In addition, on August 21, 1996 Congress passed the Health Insurance Portability and Accountability Act of 1996 (HIPAA), P.L. 104-191. This legislation required the Secretary of the Department of Health and Human Services to adopt national standards for electronic health transactions and the data elements used in such transactions. Patient Infosystems and its customers may be subject to Federal and state laws and regulations that govern financial and other arrangements among health care providers. Furthermore, Patient Infosystems and its customers may be subject to federal and state laws and regulations governing the submission of false healthcare claims to the government and private payers. Possible sanctions for violations of these laws and regulations include minimum civil penalties between $5,000-$10,000 for each false claim and treble damages.

Therefore, Patient Infosystems must continually adapt to changing regulations. If Patient Infosystems fails to comply with these applicable laws, Patient Infosystems may be subject to fines, civil penalties, or criminal prosecution.

Employees

As of March 15, 2005, Patient Infosystems had 145 full time and 29 part-time employees.

RISK FACTORS

Forward-Looking Statements

When used in this and in future filings by Patient Infosystems with the Securities and Exchange Commission, in Patient Infosystems press releases and in oral statements made with the approval of an authorized executive officer of Patient Infosystems, the words or phrases will likely result, expects, plans, will continue, is anticipated, estimated, project, or outlook or similar expressions (including confirmations by a authorized executive officer of Patient Infosystems of any such expressions made by a third party with respect to Patient Infosystems) are intended to identify forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Patient Infosystems wishes to caution readers not to place undue reliance on any such forward-looking statements, each of which speak only as of the date made. Such statements are subject to certain risks and uncertainties that could cause actual results to differ materially from historical earnings and those presently anticipated or projected. Patient Infosystems has no obligation to publicly release the result of any revisions that may be made to any forward-looking statements to reflect anticipated or unanticipated events or circumstances occurring after the date of such statements.

An investment in Patient Infosystems common stock is speculative in nature and involves a high degree of risk. No investment in Patient Infosystems common stock should be made by any person who is not in a position to lose the entire amount of such investment.

Risks Related to the Business of Patient Infosystems

Working Capital Shortfalls; Urgent Need for Working Capital; Possible Cessation of Operations

Patient Infosystems has never earned a profit and has depended upon the over $30 million that Patient Infosystems has raised to date through its initial public offering, private placements of its equity securities and debt, to fund its working capital requirements. Patient Infosystems incurred an operating loss of approximately $2.6 million with a net loss of approximately $3.6 million for the year ended December 31, 2004 and had an approximate $1.9 million deficit in working capital and shareholders equity of approximately $5.4 million at December 31, 2004. As of December 31, 2004, Patient Infosystems had total liabilities of $11.5 million. Throughout 2004, Patient Infosystems has supported a wholly-owned subsidiary, American Caresource Holdings, Inc. (ACS) through the sale of Patient Infosystems' equity securities and debt. Existing working capital is expected to last at least through the end of 2005, and Patient Infosystems anticipates that it will be required to raise additional funds thereafter. As with any forward-looking projection, no assurances can be given concerning the outcome of Patient Infosystems actual financial status given the substantial uncertainties that exist. There can be no assurances that Patient Infosystems can raise either the required working capital through the sale of its securities or that Patient Infosystems can borrow the additional amounts needed. If it is unable to identify additional sources of capital, Patient Infosystems will likely be forced to curtail its operations or the operations of ACS. We plan to spin-off ACS to existing shareholders see risk factor titled The spin-off of ACS will result in reduced revenues and our share price may decline .

History of Operating Losses; Continued Limited Patient Enrollment

Patient Infosystems has incurred losses in every quarter since its inception in February 1995. Patient Infosystems ability to operate profitably is dependent upon its ability to develop and market its products in an economically successful manner. To date, Patient Infosystems has been unable to do so. No assurances can be given that Patient Infosystems will be able to generate revenues or ever operate profitably in the future.

Patient Infosystems prospects must be considered in light of the numerous risks, expenses, delays and difficulties frequently encountered in an industry characterized by intense competition, as well as the risks inherent in the development of new programs and the commercialization of new services particularly given its failure to date to operate profitably. There can be no assurance that Patient Infosystems will achieve recurring revenue or profitability on a consistent basis, if at all.

Patient Infosystems currently has patients enrolled in its disease-specific programs. Through February 2005, an aggregate of approximately 765,000 persons are enrolled in Patient Infosystems programs. While Patient

Infosystems has been able to enroll a sufficient number of patients to cover the cost of its programs, it still has not been able to generate sufficient operational margin to achieve a net profit.

Significant Customer Concentration; Expected loss of significant customer rvenue

While at December 31, 2004 Patient Infosystems had more than twice as many customers as it had at December 31, 2003, there is still a significant concentration of Patient Infosystems business in a small number of customers, with Patient Infosystems most significant contract being with Institute for Healthcare Improvement ("IHI") and accounting for revenues of $5.3 million. The contract with IHI has never had a term of more than twelve months. The contract with IHI is due to renew on April 1, 2005, at which time Patient Infosystems anticipates that the revenue from this customer may decrease by as much as 45%. Park Place Entertainment which accounted for revenue of $622,067 in 2003 and $438,705 in 2004 and a smoking cessation program which accounted for revenue of $491,362 in 2003 and $415,579 in 2004 terminated their service agreements with Patient Infosystems effective December 31, 2004. Patient Infosystems expects that its sale of services will continue to be concentrated in a small number of customers for the foreseeable future. Consequently, the loss of any one of its customers could have a material adverse effect on Patient Infosystems and its operations. There can be no assurance that customers will maintain their agreements with Patient Infosystems, enroll a sufficient number of patients in the programs developed by Patient Infosystems for Patient Infosystems to achieve or maintain profitability, or that customers will renew their contracts upon expiration, or on terms favorable to, Patient Infosystems.

ACS five largest customers (including its non-continuing customers) account for approximately 91.4% of its revenues during 2004, (non-continuing customers amounted to 9.3%). In addition, ACS generally does not have long-term contracts with any of its customers. Significant declines in the level of use of ACS services by one or more of these customers could have a material adverse effect on ACS business and results of operations. Additionally, an adverse change in the financial condition of any of these customers, including an adverse change as a result of a change in governmental or private reimbursement programs, could have a material adverse effect on its business.

Consequences of the Need to Raise Additional Working Capital

As Patient Infosystems seeks additional financing or purchases, it is likely that it will issue a substantial number of additional shares that may be extremely dilutive to the current stockholders and required substantial and material charges to earnings which will impact the net loss attributable to the common shareholders. As a result, the value of outstanding shares of common stock could decline further.

The spin-off of ACS will result in reduced revenues and our share price may decline

Patient Infosystems expects to distribute approximately 10,000,000 shares of ACS common stock to its stockholders in the form of a dividend and retain 1,000,000 shares. The distribution will occur as soon as practicable following the effectiveness of a registration statement that has been filed with the Securities and Exchange Commission on February 14, 2005. The record date for stockholders eligible to receive the distribution has not yet been established. Following the spin-off, ACS will be a new independent public company with its own management and board of directors. During the year ended December 31, 2004, ACS had revenue of approximately $6 million out of the Company's total revenue of $15.7 million. Although the business of ACS has operated at a loss, the spin-off of its operations will result in a reduction of business, revenue and diversity of operations to Patient Infosystems. As a result, it may be expected that, as a portion of the operations are spun-off to the stockholders of Patient Infosystems, there will be a reduction of the total value of and the share price of Patient Infosystems. In addition, to the extent that current stockholders of Patient Infosystems will become stockholders of ACS, no assurance can be given that, as it is operated independently, that its losses will not increase and that the relative value of its shares will not decline.

Uncertainty of Market Acceptance; Resistance by Customers; Limitations of Commercialization Strategy

In connection with the commercialization of Patient Infosystems health information system, Patient Infosystems is marketing services designed to link patients, health care providers and payors in order to provide specialized disease management services for targeted chronic diseases. However, at this time, services of this type have not gained general acceptance from Patient Infosystems customers. This is still perceived to be a

new business concept in an industry characterized by an increasing number of market entrants who have introduced or are developing an array of new services. As is typical in the case of a new business concept, demand and market

acceptance for newly introduced services are subject to a high level of uncertainty, and there can be no assurance as to the ultimate level of market acceptance for Patient Infosystems system, especially in the health care industry, in which the containment of costs is emphasized. Because of the subjective nature of patient compliance, Patient Infosystems may be unable, for an extensive period of time, to develop a significant amount of data to demonstrate to potential customers the effectiveness of its services. Even after such time, no assurance can be given that Patient Infosystems data and results will be convincing or determinative as to the success of its system. There can be no assurance that increased marketing efforts and the implementation of Patient Infosystems strategies will result in market acceptance for its services or that a market for Patient Infosystems services will develop or not be limited.

Dependence on Customers for Marketing and Patient Enrollment

Patient Infosystems has limited financial, personnel and other resources to undertake extensive marketing activities. One element of Patient Infosystems marketing strategy involves marketing specialized disease management programs to pharmaceutical companies and managed care organizations, with the intent that those customers will market the program to parties responsible for the payment of health care costs, who will enroll patients in the programs. Accordingly, Patient Infosystems, will to a degree, be dependent upon its customers, over whom it has no control, for the marketing and implementation of its programs and for the receipt of valid patient information. The timing and extent of patient enrollment is completely within the control of Patient Infosystems customers. Patient Infosystems has faced difficulty in receiving reliable patient information from certain customers, which has hampered its ability to complete certain of its projects. To the extent that an adequate number of patients are not enrolled in the program, or enrollment of initial patients by a customer is delayed for any reason, Patient Infosystems revenue may be insufficient to support its activities.

Terminability of Agreements

Patient Infosystems current services agreements with its customers generally automatically renew but may be terminated by those customers without cause upon notice of between 30 and 90 days. In general, customer contracts may include significant performance criteria and implementation schedules for Patient Infosystems. Failure to satisfy such criteria or meet such schedules could result in termination of the agreements.

Unpredictability of Patient Behavior May Affect Success of Programs

The ability of Patient Infosystems to monitor and modify patient behavior and to provide information to health care providers and payors, and consequently the success of Patient Infosystems disease management system, is dependent upon the accuracy of information received from patients. Patient Infosystems has not taken and does not expect that it will take, specific measures to determine the accuracy of information provided to Patient Infosystems by patients regarding their medical histories. No assurance can be given that the information provided to Patient Infosystems by patients will be accurate. To the extent that patients have chosen not to comply with prescribed treatments, such patients might provide inaccurate information to avoid detection. Because of the subjective nature of medical treatment, it will be difficult for Patient Infosystems to validate or confirm any such information. In the event that patients enrolled in Patient Infosystems programs provide inaccurate information to a significant degree, Patient Infosystems would be materially and adversely affected. Furthermore, there can be no assurance that patient interventions by Patient Infosystems will be successful in modifying patient behavior, improving patient health or reducing costs in any given case. Many potential customers may seek data from Patient Infosystems with respect to the results of its programs prior to retaining it to develop new disease management or other health information programs. Patient Infosystems ability to market its system to new customers may be limited if it is unable to demonstrate successful results for its programs.

Substantial Fluctuation in Quarterly Operating Results

Patient Infosystems results of operations have fluctuated significantly from quarter to quarter as a result of a number of factors, including the volume and timing of sales and the rate at which customers implement disease management and other health information programs within their patient populations. Accordingly, Patient Infosystems future operating results are likely to be subject to variability from quarter to quarter and could be adversely affected in any particular quarter.

-12-

Dependence on Data Processing and Telephone Equipment

The business of Patient Infosystems is dependent upon its ability to store, retrieve, process and manage data and to maintain and upgrade its data processing capabilities. Interruption of data processing capabilities for any extended length of time, loss of stored data, programming errors, other computer problems or interruptions of telephone service could have a material adverse effect on the business of Patient Infosystems.

Quality Control

Patient Infosystems has developed quality control measures designed to insure that information obtained from patients is accurately transcribed, that reports covering each patient contact are delivered to health care providers and patients and that Patient Infosystems personnel and technologies are interacting appropriately with patients and health care providers. Quality control systems include random monitoring of telephone calls, patient surveys to confirm patient participation and effectiveness of the particular program, and supervisory reviews of telephone agents.

Control of Patient Infosystems

The executive officers, directors and certain stockholders of Patient Infosystems who beneficially own in the aggregate approximately 62% of the outstanding common stock control Patient Infosystems. As a result of such ownership, these stockholders, in the event they act in concert, will have control over the management policies of Patient Infosystems and all matters requiring approval by the stockholders of Patient Infosystems, including the election of directors.

Potential Liability and Insurance

Patient Infosystems will provide information to health care providers and managed care organizations upon which determinations affecting medical care will be made. As a result, it could share in potential liabilities for resulting adverse medical consequences to patients. In addition, Patient Infosystems could have potential legal liability in the event it fails to record or disseminate correctly patient information. Patient Infosystems maintains an errors and omissions insurance policy with coverage of $5 million in the aggregate and per occurrence. Although Patient Infosystems does not believe that it will directly engage in the practice of medicine or direct delivery of medical services and has not been a party to any such litigation, it maintains a professional liability policy with coverage of $5 million in the aggregate and per occurrence. There can be no assurance that Patient Infosystems procedures for limiting liability have been or will be effective, that Patient Infosystems will not be subject to litigation that may adversely affect Patient Infosystems results of operations, that appropriate insurance will be available to it in the future at acceptable cost or at all or that any insurance maintained by Patient Infosystems will cover, as to scope or amount, any claims that may be made against Patient Infosystems.

Intellectual Property

Patient Infosystems considers its methodologies, processes and know-how to be proprietary. Patient Infosystems seeks to protect its proprietary information through confidentiality agreements with its employees. Patient Infosystems policy is to have employees enter into confidentiality agreements that contain provisions prohibiting the disclosure of confidential information to anyone outside Patient Infosystems. In addition, the policy requires employees to acknowledge, and, if requested, assist in confirming Patient Infosystems ownership of any new ideas, developments, discoveries or inventions conceived during employment, and requires assignment to Patient Infosystems of proprietary rights to such matters that are related to Patient Infosystems business.

Risks Related to the Business of American Caresource

ACS History of Operating Losses

ACS has incurred losses since its inception. In addition, American CareSource Corporation, from whom Patient Infosystems purchased ACS assets, had not, since its inception, operated profitability.

In addition, during the end of 2003 and early 2004, Pinnacol Assurance and one of its other customers which in the aggregate accounted for over 51% of the revenues of American CareSource Corporation during the fiscal year ended December 31, 2003 terminated their relationships with ACS. Revenue from the terminated

relationships were approximately $566,000 in 2004. The termination of these contracts resulted in a significant reduction of ACS revenues in 2004. Although a variety of reasons may be provided for the termination of each of the customer agreements, the termination of such an extensive amount of customer business may reflect a substantial level of customer dissatisfaction with the services provided by ACS. No assurance can be given that more customers will not terminate their relationships with ACS. In addition, ACS generally does not have long-term contracts with its other customers. Significant declines in the level of use of ACS services by one or more of its remaining customers could have a material adverse effect on ACS business and results of operations. Additionally, an adverse change in the financial condition of any of these customers, including an adverse change as a result of a change in governmental or private reimbursement programs, could have a material adverse effect on its business.

ACS faces working capital shortfalls and has an urgent need for working capital

ACS and American CareSource Corporation have never earned profits. In addition, ACS operations have been supported substantially by the provision of working capital by Patient Infosystems. ACS will need continued funding in order to maintain its operations. After ACS becomes independent of Patient Infosystems there can be no assurance that ACS will be able to obtain additional sources of funds, or that such funds will be available on terms favorable to ACS. In addition, ACS must incur costs associated with capital expenditures to systemize operations. There can be no assurance that ACS will have sufficient funds for such capital expenditures.

ACS is dependent on payments from third party payors

The profitability of ACS will depend on payments provided by third-party payors. Competition for patients, efforts by traditional third-party payors to contain or reduce healthcare costs and the increasing influence of managed care payors such as health maintenance organizations in recent years have resulted in reduced rates of reimbursement. If these trends continue, they could adversely affect ACS results of operations unless ACS can implement measures to offset the loss of revenues and decreased profitability. In addition, changes in reimbursement policies of private and governmental third-party payors, including policies relating to the Medicare and Medicaid programs, could reduce the amounts reimbursed to these customers for ACS services and consequently, the amount these customers would be willing to pay for the services.

ACS is dependent upon discounted rates made available by ancillary service providers

ACS obtains revenue from cost savings that it is able to receive from the ancillary service providers and pass on to customers. Should the ancillary service providers not continue to provide a discount to ACS, ACS will be unable to recognize any gain from the sale of services to payors or networks. If ACS is unable to recognize these margins, it will be unable to continue its business as it is currently conducted.

The continued services and leadership of ACS senior management is critical to its ability to maintain growth and any loss of key personnel could adversely affect its business

The future of the business of ACS depends to a significant degree on the skills and efforts of its senior executives. If ACS loses the services of any of these senior executives, and especially if any of these executives joins a competitor or forms a competing company, ACS business and financial performance could be seriously harmed.

ACS future growth depends on successful hiring and retention of skilled personnel

The future growth of ACS business depends on successful hiring and retention of skilled personnel ,including a Chief Financial Officer, and ACS may be unable to hire and retain the skilled personnel it needs to succeed. Qualified personnel are in great demand throughout the healthcare industry. The failure of ACS to attract and retain sufficient skilled personnel may limit the rate at which its business can grow, which will harm its financial performance.

ACS is dependent upon data processing capabilities and telecommunications

The business of ACS is dependent upon its ability to store, retrieve, process and manage data and to maintain and upgrade its data processing capabilities. Interruption of data processing capabilities for any extended length of time, loss of stored data, programming errors, other computer problems or interruptions of telephone service could have a material adverse effect on its business.

Any inability to adequately protect its intellectual property could harm ACS competitive position

ACS considers its methodologies, processes and know-how to be proprietary. ACS seeks to protect its proprietary information through confidentiality agreements with its employees. ACS policy is to have employees enter into confidentiality agreements containing provisions prohibiting the disclosure of confidential information to anyone outside of ACS, requiring employees to acknowledge, and, if requested, assist in confirming ACS ownership of new ideas, developments, discoveries or inventions conceived during employment, and requiring assignment to ACS of proprietary rights to such matters that are related to ACS business. There can be no assurance that the steps taken by ACS to protect its intellectual property will be successful. If ACS does not adequately protect its intellectual property, competitors may be able to use its technologies and erode or negate its competitive advantage.