

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-K

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **December 31, 2008**

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 333-103781

ProUroCare Medical Inc.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction
of incorporation)

20-1212923

(IRS Employer
Identification No.)

6440 Flying Cloud Drive, Suite 101, Eden Prairie, MN

(Address of principal executive offices)

55344

(Zip Code)

Registrant's telephone number, including area code _____

952-476-9093

5500 Wayzata Blvd., Suite 310, Golden Valley, MN 55416

(Former name or former address, if changed since last report.)

Securities registered pursuant to Section 12(b) of the Exchange Act: **None**

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

Common Stock \$0.00001 par value; Common Stock Warrants

Units, consisting of one share of Common Stock and one Warrant

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.

Yes No

Indicate by check mark whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities 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 No

Indicate by check mark if disclosure of delinquent filers in response to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Non-accelerated filer

Accelerated filer

Smaller reporting company

INTRODUCTORY CAUTIONARY STATEMENT

This Annual Report on Form 10-K includes forward-looking statements within the meaning of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements are based on management's current beliefs and assumptions and on information currently available to us. Forward-looking statements include, among others, the information concerning possible or assumed future results of operations of ProUroCare Medical, Inc. and its subsidiary (the "Company," "we," "us," or "our") set forth under the heading "Management's Discussion and Analysis or Plan of Operation" and elsewhere in this Annual Report. Forward-looking statements also include statements where the words "may," "will," "should," "could," "expect," "anticipate," "intend," "plan," "believe," "estimate," "predict," "potential," or similar expressions are used. Forward-looking statements are not guarantees of future performance. Our future actual results and shareholder values may likely differ materially from those expressed in these forward-looking statements. We caution you not to put undue reliance on any forward-looking statements included in this document. See "Risk Factors Associated with our Business, Operations, and Securities."

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I</u>	
ITEM 1: BUSINESS	1
ITEM 1A: RISK FACTORS	19
ITEM 1B: UNRESOLVED STAFF COMMENTS	34
ITEM 2: PROPERTIES	35
ITEM 3: LEGAL PROCEEDINGS	35
ITEM 4: SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS	35
<u>PART II</u>	
ITEM 5: MARKET FOR COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	35
ITEM 6: SELECTED FINANCIAL DATA	37
ITEM 7: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	37
ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	42
ITEM 8: FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	F-1
ITEM 9: CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES	43
ITEM 9A(T): CONTROLS AND PROCEDURES	43
ITEM 9B: OTHER INFORMATION	44
<u>PART III</u>	
ITEM 10: DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	44
ITEM 11: EXECUTIVE COMPENSATION	46
ITEM 12: SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	49
ITEM 13: CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	52
ITEM 14: PRINCIPAL ACCOUNTANT FEES AND SERVICES	53
<u>PART IV</u>	
ITEM 15: EXHIBITS, FINANCIAL STATEMENT SCHEDULES	54
SIGNATURES	59

PART I

ITEM 1: BUSINESS

See Item 1A, “RISK FACTORS ASSOCIATED WITH OUR BUSINESS, OPERATIONS AND SECURITIES”, page 19.

Overview

We are a development stage company engaged in the business of developing for market innovative products for the detection and characterization of male urological prostate disease. Our primary focus is currently the ProUroScan™ prostate imaging system (the “ProUroScan System”).

The ProUroScan System is an imaging system designed for use as an aid to the physician in visualizing and documenting tissue abnormalities in the prostate that have been previously detected by a digital rectal exam (“DRE”). The ProUroScan System is comprised of an array of sensors mounted on a probe, a central processing unit, proprietary software and image construction algorithms, and a color monitor. As an adjunct to DRE, the ProUroScan System will be used following an abnormal DRE to generate a real time image and map of the prostate and to store this information electronically.

The ProUroScan system is not currently marketed or sold and is not cleared for marketing by the U.S. Food and Drug Administration (“FDA”). Our initial goal is to obtain a basic mapping and data maintenance claim from the FDA under a 510(k) application for the first generation system. The remaining regulatory and clinical work on the ProUroScan System will be performed under our development contract with Artann Laboratories Inc. (“Artann”), a scientific technology company based in Trenton, New Jersey, that is focused on early-stage technology development. Artann has completed all pre-clinical activities and testing on the ProUroScan System, is conducting clinical trials for the basic mapping and data maintenance claim, and will prepare and submit the 510(k) application for such claim.

The ProUroScan System will initially be marketed as an “adjunctive” tool following an abnormal DRE to create a map of the prostate and an electronic record of the image. More specifically, the proposed indication for use that Artann intends to seek for the ProUroScan System 510(k) submission, which we refer to as the “basic mapping and data maintenance claim,” is for use as an aid to the physician in visualizing and documenting abnormalities of the prostate detected by a DRE.

Once FDA 510(k) clearance is obtained on our first generation ProUroScan System, we intend to have the systems manufactured by one or more FDA-regulated contract manufacturers and market the system in cooperation with a medical device company that has an established presence in the urology market. We are currently exploring potential marketing relationships with several urology product companies interested in marketing the ProUroScan System in the prostate disease market. We expect such a relationship would provide financial resources and access to down stream marketing, engineering, manufacturing and sales support.

In the future, subject to receipt of appropriate FDA approvals or clearances, we plan to develop and introduce enhanced versions and additional indications for use of the ProUroScan System that we expect will be able to monitor changes in prostate tissue over time, guide prostate biopsies and assess changes in prostate size following drug treatment for Benign Prostatic Hypertrophy (“BPH”).

Corporate Information

ProUroCare Inc. (“PUC”) was incorporated in 1999 as a Minnesota corporation. In January 2002, PUC licensed the rights to certain advanced prostate mechanical imaging technology, and became engaged in the business of developing this technology for assessing characteristics of the prostate. In 2004, through a reverse merger transaction with Global Internet Communications (“Global”), a Nevada corporation, PUC became the wholly owned and sole operating subsidiary of Global, which was then renamed ProUroCare Medical Inc.

Market Focus—Prostate Disease

Prostate cancer is the most common form of cancer and the second leading cause of cancer death in men. According to the National Cancer Institute, more than 186,000 men were expected to be diagnosed with prostate cancer and over 28,000 were expected to die from the disease in 2008. Currently, there are approximately 42 million men in the U.S. over the age of 50. For men in this age category, the standard of care to screen for the presence of prostate cancer is to have a physical exam each year in which two tests are routinely performed: the DRE and the Prostate Specific Antigen (“PSA”) blood test. Although used for many years, the specificity of these tests has been widely questioned. Data from community based studies suggest that the positive predictive value of a DRE for prostate cancer is 15% to 30% and varies relatively little with age. For elevated PSA levels between 4 and 10ng/mL, the positive predictive value is approximately 20%. For studies in which biopsies were done when the results of either test were abnormal, 18% to 26% of screened patients had suspicious results, cancer was actually detected in approximately 4% of screened patients and the positive predictive value of the tests combined was 15% to 21%. In another study involving 6,630 volunteers, the combination of DRE and PSA detected 26% more cancers than PSA alone. Although PSA and DRE provide some positive predictive value, neither of these tests creates a physical or visual record of the abnormality or its position in the prostate.

If a patient is suspected of having an abnormal tissue formation in the prostate as a result of a positive DRE or a high PSA value, he is generally referred to a urologist. A urologist will usually perform their own DRE and may decide to perform a prostate biopsy to obtain tissue samples for microscopic analysis. The prostate is biopsied by a needle that is guided by ultrasound into the prostate through the rectal wall. Since the existence and exact location of possible cancerous tissue is not known, the urologist will usually take 10 to 14 samples in a scattered pattern throughout the prostate in an attempt to find the suspect tissue. Of the approximately 1 million prostate biopsy procedures done each year in the United States, only approximately 25 percent actually detect the presence of cancer. The low predictive ability of the DRE and PSA tests to gauge the presence of cancer tends to over-inflate the number of referrals for invasive biopsy that are necessary to confirm that a patient has cancer.

We believe there is a market need to be able to visualize and create an electronic record (map) that can show the relative size and position of abnormal tissue in the prostate gland. We believe that the ProUroScan System offers a solution that meets these needs and one that will (assuming we apply for and obtain FDA approval or clearance for this indication) enable physicians to monitor and compare images of the prostate over time. With additional development and further FDA approvals, we believe the ProUroScan System may eventually be used to guide prostate biopsy and assess the effect of medical treatments of BPH.

Prostate Cancer Screening and Diagnosis

The two most common screening tests for identifying prostate cancer are the DRE and the PSA. These tests have been used for years, but have often been criticized for their lack of specificity and selectivity.

In a DRE exam, a physician wearing a latex glove inserts a lubricated finger into the rectum to palpate the prostate gland to detect abnormalities. The clinician must rely on his or her experience and sensitivity of touch to estimate the size of the prostate and detect irregularities in shape or hardness. There is significant subjectivity inherent in the DRE exam which can be negatively affected by poor examiner training, lack of experience or poor ability to

interpret the results, as well as other patient related limitations including excessive obesity, patient discomfort and unusual anatomical positioning of the prostate.

Data from community-based studies indicate that the positive predictive value of a DRE in detecting cancer is 15% to 30% and varies relatively little with age. In a Scandinavian study, the positive predictive value of DRE was found to be only 22% to 29%. According to the Eighth Edition of Campbell's Urology, a DRE has only fair reproducibility even with experienced examiners and the test misses a substantial proportion of cancers before they become advanced and less amenable to treatment.

The other primary screening test for detecting prostate cancer is the measurement of PSA in serum. The advantages offered by PSA testing are its simplicity, objectivity, reproducibility and low level of invasiveness. Although PSA is specific to prostate tissue, it is not specific to prostate cancer. Older men that have benign enlargement of the prostate and acute prostatitis often have elevated PSA levels. Serum levels of PSA can also be elevated for a period of time after transrectal needle biopsy, acute urinary retention and prostate surgery. Because of the prevalence of these conditions in men over the age of 50, the positive predictive value of PSA measurements decreases with age.

In clinical practice, a PSA level greater than 4ng/mL is generally considered an abnormal result. Recent community-based studies show that PSA levels greater than 4ng/mL are seen in about 15% of men who are older than 50 years of age. The probability, or positive predictive value, that a man who is older than 50 having prostate cancer if his PSA level is elevated is approximately 20% to 30%. However, the likelihood of cancer depends on the degree of elevation in the PSA levels. For levels between 4 and 10ng/mL, the positive predictive value is about 20 percent. This value increases to between 42 percent and 64 percent if the PSA level is greater than 10ng/mL. Despite these variances, PSA testing has increased the detection rate of early-stage prostate cancers, which are more curable than late-stage cancers.

Most clinicians have adopted the strategy of performing both tests in combination, which has been shown to increase the combined predictive value. In fact, in a large study of volunteers, the combination of DRE and PSA detected 26% more cancers than PSA alone. However, because of the significant risk of prostate cancer, prostate biopsy is recommended for all men who have DRE abnormalities, regardless of PSA level, because 25% of men with cancer have PSA levels less than 4mg/nL.

A patient with a positive DRE or an elevated PSA is typically referred to a urologist for further diagnosis. The urologist will usually perform a prostate biopsy to obtain tissue samples for microscopic analysis. The prostate is biopsied by a needle that is guided by ultrasound into the prostate through the rectal wall. Since the existence and exact location of possible cancerous tissue is not known, the urologist will usually take 10 to 14 samples in a scattered pattern throughout the prostate in an attempt to find the suspect tissue. The tissue samples are then sent to a laboratory for analysis and interpretation, and the results are reported several days later. If the results are negative or indeterminate, the urologist may suggest a second biopsy procedure, or that the patient increase the frequency of future screening examinations. According to Oregon Health and Science University, approximately 1 million patients are biopsied each year in the United States, but only approximately 25% of biopsy procedures performed detects the presence of cancer.

The treatment path for patients who test positive for prostate cancer depends on many variables, including age, location and pathology of the cancerous tissue and general health of the patient. Generally, a younger, otherwise healthy patient will elect to have the prostate removed to eliminate the possibility that it might spread beyond the prostate. Older, less healthy patients may elect not to undergo surgery, and instead monitor the disease closely by semi-annual PSA and DRE exams, and annual biopsies. This monitoring regimen is commonly referred to as "active surveillance." Some patients may elect radiation or drug treatments, in addition to necessary ongoing active surveillance. The National Cancer Institute estimates that there are approximately 2 million men alive who have a

history of cancer of the prostate. On this basis, we estimate that the number of men over the last decade that have elected against prostate removal and thus are undergoing ongoing active surveillance exceeds one million.

The ProUroScan™ Prostate Imaging System

The ProUroScan System is an imaging system designed to provide a map of the prostate and to store a digital image for review. As an adjunctive tool to DRE, it will be used after a physician identifies abnormal tissue during a DRE examination. The first generation system will provide a map or record of the pressures that are generated from palpation of the posterior surface of the prostate using a sensor probe. The system's operation is based on measurement of the stress pattern on the rectal wall when the probe is pressed against the prostate. Temporal and spatial changes in the stress pattern provide information on the elastic structure of the gland and allow two-dimensional reconstruction of prostate anatomy and visualization of prostate mechanical properties. The data acquired allow the calculation of prostate features such as size and shape. The prostate image is displayed on a screen that allows physicians to visualize tissue abnormalities in the prostate gland. In addition to the real time visual image, the results are stored electronically as a digital record.

The ProUroScan System consists of arrays of pressure sensors mounted on a probe, a central processing unit, proprietary software and image construction algorithms, and a color monitor. The probe is specially designed for the rectal anatomy to minimize patient discomfort. It is ergonomic for the clinician and similar to a traditional DRE for the patient. The probe utilizes highly sensitive pressure sensors located on the face of the probe head to palpate the prostate. The probe's positioning system ensures that the person administering the scan examines the entire surface of the prostate, and assists prostate image construction.

To perform a scan, the clinician inserts the tip of the probe into the patient's rectum and palpates the prostate. As the prostate is palpated, a color image of the prostate is produced and displayed on the computer monitor, along with indicators of the amount of pressure being applied to help guide the clinician. Differences in tissue stiffness and elasticity will be depicted in real time on a color monitor. Total testing time for a healthy prostate is under one minute.

ProUroScan System Status

The first generation ProUroScan System has been tested in laboratory experiments on prostate models and in a pre-clinical study. In addition, the system was used for over two years and on approximately 168 patients at the Robert Wood Johnson Medical Center in New Brunswick, New Jersey. In March 2008, an article authored by Artann scientists and published in the peer-reviewed *Urology* reported that in 84% of the cases in this pre-clinical study, the ProUroScan System was able to construct a real-time color image and map of the prostate.

Based on discussions between Artann and representatives from the FDA, we believe that the ProUroScan System with a basic mapping and data maintenance claim will be regulated by the FDA as a class II device. Class II devices typically are cleared for marketing by the FDA through a 510(k) application.

Under the terms of its contract with us, Artann is responsible for submitting and obtaining the initial 510(k) clearance for the ProUroScan System for the basic mapping and data maintenance claim. In April 2008, representatives from Artann met with the FDA to solicit feedback from the agency regarding the proposed clinical testing that the FDA will require to support a 510(k). Artann commenced the clinical study in the fourth quarter of 2008. In order to meet the requirements established by the FDA for the 510(k) clinical study, three centers were identified to participate in the study and to serve as future training and referral sites for the eventual market rollout of the ProUroScan System. The sites include the Mayo Clinic in Rochester, Minnesota, the Robert Wood Johnson Medical Center in New Brunswick, New Jersey and the VA Medical Center in Minneapolis, Minnesota. Institutional Review Board ("IRB") approvals have been obtained, and ProUroScan Systems have been installed, at all three sites. Physician training has also been completed at all three sites and formal clinical studies have commenced at the Robert Wood Johnson Medical Center and the VA Medical Center. It is expected that clinical studies will commence at the

Mayo Clinic in late March or early April 2009. We expect to complete this study in May 2009, and submit the 510(k) application to the FDA shortly thereafter. Once submitted, the FDA will have 90 days to review and grant clearance, ask questions or turn the 510(k) down. However, the 510(k) application process may be significantly longer if the FDA has questions upon its review or makes a request for additional information from Artann. Once cleared and upon ProUroCare's first commercial sale of a ProUroScan System, Artann will transfer the 510(k) to ProUroCare. No assurances can be given in regard to the timing of any of these events.

Planned Development of the ProUroScan System

We believe that the ProUroScan System's existing technology provides a platform on which to develop multiple future generation systems. Once 510(k) clearance is obtained for a basic mapping and data maintenance claim and is transferred to us from Artann, we intend to work with Artann to develop more enhanced product features. Future generation systems will require us to obtain regulatory approval or clearance for use of the ProUroScan System for additional prostate related indications and file additional submissions with the FDA to obtain expanded labeling claims. Such regulatory clearances or approvals may require us to perform additional clinical studies. Future generations of the ProUroScan System may also require us to secure rights to additional intellectual property.

Active Surveillance

We believe that one of the more valuable future applications for the ProUroScan System, assuming we obtain any necessary FDA clearance or approval, will be to allow physicians to monitor changes in the prostate over time. The ProUroScan System is designed to produce a digital image of the prostate showing the size and symmetry of the prostate and the location of tissue abnormalities within the prostate. The ProUroScan System creates a digital record of the exam that can be stored and used for comparison to subsequent exams. We believe its ability to digitally store not only the scan results but all of the individual pressure readings taken during the course of the procedure should facilitate a quantitative analysis of the progression of the disease over time. By comparing the data taken in a baseline examination to subsequent examinations during the course of active surveillance, we believe the urologist will gain valuable information about changes in the patient's condition that can influence their decision to pursue additional treatment or continue surveillance. We believe that this expanded use of the ProUroScan System will provide consistent mapping over time as compared to variations resulting from differences in technique and experience of clinicians performing DREs. We believe this will enable physicians to compare and contrast the patient's results from exam to exam, and to get second opinions on the patient's status in regards to the diagnosis without an additional office visit. We believe that comparisons of multiple scans over time will also enable the physician to make longitudinal assessments of the patient's disease.

Three Dimensional Imaging

We believe that another future enhancement of the current generation system may be the capability to identify the specific three-dimensional location of lesions found in the prostate. This enhanced system may also be able to create a three-dimensional image of the position of the lesions and allow the physician to rotate the image to assist in identifying the actual position of the lesion in the prostate gland. We believe that having this capability may prove helpful in providing a diagnosis of the patient's condition in conjunction with other commercially available diagnostic tools.

Guiding Biopsy

We believe that future expansion to three dimensional imaging may facilitate guiding biopsy needles to the point where suspicious lesions exist so that a tissue sample can be obtained from the prostate gland. Having the three-dimensional coordinates of a lesion will enable the physician to precisely guide the biopsy needle to the point where he can be assured that tissue samples are being taken from that area. Having this capability increases the likelihood of finding cancerous tissue while also potentially minimizing the number of biopsies that are taken on an individual

patient. According to Oregon Health and Science University, approximately 1 million patients are biopsied each year in the United States, but only 25 percent of biopsy procedures performed detects the presence of cancer.

Evaluating Drug Treatment for BPH Patients

For patients who have symptoms of BPH, we believe that future generations of the ProUroScan System may also be used to monitor changes in prostate size before and during the course of drug treatments, allowing physicians to more quickly assess the effectiveness of alternative therapeutic approaches. Assuming future FDA approval or clearance is granted, use of the ProUroScan System in patients diagnosed with BPH will allow physicians to monitor changes in the size and volume of the prostate following treatment with drugs or other tissue reducing technologies. Timely, accurate assessment of prostate volume changes and the effectiveness of treatment should enable physicians to recommend alternative treatments sooner than current assessment methods, and thus provide more immediate relief to patients.

Marketing and Distribution

Our business plan is built on the premise that the map and physical record created by the ProUroScan System will become a valuable tool in assisting physicians and patients in understanding the scope of the abnormalities that are identified with a DRE. Physicians performing the scan will need to acquire a ProUroCare System, which will be placed under a direct purchase, lease or user utilization agreement.

Current Procedural Terminology (“CPT”) codes are used by physicians and other providers to submit claims. We anticipate that the ProUroScan System may be covered by Medicare as a diagnostic test for patients who have clinical signs or symptoms of disease. At the outset, however, there will not be a unique CPT code for the ProUroScan procedure. Consequently, obtaining coverage and reimbursement may be challenging during the initial stages of the ProUroScan System rollout. During this period of time, physicians will have the option of submitting claims under a “miscellaneous” CPT code with proper documentation. We also expect to use a “patient pay” model in which the patient would pay directly for the cost of the scan. During the first few years of use, we will collect the clinical and economic data necessary in order to apply for a unique CPT code from the American Medical Association (“AMA”).

Our initial commercial rollout will focus on urologists in the United States. By focusing on urologists, we expect to establish the clinical and economic value of the scan for patients, and to demonstrate to both private and government payors the rationale and parameters for establishing a CPT code and that the scan should be covered and adequately reimbursed.

We believe that the cost of establishing our own direct sales force of sufficient size and capability to effectively rollout the ProUroScan System in the U.S. would be cost prohibitive and that our product can be more effectively launched by establishing a distribution relationship with one or more large urology product companies that have well-established relationships with physicians. We believe that establishing such a relationship will not only allow us to quickly and effectively penetrate the urology market, but may also afford us an opportunity for additional financial support in the form of licensing fees, equity investment and “in kind” support from other key functional departments of the urology product company. We are currently exploring potential marketing relationships with several urology product companies interested in marketing products in the prostate disease market.

We anticipate that the majority of our revenue will be generated from the sale and lease of the ProUroScan System, as well as from the sale of proprietary disposable supplies consumed in the scanning process. ProUroScan Systems likely will be placed in clinics under a variety of programs, including outright sales, operating leases, financing leases or arrangements where payments are based upon the usage of the system.

Manufacturing

The ProUroScan System has two major proprietary hardware components: a central processor and a rectal probe. There are also certain off-the-shelf components that presently are widely available. Artann has provided five clinical prostate imaging systems that are being used in performing FDA-controlled clinical trials and for contract manufacturing assessment. Artann will transfer ownership of these units to us upon the date of first commercial sale of the ProUroScan System.

We are currently seeking to contract with one or more third-party manufacturers that are Quality Systems Regulation (“QSR”) compliant to produce the ProUroScan System. The QSR requires manufacturers, including certain third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process. Because of the unique nature of the two major proprietary components of the ProUroScan System, it is highly likely that different third party manufacturers will be chosen to assemble the final versions of each component. Our goal in both cases is to reduce the cost of manufacturing over the first two years, taking advantage of manufacturing scale and purchasing discounts, as well as engineering changes designed to eliminate components and reduce component costs.

ProUroScan System Development Partner

The ProUroScan System is based on work originally performed in the late 1990’s by Artann and its affiliate, ArMed LLC. In 2002, we licensed the rights to this technology developed by Artann from its owner, Profile L.L.C., a Delaware limited liability company (“Profile”), a technology holding company, and since then have worked with Artann and our other technology partners on its development. In April 2008, we acquired the patents, patent applications and other know how associated with this technology previously licensed from Profile. In July 2008, we entered into two new agreements with Artann relating to this technology, namely, a license agreement (the “Artann License Agreement”) and a development and commercialization agreement (the “Artann Development Agreement”).

Under the Artann License Agreement, Artann has granted us an exclusive, worldwide, sub-licensable license to certain patent applications and other know how needed to make, use and market certain mechanical imaging products for the diagnosis or treatment of urologic disorders of the prostate, kidney or liver. Artann also agreed to transfer to us possession of five clinical prostate imaging systems and grant us full access to all relevant documentation thereto. As an upfront license fee pursuant to the Artann License Agreement, on January 14, 2009 we paid Artann \$600,000 in cash and \$500,000 in shares of our common stock. In addition, we have agreed to pay Artann:

- a royalty fee equal to 4% of the first \$30,000,000 of net cumulative sales of licensed products, 3% of the next \$70,000,000 of net cumulative sales and 2% of net cumulative sales over \$100,000,000; and
- a technology royalty fee of 1% of net sales of the prostate imaging system products through the earlier of December 31, 2016 or the date of last commercial sale of such products.

The combined royalties are subject to a minimum annual royalty equal to \$50,000 per year for each of the first two years after FDA clearance for commercial sale and \$100,000 per year for each year thereafter until termination or expiration of the Artann License Agreement. We also agreed to grant Artann a non-exclusive, fully paid up, sub-licensable, worldwide license to our patents, patent applications and know how relating to the manufacture, use or sale of any mechanical imaging system for the diagnosis or treatment of disorders of the female human breast.

Under the Artann Development Agreement, we will collaborate with Artann to develop, commercialize and market prostate imaging systems. Artann will conduct and complete all pre-clinical activities and testing on the prostate imaging system, conduct clinical trials, prepare and submit FDA regulatory submissions and provide hardware and software development, refinement and debugging services to ready the prostate imaging system for

commercial sale. For these development services, we paid Artann \$250,000 in cash upon initiation of the clinical study to support the basic mapping and data maintenance claim, and we have agreed to pay Artann:

- \$250,000 in cash and \$1,000,000 in shares of our common stock upon completion of that study and submission of the 510(k) application to support the basic mapping and data maintenance claim;
- \$750,000 in cash and \$1,000,000 in shares of our common stock upon FDA clearance that allows the ProUroScan System to be commercially sold in the United States (subject to reduction of the number of shares by 10% for each month that FDA clearance is delayed beyond March 23, 2010); and
- a monthly retainer fee for technical advice and training by Artann personnel of \$30,000 per month for each of the first six months and \$15,000 per month for each of the following twelve months.

Under the Artann Development Agreement, Artann will also supply us with such quantities of the ProUroScan System as are reasonably required for pre-commercial testing, evaluation, marketing and clinical study and to facilitate the transfer of commercial production to a third party manufacturer. Artann also agrees to use its best reasonable efforts to provide us with a limited number of commercial systems. The pre-commercial and commercial systems will be sold to us at prices yet to be determined.

The Artann License Agreement and the Artann Development Agreement each became effective on December 23, 2008. Under the Artann License Agreement, we have a 30-day cure period from the date of receipt of written notice from Artann of a breach of our payment obligations under either the Artann License Agreement or Artann Development Agreement. If we have not cured such payment breach within five days of receipt of the Artann notice, the exclusive licenses convert to non-exclusive licenses, however, neither party may sub-license or grant additional licenses for a period of 60 days after receipt of such notice. Under the Artann Development Agreement, we have a 60-day cure period from the date of receipt of written notice from Artann of a breach of our payment obligations under either the Artann License Agreement or the Artann Development Agreement. If we do not cure a breach of our payment obligations by the end of the 30-day cure period, the licenses granted under the Artann License Agreement will terminate. Subject to earlier termination due to breach, bankruptcy and certain other events, the Artann License Agreement will terminate upon expiration of all royalty obligations, and the Artann Development Agreement will terminate on its third anniversary, subject to renewal for additional one year terms upon mutual agreement of us and Artann.

In the future, we expect to engage third parties to assist us and Artann in transitioning the technology from research and development to clinical study status, to perform verification and validation testing including certification of safety related testing standards, and to develop quality control processes for the transition to manufacturing of the ProUroScan System.

During the years ended December 31, 2008 and 2007, we recorded research and development expense of \$597,755 and \$143,628, respectively. The 2008 research and development expense amount included the \$250,000 first project milestone payment under the Artann Development Agreement upon the initiation of clinical trials, additional research and development expenses totaling \$50,000 related to work performed by Artann under the same agreement, and the expensing of our \$300,000 acquisition of certain intellectual property and know-how from Profile. Fiscal 2007 expenses included a \$35,000 payment and the issuance of warrants valued at \$72,000 to Artann pursuant to a cooperation agreement signed in April 2007 and \$24,407 of research costs related to a prostate visioning system project.

Intellectual Property

Our objective as a medical device company is to effectively and aggressively obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets and licenses, and operate without infringing the proprietary rights of other parties both in the United States and in all other countries where we may do business. We seek to obtain, where appropriate and financially

feasible, the broadest intellectual property protection possible for our products, proprietary information and proprietary technology through a combination of contractual arrangements, licenses, and patents, both in the United States and throughout the rest of the world.

We also depend upon the skills, knowledge and experience of scientific and technical personnel that we hire or outside organizations with whom we contract, as well as our advisors and consultants. To help protect our proprietary know-how that is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade-secret protection and confidentiality agreements. To this end, it is our practice to require employees, consultants, advisors and other contractors, as appropriate, to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

We own patents, patent applications and know-how associated with mechanical prostate-imaging systems. These patents and patent applications relate to real-time mechanical imaging of the prostate (patent expires in 2021), a method and device for mechanical imaging of the prostate (patent expires in 2012), an intracavity ultrasonic device for elasticity imaging (patent expires in 2012), a method and device for elasticity imaging (patent expires in 2013), an apparatus for measuring mechanical parameters of the prostate and for imaging the prostate (patent expires in 2012), a device for palpation and mechanical imaging of the prostate (patent expires in 2012), and a method for using a transrectal probe to mechanically image the prostate gland (patent expires in 2012). Together, our mechanical imaging technology is protected by seven U.S. patents, seven foreign patents (foreign patents expire in 2017), five foreign patent applications and, along with the Artann patent applications discussed below, is the basis for the imaging technology used in our ProUroScan System. We own similar patents, patent applications and know-how associated with breast imaging. However, we do not intend to pursue any such applications within our near-term business plan. Under the Artann License Agreement, we agreed to grant Artann a non-exclusive, fully paid up license to make, use or sell any imaging system for the diagnosis or treatment of disorders of the human breast.

Artann has filed four additional U.S. patent applications (filed in May and June of 2005 and June of 2008) that are licensed to us under the Artann License Agreement. These patent applications relate to a method and device for analyzing overlaps between sensed mechanical images to generate a composite image (map) and sensors arranged to locate the prostate.

Third-Party Reimbursement

In the U.S., health care providers that use the ProUroScan System will generally rely on third-party payors, including private payors and governmental payors such as Medicare and Medicaid, to cover and reimburse all or part of the cost of using the ProUroScan System. Consequently, sales of the ProUroScan System depend in part on the availability of coverage and reimbursement from third-party payors. The manner in which reimbursement is sought and obtained varies based upon the type of payor involved and the setting in which the procedure is furnished. In general, third-party payors will provide coverage and reimbursement for medically reasonable and necessary procedures and tests. Most payors, however, will not pay separately for capital equipment, such as the ProUroScan System. Instead, payment for the cost of using the capital equipment is considered to be covered as part of payments received for performing the procedure. In determining payment rates, third-party payors increasingly are scrutinizing the amount charged for medical procedures.

Medicare and Medicaid

Procedures using the ProUroScan System may be considered by Medicare as either a screening test or a diagnostic test depending on whether it is conducted routinely on healthy individuals or whether the patient presents with a sign or symptom of the relevant disease. In order for Medicare to cover procedures using the ProUroScan System as screening, the Secretary of Health and Human Services (the “Secretary”) would need to add the scan to the list of appropriate procedures for prostate cancer screening or the procedure would need to be appropriately

recommended by the United States Preventative Services Task Force (“USPSTF”) and added through the national coverage determination (“NCD”) process.

Recently, Congress expanded the ability for Medicare to cover additional preventive services under certain circumstances. In order to be covered by Medicare, Congress required the following three conditions to be satisfied: (1) the service must be reasonable and necessary for the prevention or early detection of an illness or disability; (2) the service must be recommended with a grade of “A” or “B” by the USPSTF; and (3) the service must be appropriate for Medicare beneficiaries. Congress also required that the Centers for Medicare and Medicaid (“CMS”) use the NCD process to add covered preventative services.

The USPSTF has evaluated the benefits of prostate screening and concluded that the current evidence is insufficient to make an “A” or “B” recommendation, regardless of age. Should the USPSTF change its recommendation, CMS still would need to use the NCD process to make prostate screening with the ProUroScan System a covered service. The NCD process is at least nine months long and in most cases lasts one year. There is no guarantee that this process will result in a positive outcome. In fact, CMS could decide not to cover prostate screening procedures using the ProUroScan System nationally. It is very difficult to overturn a negative NCD without the further development of substantial clinical evidence.

Medicare coverage as a screening test could be a significant hurdle to overcome. We anticipate, however, that the ProUroScan System may be covered by Medicare as a diagnostic test for patients who have clinical signs or symptoms of disease. We anticipate that the first generation of the ProUroScan System will be used to map the prostate and to maintain historical records for future tracking for men who have an abnormal DRE or other signs or symptoms of disease. Thus, providers who perform prostate mapping using the first generation ProUroScan System likely will seek Medicare coverage as a diagnostic, rather than a screening test, presuming that the patient presents with a sign or symptom of disease. Even as a diagnostic test, however, CMS or its contractors could determine that procedures using the ProUroScan System are not medically necessary and therefore decide not to cover them.

Regardless of how they are covered, we anticipate that procedures using the ProUroScan System will be reimbursed either based upon the value of their unique billing and procedure code or as part of an office visit. Until a unique billing and procedure code is established, we expect that providers will be able to bill for the procedure using a miscellaneous Current Procedural Terminology (“CPT”) code. Claims submitted under a miscellaneous code are processed manually and the provider must include additional information to be used by the payor in determining the medical appropriateness of the procedure. The lack of a unique, permanent CPT code could slow market uptake of the ProUroScan System.

In order to apply for a new, unique code, an application must be submitted to the AMA’s CPT Editorial Panel. The process of obtaining a new CPT code typically takes 14 months to three years. Once a new CPT code is created, the AMA’s Relative Value Scale Update Committee (“RUC”) recommends relative value units (“RVUs”) for it. CMS then takes these recommendations into account when establishing the Medicare Physician Fee Schedule values. The amount of reimbursement the provider receives generally depends on the RVUs assigned to the procedure multiplied by a conversion factor. Most private payers also base their payment rates based on the RVUs adopted by CMS. There is a significant risk that the reimbursement rate that results from this process could be insufficient, hampering our ability to market and sell the ProUroScan System. In the alternative, CMS may decide that payment for the ProUroScan System procedure should be bundled into the payment for a covered office visit furnished to the patient on the same day. Such a determination would impede our ability to commercialize the ProUroScan System as physicians and providers would probably not want to absorb the additional expense of our product without additional reimbursement.

Initially, we anticipate using a “patient pay model” for physicians to receive payment for performing the ProUroScan System procedure. Under a patient pay model, in the absence of coverage from their health insurance, patients pay for the scan out of their own funds. Medicare beneficiaries would sign an Advanced Beneficiary Notice

("ABN") that would allow the provider to collect from the patient. Only one in four biopsies performed based on an abnormal PSA reading reveal prostate cancer, and only 50 percent of suspicious lesions found by DRE presented cancer on prostate biopsy. Given these statistics, in cases where patients have abnormal DRE or PSA test results or when a test result may not be clear, there is a high incentive to seek additional information so that patients can make an informed and reasonable decision for themselves and their family. We believe that a sufficient number of patients will be willing to pay for the ProUroScan System procedure out of their personal funds to support the launch of our product in advance of receiving favorable coverage decisions from third-party insurers. The concept of a patient pay model has been used successfully for a few other procedures (e.g., computer-aided detection ("CAD") for mammography), and we expect this to be our approach for generating revenues during at least the early phases of product rollout. As described above, providers also will be able to bill under a miscellaneous CPT code until a unique CPT code is created for the ProUroScan System procedure.

Commercial Insurers

Many private payors look to Medicare as a guideline in setting their coverage policies and payment amounts. Unlike the Medicare program, however, private payors have no statutory impediment to covering screening tests. They do tend to seek guidance from USPSTF recommendations, however. The current coverage policies of these private payors may differ from the Medicare program, and the payment rates they make may be higher, lower, or the same as the Medicare program. If CMS or other agencies decrease or limit reimbursement payments for physicians, this may affect coverage and reimbursement determinations by many private payors. Additionally, some private payors do not follow the Medicare guidelines, and those payors may reimburse only a portion of the costs associated with the use of our products, or not at all.

Competition

Although we expect competition to intensify in the prostate imaging and prostate disease diagnostic market, we are not aware of any competitive product currently being sold based on the same technology platform with comparable real-time color images or other product features that the ProUroScan System provides. In addition, we do not expect to market the ProUroScan System as a general screening tool, and therefore will not be positioning the system to compete directly with currently available screening tests, including the DRE and PSA tests. The ProUroScan System will be positioned as an "adjunctive" tool following an abnormal DRE to create a map of the prostate and an electronic record of the image. More specifically, the proposed indication for use of the ProUroScan System is for use as an aid to the physician in visualizing and documenting abnormalities of the prostate detected by a DRE.

Another test that uses inferred data to identify prostate cancer, yet to be approved in the United States, is the PCA3 Marker (the "PCA3"). The PCA3 is a non-coding ribonucleic acid ("RNA") believed to be a more accurate marker of prostate cancer than currently used diagnostics tests. The PCA3 marker was licensed in 2000 by DiagnoCure Inc. of Quebec, Canada. In 2003, DiagnoCure granted a worldwide license to Gen-Probe, based in San Diego, CA, for the development and licensing of a second generation PCA3-based test using their proprietary platform. In 2006, Gen-Probe made the test available in analyte specific reagent format to U.S. laboratories and launched a full CE-marked PCA3 test in Europe. Although this test has not been approved in the United States, it potentially represents a significant advance in the development of more sophisticated and sensitive detection methods for identifying early stage prostate cancer. Gene fusion is another discovery that may lead to a test that potentially will be used to diagnose prostate cancer more accurately than current tests as well as predict prognosis. Gen-Probe has licensed this technology as well.

In contrast to the DRE, PSA and PCA3 tests, the ProUroScan System creates a visual and physical record of the prostate gland. We will seek expanded labeling claims on future generations of the ProUroScan System so that it can also be used to conduct ongoing monitoring and surveillance of the status of the abnormal tissue that is found by

either a DRE or with the ProUroScan System. We believe that the current generation of the ProUroScan System will have several features that are complementary to a traditional DRE examination, such as:

- it is designed to produce a real-time color image of the prostate; and
- it is designed to enable physicians to electronically store the images in patient files.

Aside from large-scale imaging modalities such as magnetic resonance imaging, computed tomography and nuclear medicine, which due to their cost and limited availability will not be direct competitors of the ProUroScan System, the only imaging system in common use for prostates is the transrectal ultrasound (“TRUS”). TRUS is employed by urologists following the referral of a patient that has had a positive result from a DRE or PSA test, primarily to guide the placement of prostate biopsy needles. We believe that the ProUroScan System will be easier to operate and require less training than TRUS. We also believe it will be less costly to acquire and maintain in a traditional medical office setting.

Subject to FDA clearance or approval, we believe that future uses of the ProUroScan System will include providing a permanent record of the prostate that can be used to identify changes over time. Nevertheless, technology is rapidly changing in the prostate imaging and the prostate disease diagnostic market, and other technology could come to market potentially displacing the ProUroScan System.

Government Regulation

The ProUroScan System is subject to the Federal Food, Drug, and Cosmetic Act (“FDCA”) as implemented and enforced by the FDA and by comparable agencies in various states and various foreign countries. To ensure that medical products distributed domestically and internationally are safe and effective for their intended use, FDA and comparable authorities in other countries have imposed regulations that govern, among other things, the following activities that we or our third-party manufacturers and suppliers perform or will perform:

- product design and development;
- product testing;
- product manufacturing;
- product labeling;
- product storage;
- premarket clearance or approval;
- advertising and promotion;
- product marketing, sales and distribution; and
- post-market surveillance reporting death or serious injuries and medical device reporting.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device we wish to market in the U.S. will require either 510(k) clearance or approval of a Premarket Approval Application (“PMA”) from the FDA. The FDA classifies medical devices into one of three classes:

- Class I devices, which are subject to only general controls (e.g., labeling, medical devices reporting, and prohibitions against adulteration and misbranding) and, in some cases, to the 510(k) premarket clearance requirements;
- Class II devices, generally requiring 510(k) premarket clearance before they may be commercially marketed in the United States (based on discussions between Artann and the FDA, we believe the use of the ProUroScan System will be classified as a class II device); and
- Class III devices, consisting of devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device, generally requiring submission of a PMA supported by clinical trial data.

Devices deemed to pose lower risks are placed in either class I or II, which typically requires the manufacturer to submit to the FDA a 510(k) requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risks, or for which there is no predicate, are placed in class III, requiring approval of a PMA.

510(k) Clearance Pathway

When a 510(k) clearance is required, we or Artann, as the case may be, will be required to submit a 510(k) demonstrating that our proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of PMAs. By regulation, the FDA is required to clear or deny a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, clearance may take longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence.

Once filed, the FDA has 90 days in which to review the 510(k) application and respond. Typically, the FDA's response after reviewing a 510(k) is a request for additional data or clarification. Depending on the complexity of the application and the amount of data required, the process may be lengthened by several months or more. If additional data, including clinical data, are needed to support our claims, the 510(k) application process may be significantly lengthened. Published FDA statistics from 2006 (the most recent available) indicate that the average total time from receipt of a 510(k) application to final action (not including the time a submission is on hold pending receipt of additional information) is 95 days.

If the FDA issues an order declaring the device to be Not Substantially Equivalent ("NSE") and places it into a class III or PMA category, we can then request a de novo classification of the product. De novo generally applies where there is no predicate device and the FDA believes the device is sufficiently safe so that no PMA should be required. The request must be in writing and sent within 30 days from the receipt of the NSE determination. The request should include a description of the device, labeling for the device, reasons for the recommended classification and information to support the recommendation. The de novo process has a 60 day review period. If the FDA classifies the device into class II, the Company will then receive an approval order to market the device. This device type can then be used as a predicate device for future 510(k) submissions. However, if the FDA subsequently determines that the device will remain in the class III category, the device cannot be marketed until the Company has obtained an approved PMA. If we are required to follow a de novo process, an additional 60 to 90 days or more will be added on to the original 90 days required for the initial 510(k) review.

Any modification to a 510(k)-cleared device that would constitute a major change in its intended use, or any change that could significantly affect the safety or effectiveness of the device, requires a new 510(k) clearance and may even, in some circumstances, require a PMA, if the change raises complex or novel scientific issues or the product has a new intended use. The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. If the FDA

were to disagree with any of our determinations that changes did not require a new 510(k), it could require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or PMA approval is obtained. If the FDA requires us to seek 510(k) clearance or PMA approval for any modifications, we may be required to cease marketing and/or recall the modified device, if already in distribution, until 510(k) clearance or PMA approval is obtained and we could be subject to significant regulatory fines or penalties.

There is no guarantee that the FDA will grant 510(k) clearance of the ProUroScan System for a basic mapping and data maintenance claim, or 510(k) clearance or PMA approval, of any of our future products. Failure to obtain such clearances or approvals could adversely affect our ability to grow our business. Delays in receipt or failure to receive clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements could have a material adverse effect on our business.

Premarket Approval (PMA) Pathway

A PMA must be submitted to the FDA if the device cannot be cleared through the 510(k) process. A PMA must be supported by extensive data, including but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. During the review period, the FDA will typically request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the QSRs.

New PMAs or PMA supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. There is no guarantee that the FDA will grant PMA approval of any new indications for use of the ProUroScan System or for our future products. Failure to obtain such approvals would adversely affect our ability to grow our business. Delays in receipt or failure to receive approvals, the loss of previously received approvals, or the failure to comply with existing or future regulatory requirements could reduce our sales, profitability and future growth prospects.

Clinical Trials

Clinical trials are generally required to support a PMA application and are sometimes required for 510(k) clearance. If the device presents a "significant risk," as defined by the FDA, to human health, the FDA requires the device sponsor to file an investigational device exemption (an "IDE") application with the FDA and obtain IDE approval prior to commencing the human clinical trials. Such trials generally require an IDE application approved in advance by the FDA for a specified number of patients and study sites, unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an institutional review board ("IRB") for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. To conduct a clinical trial, we also are required to obtain the patients' informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. If the clinical trial is not performed in accordance with the FDA's IDE regulations, the FDA could seek an enforcement action against the sponsor and the investigators. In addition, the sponsor, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the U.S. Similarly, in Europe the clinical study must be

approved by a local ethics committee and in some cases, including studies with high-risk devices, by the ministry of health in the applicable country.

Pervasive and Continuing Regulation

After a device is placed on the market, numerous regulatory requirements apply. These include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of our approved devices;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; and
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In addition, we are required to meet regulatory requirements in countries outside the U.S., which can change rapidly with relatively short notice. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved or uncleared use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

Furthermore, our products could be subject to voluntary recall if we or the FDA determine, for any reason, that our products pose a risk of injury or are otherwise defective. Moreover, the FDA can order a mandatory recall if there is a reasonable probability that our device would cause serious adverse health consequences or death.

The FDA has broad post-market and regulatory enforcement powers. Our facilities and the manufacturing facilities of our subcontractors will be subject to unannounced inspections by the FDA to determine our level of compliance with the QSR and other regulations. Failure by us or by our third-party manufacturers and suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions including, but not limited to:

- warning letters or untitled letters;
- fines and civil penalties;
- unanticipated expenditures to address or defend such actions;
- delays in clearing or approving, or refusal to clear or approve, our products;
- withdrawal or suspension of approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies;
- product recall or seizure;
- orders for physician notification or device repair, replacement or refund;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

Regulation of the ProUroScan System

The ProUroScan System is being developed under development contracts with Artann. We are implementing a regulatory strategy to obtain 510(k) clearance of the ProUroScan System for a basic mapping and data maintenance claim and for the ProUroScan System to serve as an adjunct to a DRE. We believe that this basic mapping and data maintenance claim reflects the current needs of the market and the capabilities of the system. Based on discussions between Artann and representatives from the FDA, we believe that the ProUroScan System with a basic mapping and data maintenance claim will be regulated by the FDA as a class II device. Class II devices typically are cleared for marketing by the FDA through a 510(k) application.

In an April 2008, representatives from Artann met with the FDA to solicit feedback from the agency regarding the proposed clinical testing that the FDA will require to support a 510(k). At that meeting, the FDA indicated that Artann will need to conduct a 40 patient clinical trial on the ProUroScan System. In this study, which will be conducted by Artann, clinical investigators from at least three different sites will be trained to use the ProUroScan System on prostate models. Subsequently, each of the trained investigators will be asked to perform a standard DRE examination followed by the ProUroScan System on study patients with a DRE detected abnormality. The study subjects will also have pathology characterization of the DRE detected prostate abnormality as the patients included in the study will have been referred for a TRUS guided biopsy or radical prostatectomy. Artann intends to conduct this study as a non-significant risk study. As a result, FDA approval of an IDE is not required. However, Artann will still

be required to comply with FDA's abbreviated IDE regulations, including, among other things, protecting the rights and welfare of all participants and obtaining IRB approval from each study center.

In order to meet the requirements established by the FDA for the 510(k) clinical study, three centers were identified to participate in the study and to serve as future training and referral sites for the eventual market rollout of the ProUroScan System. The sites include the Mayo Clinic in Rochester, Minnesota, the Robert Wood Johnson Medical Center in New Brunswick, New Jersey and the VA Medical Center in Minneapolis, Minnesota. Institutional Review Board ("IRB") approvals have been obtained, and ProUroScan Systems have been installed, at all three sites. Physician training has also been completed at all three sites and formal clinical studies have commenced at the Robert Wood Johnson Medical Center and the VA Medical Center. It is expected that clinical studies will commence at the Mayo Clinic in late March or early April 2009. We expect to complete this study in May 2009.

In accordance with the Artann Development Agreement, Artann is responsible for submitting and obtaining the initial 510(k) clearance for the ProUroScan System. We believe that this 510(k) will be submitted to the FDA shortly after completion of the clinical studies. Once submitted, the FDA will have 90 days to review and grant clearance. However, the 510(k) application process may be significantly longer if the FDA has questions upon its review or makes a request for additional information, including clinical data, from Artann. Once cleared, in accordance with the Artann Development Agreement, Artann will transfer the 510(k) for the ProUroScan System upon ProUroCare's first commercial sale of a ProUroScan System unit.

Depending on the exact nature of future claims, the approval process may require more extensive clinical studies and possibly the submission of a PMA. Such an application will likely take significantly more time to prepare and review and be more comprehensive than the 510(k) clearance process.

Once we obtain the 510(k) for the ProUroScan System, or obtain FDA clearance or approval for future products, the manufacturing, sale and performance of our products will be subject to the ongoing FDA regulation and inspection processes as described above.

Fraud and Abuse Laws

Because of the significant federal funding involved in Medicare and Medicaid, Congress and the states have enacted, and actively enforce, a number of laws whose purpose is to eliminate fraud and abuse in federal health care programs. Once we commercialize the ProUroScan System, our business is subject to compliance with these laws.

Anti-Kickback Statutes and Federal False Claims Act

The federal healthcare programs Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid. The definition of "remuneration" has been broadly interpreted to include anything of value, including for example gifts, discounts, the furnishing of free supplies, equipment or services, credit arrangements, payments of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. In addition, some kickback allegations have been claimed to violate the Federal False Claims Act, discussed in more detail below.

The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the Office of Inspector General of the

U.S. Department of Health and Human Services, or OIG, to issue a series of regulations, known as “safe harbors.” These safe harbors, issued by the OIG beginning in July 1991, set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG.

Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

Government officials have focused their enforcement efforts on marketing of healthcare services and products, among other activities, and recently have brought cases against companies, and certain sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

Another development affecting the healthcare industry is the increased use of the federal Civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act’s “whistleblower” or “*qui tam*” provisions. The False Claims Act imposes liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The *qui tam* provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government and to share in any monetary recovery. In recent years, the number of suits brought against healthcare providers by private individuals has increased dramatically. In addition, various states have enacted false claim laws analogous to the Civil False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program.

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between \$5,500 to \$11,000 for each separate false claim. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act has been used to assert liability on the basis of inadequate care, kickbacks and other improper referrals, and improper use of Medicare numbers when detailing the provider of services, in addition to the more predictable allegations as to misrepresentations with respect to the services rendered. In addition, companies have been prosecuted under the False Claims Act in connection with alleged off-label promotion of products. Our future activities relating to the reporting of wholesale or estimated retail prices for our products, the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products, and the sale and marketing of our products, may be subject to scrutiny under these laws. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

HIPAA and Other Fraud and Privacy Regulations

Among other things, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The HIPAA health care fraud statute prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment and/or exclusion from government-sponsored programs. The HIPAA false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making

any materially false, fictitious or fraudulent statement or representation in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines and/or imprisonment.

In addition to creating the two new federal healthcare crimes, regulations implementing HIPAA also establish uniform standards governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses, which are referred to as "covered entities." Three standards have been promulgated under HIPAA's regulations: the Standards for Privacy of Individually Identifiable Health Information, which restrict the use and disclosure of certain individually identifiable health information, the Standards for Electronic Transactions, which establish standards for common healthcare transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures, and the Security Standards, which require covered entities to implement and maintain certain security measures to safeguard certain electronic health information. Although we are not a covered entity and therefore not directly subject to these standards, we expect that our customers generally will be covered entities and may ask us to contractually comply with certain aspects of these standards, particularly because we expect that the ProUroScan System will store patient information and scan results. The government intended this legislation to reduce administrative expenses and burdens for the healthcare industry; however, our compliance with certain provisions of these standards entails significant costs for us.

In addition to federal regulations issued under HIPAA, some states have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA. In those cases, it may be necessary to modify our planned operations and procedures to comply with the more stringent state laws. If we fail to comply with applicable state laws and regulations, we could be subject to additional sanctions.

Employees

We currently have only two full-time employees, and expect to conduct much of our research and development, market research, clinical and regulatory function, and other business operations through the use of a variety of consultants and medical-device development contractors. We believe that using consultants and contractors, including the significant scientific and engineering resources of Artann, to perform these functions is more cost effective than hiring full-time employees, and affords us flexibility in directing our resources toward specific and changing goals during our development stage. We anticipate hiring approximately eight additional employees during the remainder of 2009 in the areas of manufacturing management, marketing, sales training, administration and quality assurance. Some or all of these functions may be performed by contracted individuals or consultants as management deems most effective. To date, we have conducted our research and development activities related to our acquired technologies and proposed products on a contract basis with Artann, Devicix, LLC and Minnetronix, Inc.

ITEM 1A. RISK FACTORS

Important Notices to Investors; Safe Harbor Statement

Statements in this Annual Report on Form 10-K which are not purely historical are forward-looking statements. These statements with respect to the goals, plan objectives, intentions, expectations, financial condition, results of operations, future performance and business of our Company, including, without limitation: (i) our ability to successfully complete all clinical trials and commercial development of our products and secure all necessary federal and other regulatory approvals to introduce and market our products in the United States and around the world; (ii) our ability to fund our working capital needs over the next 12 to 24 months; (iii) our ability to successfully introduce our products into the medical device markets; and (iv) all statements preceded by, followed by or that include the words "may," "would," "could," "should," "expects," "projects," "anticipates," "believes," "estimates," "plans," "intends," "targets" or similar expressions.

Forward-looking statements involve inherent risks and uncertainties, and important factors (many of which are beyond our control) that could cause actual results to differ materially from those set forth in the forward-looking statements, including the following, in addition to those contained in our Company's reports on file with the Securities and Exchange Commission: general economic or industry conditions, nationally and in the physician, urology and medical device communities in which we intend to do business; our ability to fund our working capital needs over the next 12 to 24 months; our ability to complete the development of our existing and proposed products on a timely basis if at all; legislation or regulatory requirements, including our securing all FDA and other regulatory approvals on a timely basis, if at all, prior to being able to market and sell our products in the United States; competition from larger and more well established medical device and other competitors; the development of products that may be superior to the products offered by us; securing and protecting our intellectual property and assets and enforcing breaches of the same; clinical results not anticipated by management of the Company; the quality or composition of our products and the strength and reliability of our contract vendors and partners; ability to raise capital to fund our 2009 and 2010 working capital needs and launch our products into the marketplace in subsequent years; changes in accounting principles, policies or guidelines; financial or political instability; acts of war or terrorism; and other economic, competitive, governmental, regulatory and technical factors affecting our operations, proposed products and prices.

Accordingly, results actually achieved may differ materially from expected results in these statements. Forward-looking statements speak only as of the date they are made. We do not undertake, and specifically disclaim, any obligation to update any forward-looking statements to reflect events or circumstances occurring after the date of such statements.

Risk Factors Associated with our Business, Operations and Securities

We are a development stage company. We have no operating history and our business plan has not yet been fully tested. We anticipate incurring future losses and may continue incurring losses after our products are completed, regulatory clearance or approval is secured and our products are introduced and accepted in the United States and worldwide markets.

We are a development-stage company. We have yet to commence active operations to manufacture or sell any products associated with the proprietary urology-based imaging technologies that we intend to market. We have no prior operating history from which to evaluate our likelihood of success in operating our business, generating any revenues or achieving profitability. As of December 31, 2008, we have generated no revenue and have recorded losses since inception of approximately \$21 million. There can be no assurance that our plans for developing and marketing our urology-based products will be successful, or that we will ever attain significant sales or profitability. We anticipate that we will incur losses in the near future.

We have a history of operating losses and have received a “going-concern” qualification from our independent registered public accounting firm.

We have incurred operating losses and negative cash flows from operations since inception. As of December 31, 2008, we had an accumulated shareholders' deficit of approximately \$7.3 million. We have not yet generated any revenues. These factors, among others, raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements included in this Annual Report on Form 10-K do not include any adjustments related to recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result should we be unable to continue as a going concern.

Our independent registered public accounting firm included an explanatory paragraph in their report on our financial statements indicating that such deficit accumulated during the development stage raises substantial doubt as to our ability to continue as a going concern. The likelihood of our success must be considered in light of the expenses, difficulties and delays frequently encountered in connection with development stage businesses and the

competitive environment in which we will operate. Our ability to achieve profitability is dependent in large part on obtaining FDA clearance or approval for the ProUroScan System, implementing a “patient pay” sales model, achieving third party coverage and reimbursement, establishing distribution channels, forming relationships with third-party manufacturers and gaining market acceptance of the ProUroScan System. There can be no assurance that the Company will successfully market the ProUroScan System or operate profitably.

We will need additional financing, and any such financing will likely be dilutive to our existing shareholders.

As of February 28, 2009, we had approximately \$774,000 of cash on hand and current liabilities of \$3.5 million, including \$2.2 million of secured debt that was due on that date. In March 2009, we renewed \$1.8 million of the secured debt to mature on March 28, 2010, and temporarily paid down \$400,000 of the secured debt pending the Company obtaining a satisfactory guaranty of that amount. It is our intent to renew the \$400,000 secured debt before the end of May 2009; however, there can be no assurance that a satisfactory guaranty can be obtained. We expect that our existing cash will be sufficient to allow us to complete the ProUroScan system clinical trials, submit a 510(k) application to the FDA and obtain clearance for a basic mapping and data maintenance claim. However, if our clinical trials experience unforeseen delays, or FDA regulatory clearance delays, or are unable to establish a satisfactory guaranty of the secured debt, we may not have sufficient funds to complete these objectives, and will require additional financing. In addition, we will need funding to pay, for example, up to \$1,000,000 of future payments to Artann related to FDA 510(k) clearance milestones.

If product development is completed on schedule, we expect to pursue one or more additional rounds of funding in 2009 and 2010 to provide the working capital needed to repay our existing debt and to fund a commercial launch into the urology market. In addition, if we fail to secure a distribution partner on terms acceptable to us, or at all, we could be required to undertake distribution activity at our expense, which could significantly increase our capital requirements and may delay the commercialization of our products.

If additional funds are raised by the issuance of convertible debt or equity securities, such as the issuance of stock, or the issuance and exercise of warrants, the issuance and conversion of convertible debentures, then existing shareholders will experience dilution in their ownership interest. If additional funds are raised by the issuance of debt or certain equity instruments, we may become subject to certain operational limitations, and such securities may have rights senior to those of existing holders of common stock. There can be no assurance that we will be successful in obtaining such additional financing, if needed. Additional financing may not be available to us, may not be available on favorable terms and will likely be dilutive to existing shareholders.

Our assets are pledged to secure \$1.6 million of senior bank notes and a \$600,000 note issued to an investor which become due in March 2010 and, as a result, are not available to secure other senior debt financing. Upon the occurrence of an event of default, our assets will be assigned to guarantors of the senior bank note and the holder of such \$600,000 promissory note.

Our \$1.6 million senior debt financing through Crown Bank, Minneapolis, Minnesota, has required us to pledge all of our assets and certain licenses, as well as to provide personal guarantees of certain shareholders. In addition, we have issued a subordinated promissory note in the amount of \$600,000 to an investor. Such note has a subordinated interest in all of our assets and certain licenses. Both the \$1.6 million senior bank notes and the \$600,000 note issued to an investor become due on March 28, 2010. Due to such security interests, the Company will not be in a position in the future to pledge its assets to secure any debt or lending facility, in the event we desire or need to borrow such funds on a secured lending basis. It is doubtful that the Company would be able to obtain significant additional debt financing on an unsecured basis.

Moreover, under the terms and conditions of the Crown Bank facility, and our agreement with such guarantors, in the event of any default by us with our senior lender that causes the personal guarantees to be called and honored, we and our lender have agreed that all of the Company’s assets shall be assigned to such guarantors, pro rata,

in consideration of such breach and obligation to pay under the respective guarantees. In addition, the holder of the \$600,000 promissory note has a subordinated interest in all of the Company's assets in the event of a default under the note. Thus, our common shareholders, and any existing and future investors in our common stock, would, if the foregoing breach and circumstances occurred, not have access or recourse to the Company's assets and collateral, and thus, would likely face a complete loss of their investment in the Company.

If adequate funds are not available on a timely basis, we could potentially be forced to cease operations.

If adequate funds are not available on a timely basis, or are not available on acceptable terms, we may be unable to repay our existing debt, to fund expansion, or to develop or enhance our products. If we are forced to slow our development programs, or put them on hold, it would delay our efforts to obtain regulatory clearances or approvals needed, and thus delay market entry for our products. Ultimately, if adequate financing is not obtained, we could potentially be forced to cease operations.

The current unprecedented volatility in the worldwide credit and equity markets may have an impact on our ability to obtain future financing.

We do not know what impact the current unprecedented volatility in worldwide credit and equity markets may have on our ability to obtain future financing. Since September 2008, we have seen unprecedented turmoil in equity and credit markets that has resulted in record-setting losses in the stock markets, dramatic decreases of liquidity in the credit markets, bank failures, hedge fund closures and massive market intervention by the United States and foreign governments. Because of the unprecedented nature of these market events, and because the markets remain highly-volatile today, we cannot predict what effect these events will have on our ability to obtain financing in the future. If we are unable to raise sufficient capital, including funds necessary to repay our loans due on March 28, 2010, it will have a material adverse effect on our financial condition and our ability to remain in business.

The ProUroScan System has not been, and may never be, fully commercially completed and developed.

Only a limited number of complete ProUroScan Systems have been built for testing, clinical validations and demonstration purposes to assess the feasibility of the device and to provide a means to test and develop future systems and we have not built any systems for commercial sale. The completion of development of the ProUroScan System, or future generations of the ProUroScan System, remains subject to all the risks associated with the development and manufacture of new products based on innovative technologies, including unanticipated technical or other problems, failures to meet FDA requirements or performance objectives and the possible insufficiency of the funds allocated for the completion of such development, which could result in a change in the design, delay in the development or abandonment of such applications and products. Consequently, there can be no assurance that the ProUroScan System will be successfully developed or manufactured. Our failure to complete the development of the ProUroScan System, or to work with Artann or other third parties to develop new products, will have a materially adverse effect on our business.

We are relying upon Artann to submit and obtain 510(k) clearance of the ProUroScan System. There is no guarantee that the FDA will grant timely 510(k) clearance of the ProUroScan System, if at all, and failure to obtain such timely clearance would adversely affect our ability to market that product and expand utilization of the technology in other prostate applications or in other soft tissue organs in the body, which may affect our ability to grow our business.

The ProUroScan System is subject to regulation by the FDA and by comparable agencies in various foreign countries. The process of complying with the requirements of the FDA and comparable agencies is costly, time consuming and burdensome. We believe the ProUroScan System with a basic mapping and data maintenance claim will be regulated by the FDA as a class II device and will require the clearance of a 510(k) application. By regulation,

the FDA is required to clear or deny a 510(k) application within 90 days of submission of the application, but as a practical matter, clearance may take much longer.

Under our current development and commercialization agreement, dated July 25, 2008, with Artann (the “Artann Development Agreement”), Artann is responsible for filing the initial 510(k) for the ProUroScan System with the FDA. Artann has not yet submitted that 510(k) to obtain FDA clearance and no assurances can be given that such filing will be submitted, and, once submitted, will be acceptable to the FDA. Prior to submitting such a 510(k) to the FDA, Artann will need to conduct additional preclinical and clinical testing of the device to support clearance of the current device. In addition, although Artann is contractually obligated to perform certain tasks for us under the Artann Development Agreement, there can be no assurance that Artann’s existing grant-based resources or other funding will be adequate to enable Artann to complete these tasks on a timely basis or at all.

There is no guarantee that the FDA will grant 510(k) clearance in a timely manner, if at all, for the ProUroScan System with basic mapping and data maintenance claims. Failure to obtain clearance for the ProUroScan System would require Artann to re-apply for 510(k) clearance with additional supporting data or information or for a different labeling claim, submit a Premarket Approval Application (a “PMA”) for FDA approval, or abandon the product. Even if FDA 510(k) clearance is received, Artann may encounter significant delays in receiving such clearance. If unexpected clearance delays occur, or if Artann needs to re-apply for FDA clearance or submit a PMA, it could have a material adverse effect on our business as Artann is to transfer such clearance or approval to us once we make the first commercial sale of the ProUroScan System. If such delays occur, we would need to obtain additional financing to continue operations.

Even if successfully developed, our products may not be commercially viable or may not be accepted by the marketplace.

Even if Artann is able to successfully develop the ProUroScan System and we are able to successfully develop future products, we may not be able to contract for the manufacture of such products in commercial quantities at prices that will be commercially viable. Further, there is risk that the ProUroScan System and our future products may not prove to be as effective as currently available medical or diagnostic products or those developed in the future. The inability to successfully complete development of a product or application or a determination by us, for financial, technical or other reasons not to complete development of any product or application, particularly in instances in which we have made sufficient capital expenditures, could have a material adverse effect on our business. With respect to the ProUroScan System, under our current Artann Development Agreement, Artann is to transfer the 510(k) to us once we make the first commercial sale of the ProUroScan System. If we are not able to procure a commercial sale of at least one ProUroScan System, Artann would not be obligated to transfer the 510(k) to us and might not do so, thus inhibiting our ability to develop future generations of the product.

Even if successfully developed, the ProUroScan System and our future products will be competing against other imaging and diagnostic products in the medical device marketplace, including those developed in the future that may render the ProUroScan System obsolete. The DRE, in combination with a PSA test, is part of today’s “standard of care” to evaluate patients over the age of 50 for prostate cancer or other ailments relating to the prostate. In addition, other modalities that can be used for diagnostic imaging include transrectal ultrasound (“TRUS”), magnetic resonance imaging, computed tomography and nuclear medicine. Therefore, there can be no assurance that physicians, providers, patients, third party payors or the medical device market, in general, will accept our products.

There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future products and claims and failure to obtain necessary clearances or approvals for our future products and claims would adversely affect our ability to expand utilization of the technology in other prostate applications or in other soft tissue organs in the body, which may affect our ability to grow our business.

In the future, we may seek to obtain additional indications for use of the ProUroScan System beyond the basic mapping and data maintenance claim, as well as clearance and approval of new products. Some of these expanded claims and future products may require FDA clearance of a 510(k). Other claims and future products will require FDA approval of a PMA. Moreover, some of our future products and the additional claims on the ProUroScan System we may seek may require clinical trials to support regulatory approval, and we may not successfully complete these clinical trials. The FDA may not approve or clear these future products, or future generations of the ProUroScan System for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or PMA approval of new products. Failure to receive clearance or approval for additional claims for the ProUroScan System, or for our future products, would have an adverse effect on our ability to expand our business.

We are relying upon Artann to conduct a non-significant risk clinical trial necessary to obtain the initial 510(k) clearance of the ProUroScan System. The results of that clinical trial may not support a basic mapping and data maintenance claim or may result in the discovery of adverse side effects.

Under the Artann Development Agreement, Artann is responsible for conducting all clinical trials necessary to support an initial 510(k) for the ProUroScan System with a basic mapping and data maintenance claim. We cannot be certain that the results will support a basic mapping claim. Success in early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that Artann's 40 patient trial will replicate the results of the earlier study at the Robert Wood Johnson Medical Center. The clinical trial process may fail to meet its desired endpoints, which could cause us to abandon, or delay the development of the ProUroScan System, or necessitate modifications thereto. Any delay or termination of Artann's clinical trial will delay their filing of the 510(k) and ultimately, our ability to commercialize the product and generate revenues. It is also possible that patients enrolled in that clinical trial will experience adverse side effects that are not currently part of the ProUroScan System's profile. In addition, the clinical trials for the ProUroScan System involve a relatively small patient population. Because of the small sample size, these results may not be indicative of future results.

If Artann does not perform, or if any third parties on which we will rely to conduct our clinical trials in the future do not perform, as contractually required or expected, we may not be able to obtain regulatory clearance or approval for, or commercialize, our products.

We are highly dependent on the services provided by Artann. In addition, we intend to rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories, to conduct clinical trials. If Artann or these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if Artann or any of these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. If our clinical trials are not conducted in accordance with the FDA's IDE regulations, the FDA may seek an enforcement action, such as the issuance of a warning letter, against us or the third parties conducting our trials. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

Clinical trials necessary to support our future products and claims will be expensive and may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. These trials may require the submission of an IDE, for which there is not guarantee that the FDA will approve. Delays or failures in our clinical trials will prevent us from commercializing any modified or new products and will adversely affect our business, operating results and prospects.

Initiating and completing clinical trials necessary to support 510(k)s or PMAs for future generations of the ProUroScan System will be time consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials.

Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including: the size of the patient population; the number of patients to be enrolled; the nature of the trial protocol; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites; and the patients' ability to meet the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to investigational products.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required, and we may not adequately develop such protocols to support clearance and approval. Significant risk trials will require the submission and approval of an IDE from the FDA. There is no guarantee that the FDA will approve our future IDE submissions. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, the FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

We have no manufacturing experience, and will rely on third parties to manufacture the ProUroScan System in an efficient manner. If design specification changes are needed to develop an efficient manufacturing process, those changes may require FDA clearance of a new 510(k) or approval of a PMA, which we may not be able to obtain in a timely manner, if at all.

To be successful, the ProUroScan System will need to be manufactured in sufficient quantities, in compliance with regulatory requirements and at an acceptable cost. We have no manufacturing experience. We are in the process of identifying a third-party manufacturer to produce commercial units of the ProUroScan System for distribution after 510(k) clearance or PMA approval is obtained. Prior to commercialization, this third-party manufacturer will identify the most efficient manufacturing process to produce commercial ProUroScan Systems. If device design changes are required to implement an efficient manufacturing process, these design changes will need to be evaluated and implemented in accordance with applicable Quality Systems Regulation ("QSR") requirements. If we implement design changes after the FDA has cleared the ProUroScan System 510(k), we will need to assess whether those design changes could significantly affect the safety or effectiveness of the device, and require the submission and clearance of a new 510(k), or even require the submission of a PMA. If we determine that these modifications require a new 510(k) clearance or PMA approval, we may not be able to obtain this additional clearance in a timely manner, or at all. In general, obtaining additional clearances can be a time consuming process, and delays in obtaining required

future clearances would adversely affect our ability to market the ProUroScan System in a timely manner, which in turn would harm our future growth.

If we or our third-party manufacturers or suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain FDA clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our third-party manufacturers and certain of our suppliers will be required to comply with the FDA's QSR, regulations for the manufacture of our products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. The failure by us or one of our third-party manufacturers or suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- warning letters or untitled letters;
- fines and civil penalties;
- unanticipated expenditures to address or defend such actions;
- delays in clearing or approving, or refusal to clear or approve, our products;
- withdrawal or suspension of approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies;
- product recall or seizure;
- orders for physician notification or device repair, replacement or refund;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our third-party manufacturers and suppliers may not be in compliance with all applicable regulatory requirements which could result in failure to supply our products in required quantities, if at all.

Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to serious regulatory

enforcement actions, including some of those listed above. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, or regulatory enforcement actions.

Our products may in the future be subject to product recalls that could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a mandatory recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, initiate a field correction or removal, known as a recall, for a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our third-party manufacturers or suppliers could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

If our marketed products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulation, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

We will depend upon others for the manufacturing of our products, which will subject our business to the risk that we will be unable to fully control the supply of our products to the market.

Our ability to develop, manufacture and successfully commercialize our future products depends upon our ability to enter into and maintain contractual and collaborative arrangements with others. We do not intend to establish any of our own manufacturing facilities for the ProUroScan System or any of our future products. Instead,

we intend to retain QSR compliant and FDA registered contract manufacturers. We may also have to rely on a sole supplier for certain components of our ProUroScan System. There can be no assurance that such manufacturers will be able to supply our products in the required quantities, at appropriate quality levels or at acceptable costs. We may be adversely affected by any difficulties encountered by such third-party manufacturers that result in product defects, production delays or the inability to fulfill orders on a timely basis. If a manufacturer cannot meet our quality standards and delivery requirements in a cost-efficient manner, we could suffer interruptions of delivery while we arrange for alternative manufacturing sources. Any extended disruption in the delivery of our products could result in our inability to satisfy customer demand for our products. Consequently, our inability to obtain alternative sources on a timely basis may have a material adverse effect on our business.

We may incur significant liability if it is determined that we are promoting off-label use of our products in violation of federal and state regulations in the United States or elsewhere.

Artann initially intends to seek clearance of the ProUroScan System from the FDA solely for a basic mapping and data maintenance claim. We believe that seeking 510(k) clearance for this limited indication is the least burdensome path to initial regulatory clearance. Our business and future growth, however, will depend primarily on the use or enhancement of the ProUroScan System to identify the specific 3-dimensional location of lesions in the prostate, to create a 3-dimensional image of the position of the lesions, and allow the physician to rotate the image to assist in identifying the actual position of the lesion in the prostate gland in order to provide a diagnosis of the patient's condition. Once 510(k) clearance is obtained and the ProUroScan System 510(k) is transferred to us from Artann, we intend to subsequently seek regulatory clearance or PMA approval for use of the ProUroScan System for a variety of other prostate related indications. Unless and until we receive regulatory clearance or approval for use of the ProUroScan System in these procedures, uses in procedures other than basic mapping and data maintenance will be considered off-label uses of the ProUroScan System. Under the Federal Food, Drug, and Cosmetic Act (the "FDCA") and other similar laws, we are prohibited from labeling or promoting our products, or training physicians, for such off-label uses. This prohibition means that the FDA could deem it unlawful for us to make claims about the safety or effectiveness of the ProUroScan System in the diagnosis of lesions or proactively discuss or provide information or training on the use of the ProUroScan System for the diagnosis of prostate lesions, with very limited exceptions. However, although manufacturers are not permitted to promote for off-label uses, in their practice of medicine, physicians may lawfully choose to use medical devices for off-label uses. Even if the FDA grants 510(k) clearance for the ProUroScan System for use in a basic mapping and data maintenance claim, a physician could use the ProUroScan System for uses not covered by the cleared labeling. This would constitute an off-label use. We expect that hospitals and physicians will use the ProUroScan System for a variety of uses beyond mapping prostate anatomy.

The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. Due to these legal constraints, our sales and marketing efforts will focus only on the general technical attributes and benefits of the ProUroScan System and the FDA cleared or approved indications for use.

Federal regulatory reforms may adversely affect our ability to sell our products profitably.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of a medical device. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Without limiting the generality of the foregoing, last year, the Food and Drug Administration Amendments Act of 2007 (the "Amendments") were enacted. The Amendments require, among other things, that the FDA propose,

and ultimately implement, regulations that will require manufacturers to label medical devices with unique identifiers unless a waiver is received from the FDA. Once implemented, compliance with those regulations may require us to take additional steps in the manufacture of our products and labeling. These steps may require additional resources and could be costly. In addition, the Amendments will require us to, among other things, comply with clinical trial registration requirements once our clinical trials are initiated.

A failure to successfully implement a “patient pay” sales model prior to establishing third party reimbursement would have a material adverse effect on our product sales and financial results.

Until third-party reimbursement coverage for the ProUroScan System procedure is established, if at all, we anticipate using a “patient pay model” for physicians to receive payment. Under a patient pay model, in the absence of coverage from their health insurance, patients pay for the scan out of their own funds. Any failure to successfully establish a patient pay model would have a material adverse effect on our product sales and financial results.

The financial success of the ProUroScan System and other future medical device products will materially depend on our ability to obtain coverage and reimbursement for them.

The financial success of the ProUroScan System and other medical device products will materially depend on the scope of coverage for each device and the ability of medical service providers to obtain third-party reimbursement from private and public insurance sources, such as Medicare, Medicaid and private payors. It is difficult to predict the timing and outcome of coverage and reimbursement decisions. There can be no assurance that coverage and reimbursement will be obtained or will be obtained at a level that will provide a suitable return to providers of services using our technology.

Because the incidence of prostate cancer increases with age, we expect that a significant percentage of our patients will be Medicare beneficiaries. Obtaining Medicare coverage and reimbursement will be critical to our success. Ensuring adequate Medicare coverage and reimbursement, however, can be a lengthy and expensive endeavor and we cannot provide assurances that we will be successful.

Significantly, the U.S. Congress may pass laws that impact coverage and reimbursement for healthcare services, including Medicare reimbursement to physicians and hospitals. Furthermore, many private payors look to Medicare’s coverage and reimbursement policies in setting their coverage policies and reimbursement amounts. If the Centers for Medicare and Medicaid Services (“CMS”), the federal agency that administers the Medicare program, or Medicare contractors limit coverage or payments to physicians for the ProUroScan System, private payors may similarly limit coverage or payments. In addition, state legislatures may enact laws limiting or otherwise affecting the level of Medicaid reimbursement for procedures using the ProUroScan System. As a result, physicians may not purchase our ProUroScan System, and, consequently, our business and financial results would be adversely affected.

We do not currently receive coverage and reimbursement from any party for the use of our products because we have no products fully developed and currently available for sale in the marketplace. As a result, we have not taken any steps to obtain approval for coverage and reimbursement for the use of the ProUroScan System.

Our failure to receive the third-party coverage for our products could result in diminished marketability of our products.

Generally, Medicare does not cover and pay for items and services that are not reasonable or necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. This means that Medicare does not usually cover and pay for preventative services, including routine screening tests for patients who do not present with any signs or symptoms of disease, unless the law specifically provides for such preventative coverage. Such statutory coverage currently exists for prostate cancer screening tests. Specifically, the law states that Medicare will cover a prostate screening test that consists of a DRE and/or a PSA test provided for the purpose of early detection of prostate cancer to a man over 50 years of age who has not had such test during the preceding year. In addition, the law provides the Secretary of Health and Human Services (the “Secretary”) the authority to cover

other prostate screening tests based upon changes in technology and standards of medical practice, availability, effectiveness, costs and other factors deemed appropriate by the Secretary. Thus, for the ProUroScan System to receive Medicare coverage as a prostate screening test, the Secretary would need to add the scan to the list of appropriate procedures for prostate cancer screening. This could be a significant hurdle for the ProUroScan System to receive Medicare coverage as a prostate screening test. Additionally, Congress recently created an alternative pathway for Medicare to cover preventative services. Preventative services that receive a grade “A” or “B” by the United States Preventive Services Task Force (USPSTF) are eligible for Medicare coverage. The USPSTF does not currently recommend prostate cancer screening with either grade.

We anticipate, however, that the ProUroScan System may be covered by Medicare as a diagnostic test for patients who have clinical signs or symptoms of disease. Obtaining Medicare coverage as a diagnostic test is more straightforward as long as the test is reasonable and necessary. For example, the PSA test is covered as a diagnostic test when used to differentiate benign from malignant disease in men with lower urinary tract signs and symptoms (e.g., hematuria, slow urine stream, hesitancy, urgency, frequency, nocturia and incontinence) as well as with patients with palpably abnormal prostate glands on physician exam, and in patients with other laboratory or imaging studies that suggest the possibility of a malignant prostate disorder. We anticipate that the first generation of the ProUroScan System will be used to map the prostate and to maintain historical records for future tracking for men who have an abnormal DRE or other signs or symptoms of disease. Thus, providers who perform prostate mapping using the first generation ProUroScan System likely will seek Medicare coverage and payment as a diagnostic, rather than a screening test. Even as a diagnostic test, however, CMS or its contractors could determine that procedures using the ProUroScan System are not medically necessary and therefore decide not to cover them.

Even if covered, our failure to receive appropriate reimbursement from third-party payors could slow market uptake of our products.

Regardless of whether the ProUroScan System is covered as a screening tool or a diagnostic test, there is a risk that Medicare and other payors will bundle payment for it into the payment for a covered office visit furnished to the patient on the same day. For example, Medicare currently bundles billing and payment for a DRE into payment for a covered evaluation and management office visit when the two services are furnished to a Medicare beneficiary on the same day. If the DRE is the only service or is provided as part of an otherwise non-covered service, it may be separately paid if other coverage requirements are met. On the other hand, the PSA typically is separately paid as a clinical diagnostic laboratory service. Specifically, CMS could determine that due to the ease and short amount of time needed to perform the ProUroScan System procedure, separate reimbursement is not warranted if the physician already is billing an office visit.

In order for physicians and providers who perform procedures using the ProUroScan System to receive separate reimbursement, they must bill a Current Procedure Terminology (“CPT”) code that appropriately describes the service performed. Although initially physicians and providers will be able to bill a miscellaneous code to submit claims for ProUroScan System procedures, eventually we will want to apply for a unique CPT code. The CPT application process is lengthy, and there is no guarantee that we will receive a unique CPT code or that we will receive a unique CPT code in a timely manner. Should we receive a unique CPT code, the code is then valued for purposes of receiving reimbursement by the American Medical Association’s Relative Value Scale Update Committee. The valuation process depends on the amount of time the procedure takes and difficulty of work involved, the practice expense and the malpractice expense associated with using the ProUroScan System. CMS then takes the recommendation of this committee into account when establishing the reimbursement amount. The amount of reimbursement the physician will receive generally depends on the values assigned to the various components of the procedure multiplied by a conversion factor. This value is updated annually as part of the Medicare Physician Fee Schedule. There is no guarantee that this process will result in an appropriate level of reimbursement or an amount that supports the price and revenues we have projected.

Even if a unique CPT code is obtained for the test, the level of reimbursement established may not provide adequate economic incentive to physicians, which could deter them from using our products and limit our sales growth.

At this time, we do not know the extent to which physicians or providers would consider third-party reimbursement levels adequate to cover the cost of our products. Failure by physicians or providers to receive an amount that they consider to be adequate reimbursement could deter them from using our products and limit our sales growth. In addition, Medicare physician fee schedule payments may decline over time, which could deter physicians from using the ProUroScan System. If physicians or providers are unable to justify the costs of the ProUroScan System or they are not adequately compensated for using our product, they may experience an economic disincentive to purchase or use them, which would significantly harm our business.

Notwithstanding current or future FDA clearances, if granted, third-party payors may deny reimbursement if the payor determines that the ProUroScan System is unnecessary, inappropriate, not cost-effective or experimental, or is used for a non-approved indication. Further, all third-party payors, whether governmental or private, whether inside the U.S. or outside, are developing increasingly sophisticated methods of controlling healthcare costs. These cost control methods include prospective payment systems, capitated rates, benefit redesigns, or pre-authorization requirements. Increased scrutiny particularly is being placed on medical imaging. Additionally, payors are emphasizing and covering wellness and healthier lifestyle interventions and other cost-effective methods of delivering healthcare in exchange for covering more procedures. These cost control methods also potentially limit the amount that healthcare providers may be willing to pay for medical technology which could, as a result, adversely affect our business and financial results. In addition, in the U.S., no uniform policy of coverage and reimbursement for medical technology exists among all third party payors. Therefore, coverage and reimbursement for medical technology can differ significantly from payor to payor. There also can be no assurance that current levels of reimbursement will not be decreased or eliminated in the future, or that future legislation, regulation, or reimbursement policies of third-party payors will not otherwise adversely affect the demand for the ProUroScan System or our ability to sell the ProUroScan System on a profitable basis.

If we commercialize the ProUroScan System, we will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

Although we do not control referrals of healthcare services or directly bill Medicare, Medicaid or other third-party payors directly, many healthcare laws and regulations will apply to our business. For example, we could be subject to healthcare fraud and abuse and patient privacy regulation and enforcement by both the federal government and the states in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- the federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, in return for or to induce either the referral of an individual for, or the purchase order or recommendation of, any item or service for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or are for items or services not provided as claimed, and which may apply to entities like us to the extent that our interactions with customers may affect their billing or coding practices;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established new federal crimes for knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services, as well as leading to regulations imposing certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The healthcare sector is, and in recent years has been, under heightened scrutiny as the subject of government investigations and enforcement actions involving manufacturers who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business, including specifically arrangements with physician consultants. We may have arrangements with physicians and other entities which may be subject to scrutiny. For example, we may lease the ProUroScan System to physicians or others through consulting agreements. Payment for these consulting services sometimes may be in the form of cash, stock options or royalties. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, exclusions, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If the physicians or other providers or entities with whom we do business are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business.

Any failure in our efforts or our contractor's efforts to train physicians or other medical staff could result in lower than expected product sales.

A critical component of our sales and marketing efforts is the training of a sufficient number of physicians and other medical staff to properly use the ProUroScan System. We rely on physicians and other medical staff to devote adequate time to learn to use our products. Convincing physicians and other medical staff to dedicate the time and energy for adequate training in the use of our system may be challenging, and we cannot guarantee that this will occur. If physicians and other medical staff are not properly trained, they may misuse or ineffectively use our products. Insufficient training may result in unsatisfactory patient outcomes, patient injury and related liability or negative publicity, which could have an adverse effect on our product sales or create substantial potential liabilities.

Rapid technological change in our competitive marketplace may render the ProUroScan System obsolete or may diminish our ability to compete in the marketplace.

The prostate cancer detection, imaging and medical device markets are extremely competitive, dominated by large and well financed competition and are subject to rapid technological advances and changes. The discovery of new technologies and advances in the application of such technologies to the medical marketplace in general, and the market for urology-based imaging products in particular, may render our products obsolete or non-competitive. Any such changes and advances could force us to abandon our currently proposed products, which would have a material adverse effect on our business.

We may not be able to enter into manufacturing agreements or other collaborative agreements on terms acceptable to us, if at all, which could have a material adverse effect on our business.

We cannot be sure that we will be able to enter into manufacturing or other collaborative arrangements with third parties on terms acceptable to us, if at all. If we fail to establish such arrangements when, and as necessary, we could be required to undertake these activities at our own expense, which would significantly increase our capital requirements and may delay the development, manufacturing and commercialization of our products. If we are unable to address these capital requirements, it may have a material adverse effect on our business.

We expect to rely materially on Artann and other consultants and contractors, some of whom may be partially or wholly paid through issuances of common stock dilutive to our shareholders.

We materially rely on consultants and contractors to perform a significant amount of research and development, pre-manufacturing, clinical, regulatory and marketing activities. Specifically, over the contract periods of the Artann License Agreement and the Artann Development Agreement, we expect to issue equity securities to Artann valued up to \$2.5 million (\$500,000 of which was issued in January, 2009). We expect that certain other consultants and contractors will also accept payment of a portion of their compensation in the form of our equity securities. Any such issuances would be dilutive to shareholders.

We are highly dependent on the services provided by certain key personnel.

We are highly dependent upon the services of our sole executive officers, Richard Carlson and Richard Thon. We have not obtained “key-man” life insurance policies insuring the lives of either of these persons. If the services of either of these persons become unavailable to us, for any reason, our business could be adversely affected.

If we lose our right to license and use from Artann certain critical intellectual property for any reason, our entire business would be in jeopardy.

If we breach or fail to perform the material conditions including payment obligations of, or fail to extend the term of, the agreement with Artann that licenses critical intellectual property, we may lose all or some of our rights to such critical intellectual property and our license may terminate. If we should lose our right to license and use technology covered by such license that is critical to our business, such loss would have a materially adverse effect on our business. In such a case, the viability of the Company would be in question. Our only alternatives would be to find existing and non-infringing technology to replace that lost, if any exists, or develop new technology ourselves. The pursuit of any such alternative would likely cause significant delay in the development and introduction of our proposed products.

The protections for our key intellectual property may be successfully challenged by third parties.

We own various key intellectual properties. No assurance can be given that any intellectual property claims will not be successfully challenged by third parties. Any challenge to our intellectual property, regardless of merit, would likely involve costly litigation which could have a material adverse effect on our business. If a successful challenge were made to intellectual property that is critical to our proposed products, the pursuit of any such alternative would likely cause significant delay in the development and introduction of such products. Moreover, a successful challenge could call into question the validity of our business.

As we lose patent protection on our critical technologies, it may have a material adverse effect on our business.

We rely on certain patents to provide us with exclusive rights for our technology. The first of our primary patents on our core technology will expire in December 2012. As we begin to lose certain patent protections on our prostate-imaging systems and related critical patented technologies, we may face strong competition as a result, which could have a material adverse effect on our business.

The government has rights to certain of our patents.

Certain of our patents emanated from work performed by Artann under grants from the National Institutes of Health (“NIH”). As a result, certain standard NIH grant obligations apply, which are designed to ensure that the U.S. investment is used in the interest of U.S. industry and labor and that inventions are reported to NIH. Additionally, the U.S. government retains a non-exclusive license to these patents. As a non-exclusive licensee of certain of these patents, the U.S. government, in addition to utilizing the inventions itself, could in certain limited circumstances, request additional licenses to the patents be granted to other parties and, if such license request is refused, grant the licenses itself. Any actions by the U.S. government to require the grant of additional licenses could materially and adversely affect our business.

We may not be able to successfully compete against companies in our industry with greater resources, or with any competition.

If our development plan is successful, we expect to experience significant competition in the medical device market. Although we believe that we may currently have a niche in the prostate-imaging marketplace, many factors beyond our control will likely encourage new competitors. In particular, there are several large companies that have indicated an interest in the prostate-imaging business. Therefore, no assurance can be given that we will be able to successfully compete with these, or any other companies in the marketplace, if at all.

The Shares and Warrants issued in the 2009 Public Offering constitute an “ownership change” as defined by the Internal Revenue Code of 1986, as amended (the “Code”) and our ability to use operating loss carryforwards to offset income in future years will be limited.

As of December 31, 2008, the Company had generated net operating loss carryforwards of approximately \$5.0 million which, if not used, will begin to expire in 2021. Federal and state tax laws impose significant restrictions on the utilization of net operating loss carryforwards in the event of a change in ownership of the Company that constitutes an “ownership change,” as defined by Section 382 of the Code. The Company has analyzed the public offering of approximately \$3.1 million of our equity securities with net proceeds to the Company of approximately \$1.9 million (the “2009 Public Offering”) along with previous changes and believes that such an ownership change has not occurred, and that the Company’s use of its net operating loss carryforwards is not subject to such restrictions.

Our business and products subject us to the risk of product liability claims.

The manufacture and sale of medical products and the conduct of clinical trials using new technology involve customary risks of product liability claims. There can be no assurance that our insurance coverage limits will be adequate to protect us from any liabilities which we might incur in connection with the clinical trials or the commercialization of any of our products. Product liability insurance is expensive and in the future may not be available on acceptable terms, if at all. A successful product liability claim or series of claims brought against us in excess of our insurance coverage would have a material adverse effect on our business. In addition, any claims, even if not ultimately successful, could have a material adverse effect on the marketplace’s acceptance of our products.

We have never paid dividends and do not expect to pay dividends in the foreseeable future.

We have never paid dividends on our capital stock and do not anticipate paying any dividends for the foreseeable future. Future debt covenants may prohibit payment of dividends.

ITEM 1B: UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2: PROPERTIES

Our executive offices are located at 6440 Flying Cloud Drive, where we rent approximately 500 square feet of office space on a month-to-month basis. Our rental cost for this office space is approximately \$550 per month, which we believe is at market for similar office space in Minneapolis, Minnesota. We do not own any real property.

ITEM 3: LEGAL PROCEEDINGS

Although we are subject to litigation or other legal proceedings from time to time in the ordinary course of our business, we are not a party to any pending legal proceedings and are not aware of any threatened legal proceeding.

ITEM 4: SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

PART II

ITEM 5: MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

General

Our common stock has been quoted on the Over-The-Counter Bulletin Board (the "OTCBB") since December 2003. Our common stock is currently quoted under the symbol "PUMD." The following table lists the high and low bid information for our common stock as quoted on the OTCBB by quarter from January 1, 2007 through December 31, 2008

<u>Quarter Ended</u>	<u>Price Range</u>	
	<u>High</u>	<u>Low</u>
March 31, 2007	\$4.50	\$2.60
June 30, 2007	\$5.10	\$2.00
September 30, 2007.....	\$3.00	\$0.50
December 31, 2007	\$2.50	\$0.51
March 31, 2008	\$0.95	\$0.30
June 30, 2008	\$2.01	\$0.30
September 30, 2008.....	\$3.05	\$0.30
December 31, 2008	\$1.85	\$0.41

The above quotations from the OTCBB reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions. The number of holders of record of our common stock as of March 23, 2009 was approximately 165.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and do not expect to pay any dividends for the foreseeable future. We intend to use future earnings, if any, in the operation and expansion of our

business. Any future determination relating to our dividend policy will be made at the discretion of our board of directors, based on our financial condition, results of operations, contractual restrictions, capital requirements, business properties, restrictions imposed by applicable law and other factors our board of directors may deem relevant. Future debt covenants may prohibit payment of dividends.

Recent Sales of Unregistered Securities

The issuances of our securities listed below were made in reliance on exemption from registration under Section 4(2) of the Securities Act of 1933, as amended (the “Securities Act”), as we reasonably believed that the investors were sophisticated, that no general solicitations were involved and the transactions did not otherwise involve a public offering.

Common Stock and Warrant Issuances

On October 24, 2008, pursuant to a June 1, 2006 promissory note and amendments thereto, we issued to Roman Pauly a 5-year warrant (immediately exercisable) to purchase 31,817 shares of our common stock at an exercise price of \$5.00 per share and a 5-year warrant (immediately exercisable) to purchase 3,000 shares of our common stock at an exercise price of \$1.50 per share.

On October 31, 2008, we issued a total of 17,778 shares of our common stock and five-year, immediately exercisable warrants to purchase in the aggregate 44,445 shares of our common stock at a price of \$2.00 per share to James Davis, Bruce Culver and William Reiling pursuant to the terms of the October 31, 2007 extensions of their guarantees of our Crown Bank loans.

On October 31, 2008, we issued 6,667 shares of our common stock and a five-year, immediately exercisable warrant to purchase 16,667 shares of our common stock at a price of \$2.00 per share to the Smith Family Trust pursuant to the terms of a \$600,000 promissory note dated October 31, 2007.

Unit Put Agreements

On September 16, 2008, we received \$325,000 of funding commitments to purchase \$325,000 of units in accordance with the terms of a unit put agreement (the “Unit Put Agreement”). Upon our exercise of the put, each investor that has signed a Unit Put Agreement agreed to purchase the units being put by us on a pro rata basis within 5 days after receiving the put notice from us.

Each unit consists of a note in the principal amount of \$9,500 and a warrant to purchase 2,000 shares of our common stock. The purchase price of the warrant portion of each unit is \$500. The notes bore interest at ten percent per year, mature on the 18-month anniversary of the date of the Unit Put Agreement, and converted into common stock at \$0.70 per share (based on 70% of the 2009 Public Offering price). The warrants will be exercisable immediately upon issuance and will remain exercisable until December 31, 2012 at an exercise price of \$1.00 per share.

In consideration of each purchaser’s future funding commitment, each purchaser received an origination warrant (“Origination Warrants”) to purchase 1,000 shares of our common stock for each \$10,000 unit that an investor committed to purchase. Each Origination Warrant is exercisable until December 31, 2012 at an exercise price of \$1.00 per share. We have issued Origination Warrants to purchase an aggregate 32,500 shares of our common stock, although 1,000 of such warrants were forfeited due to a failure to fulfill a \$10,000 obligation under the Unit Put Agreement.

On September 16, 2008, we exercised \$162,500 of our put options under the Unit Purchase Agreement, and upon the September 24, 2008 closing thereof, issued Unit Put Notes in the principal amount of \$154,375 and 32,500

Unit Put Warrants. On October 17, 2008, we exercised the remaining \$162,500 of our put options and on October 28, 2008 and December 11, 2008, closed on put options of \$127,500 and \$25,000, respectively. Pursuant to the October 28, 2008 and December 11, 2008 closings, we issued Unit Put Notes in the principal amount of \$121,125 and \$23,750, respectively, along with 25,500 and 5,000 Unit Put Warrants, respectively.

ITEM 6: SELECTED FINANCIAL DATA

Not applicable.

ITEM 7: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements, and notes thereto, included in this Annual Report on Form 10-K. This discussion should not be construed to imply that the results discussed herein will necessarily continue into the future, or that any conclusion reached herein will necessarily be indicative of actual operating results in the future.

Results of Operations

Current Operations

We currently employ only two employees. We conduct our research and development, market research, regulatory and other business operations through the use of consultants and medical device development contractors, primarily Artann. We believe that using consultants and contractors to perform these functions is more cost effective than hiring full-time employees and affords us flexibility in directing our resources during our development stage. During the first half of 2009, we expect to complete the clinical and regulatory process leading to FDA 510(k) market clearance and establish strategic marketing and contract manufacturing relationships in anticipation of regulatory clearance to enter the market.

We incur ongoing expenses that are directly related to being a publicly traded company, including professional audit and legal fees, financial printing, press releases and transfer agent fees. We currently rent approximately 500 square feet of office space on a month-to-month basis at a cost of approximately \$550 per month. Other expenses incurred include executive officer compensation, travel, insurance, telephone, supplies and other miscellaneous expenses.

Pursuant to the terms of the Artann Development Agreement, we are required to make cash and equity payments upon the achievement of several project milestones along with a monthly retainer fee. Upon the submission of our 510(k) application to the FDA, we are to make a cash payment to Artann of \$250,000 and an equity payment of our common shares valued at \$1,000,000. Upon receipt of FDA 510(k) clearance, we are to make a further cash payment of \$750,000 and a second \$1,000,000 equity payment. In addition, we expect to make cash payments to Artann totaling approximately \$150,000 for development services they are to provide during the last nine months of 2009. See "ProUroScan System Development Partner" for more information.

During the remainder of 2009, assuming that we are successful in obtaining FDA clearance on our ProUroScan system, we expect to engage contract manufacturing, engineering and clinical resources to produce our products as we begin to commercialize our product. As we build inventory, and ultimately accounts receivable as a result of our commercialization activity, we will require an estimated \$800,000 by year end to fund this build-up of working capital. In addition, we expect to hire approximately eight employees in the areas of manufacturing management, marketing, sales training, administration and quality assurance. Consequently, our operating expenses will increase sharply during the second half of the year. We estimate that we will require between \$600,000 and \$650,000 to fund staff compensation costs over the last three quarters of 2009. During this same period, we expect to

supplement our internal resources by the use of consultant and contracted personnel. We estimate the cost of such contracted resources to be approximately \$400,000.

Year ended December 31, 2008 compared to the year ended December 31, 2007:

Operating Expenses/Operating Loss. Our operating loss equals our operating expenses because we have no revenue. For the year ended December 31, 2008, our operating expenses (and our operating loss) were \$4,657,717, an increased loss of \$1,544,420 or 50 percent, compared to \$3,113,297 last year.

Total employee compensation and benefits costs decreased to \$390,797 from \$972,731 last year, or 60 percent. In the year ended December 31, 2007, we incurred stock-based compensation of \$316,500 related to the extension of the exercise period of certain stock options and warrants issued pursuant to separation agreements with three former employees. The remaining compensation expense reduction came primarily as a result of the termination of the three employees in early 2007 and reduced stock option expense, as certain options granted in prior years became fully expensed in 2007. General and administrative expenses in 2008 also included \$1,100,000 related to technology licensing from Artann under the Artann Licensing Agreement, with \$600,000 to be paid in cash and \$500,000 to be paid in common stock. Fees for legal services in the year ended December 31, 2008 increased \$93,016, or 78 percent, compared to last year, due to legal fees associated with our negotiations with Artann, one-time costs of our reverse stock split, the filing of our Registration Statement on Form S-8 and other SEC filings and patent related legal expenses. Fees accrued or paid to outside directors increased to \$70,717 for the year ended December 31, 2008 compared to \$25,417 last year, due primarily to a one-time stock grant to the directors in recognition of their efforts in our repositioning and financing since the beginning of 2007.

Research and development costs in the year ended December 31, 2008 were \$597,755. This represents an increase of \$454,127, or 316 percent, compared to the \$143,628 recognized as research and development expense during the year ended December 31, 2007. The 2008 research and development expense amount included \$250,000 of expense related to Artann's achievement of the first project milestone under the Artann Development agreement, additional research and development expenses totaling \$50,000 related to work performed by Artann under our development agreement, and the expensing of our \$300,000 acquisition of certain intellectual property and know-how from Profile. Fiscal 2007 expenses included a \$35,000 payment and the issuance of warrants valued at \$72,000 to Artann pursuant to a cooperation agreement signed in April 2007 and \$24,407 of research costs related to a prostate visioning system project.

Interest Expense. Total interest expense for the year ended December 31, 2008 was \$1,910,037, an increase of \$597,817 or 46 percent, compared to \$1,312,220 last year. The increased interest expense can be attributed to the issuance of \$1,900,000 of convertible notes in our 2007 and 2008 private placements, \$299,250 of convertible notes in our September 2008 unit put offering, and \$262,500 of convertible notes related to our April 2008 acquisition of intellectual property from Profile. Amortization of the original issue discount attributable to shares of common stock issued, warrants issued and beneficial conversion features related to these notes resulted in \$1,055,453 of recorded interest expense in the year ended December 31, 2008 compared to \$446,359 in the year ended December 31, 2007. Amortization of debt issuance costs related to the notes issued and outstanding during the years ended December 31, 2008 and 2007 was \$421,564 and \$506,639, respectively. Interest expense based on stated interest rates was \$433,020 and \$359,222 during the years ended December 31, 2008 and 2007, respectively.

Debt Extinguishment Cost. Our total debt extinguishment cost for the year ended December 31, 2008 was \$123,785, a decrease of 64 percent, compared to \$343,454 last year. Our debt extinguishment cost resulted primarily from the cost of warrants issued in connection with the amendment of certain short term loans to defer their maturity dates. The year-to-year decrease was a result of the repayment of a significant portion of these outstanding short term loans in late 2007 and early 2008.

Year ended December 31, 2007 compared to the year ended December 31, 2006:

Operating Expenses/Operating Loss. Our operating expenses equal our operating loss because we have no revenue. A 21 percent decrease in our operating expenses for the year ended December 31, 2007 compared to the prior year, from \$1,842,169 to \$1,448,902, was directly related to our efforts to restructure the Company, with an emphasis on minimizing costs and conserving cash while repositioning the Company and raising capital to fund development. In late 2006, our former CEO retired. In the first quarter of 2007, two additional executive level positions were eliminated. These moves resulted in a reduction of salaries, payroll taxes and benefits from \$935,705 during the year ended December 31, 2006 to \$423,347 in 2007, a savings of \$512,358 or 55 percent. Offsetting this was a 41 percent increase in stock-based compensation, from \$389,034 to \$549,384 in those same periods related to the extension of exercise periods of certain options and warrants of the departing executives pursuant to termination agreements. In December we moved our headquarters into a smaller facility, resulting in a reduction of rent expense from \$47,519 in 2006 to \$21,286 in 2007, saving \$26,233 or 55 percent.

Research and development costs for the year ended December 31, 2007 were \$143,628, a decrease of \$102,491, or 42 percent, compared to 2006. The 2007 research and development costs included the issuance of warrants valued at \$72,000 and cash payments of \$45,000 to Artann pursuant to a cooperation agreement signed in April 2007 and \$24,407 of research costs related to a prostate visioning system project. Research and development costs in 2006 consisted of contracted development work on our ProUroScan System and a subsequently abandoned prostate visioning system project.

Interest Expense. Interest expense for the year ended December 31, 2007 was \$1,312,220 compared to \$1,089,762 in 2006, an increase of \$222,458 or 20 percent. The majority of our recorded interest expense represents the cost of warrants issued in conjunction with debt issuances and the cost of certain convertible features of debt issuances. \$952,998 of the 2007 interest expense and \$802,475 of the 2006 interest expense related to the cost of warrants and convertible debt features. The increased interest expense is the result of an increase in the average amount of debt outstanding over the course of 2007 compared to 2006 used to fund operations.

Debt Extinguishment Cost. Debt extinguishment costs for the year ended December 31, 2007 was \$353,454, compared to \$27,922 in 2006. These expenses represent primarily the cost of warrants issued in connection with the amendment of certain short term loans made to defer their maturity dates in late 2006 and early 2007, and the issuance of stock and warrants pursuant to the refinancing of \$600,000 of debt with the Smith Trust in October 2007.

Liquidity and Capital Resources

Assets; Property Acquisitions and Dispositions

Our primary assets are patents and patent applications, which are the foundation for our proposed product offerings. These assets secure \$1,600,000 of senior bank notes and a note issued to an investor in the amount of \$600,000 and, as a result, are not available to secure other senior debt financing.

We anticipate purchasing approximately \$400,000 of tooling molds and other capital for production, computer equipment, software and general office furniture and equipment during the remainder of 2009. We do not anticipate selling any significant assets in the near term.

Purchase of Patents

On April 3, 2008, we purchased certain previously-licensed patents, patent applications, and know-how (the "Profile Assets") associated with imaging technology from Profile L.L.C., a Delaware limited liability company

("Profile"), pursuant to an asset purchase agreement. The purchase price of the Profile Assets was \$300,000, of which \$150,000 was paid in cash and \$150,000 was financed under a secured promissory note (the "Profile Note").

Recent Financings

Between December 2007 and July 2008, we raised a total of \$2,000,000 (including conversion of \$175,000 of existing debt) from the sale of convertible promissory notes and warrants in four private placements.

In connection with the purchase of the Profile Assets, on April 3, 2008 we borrowed an aggregate of \$112,500 pursuant to three convertible promissory notes each in the amount of \$37,500. Payment in full of the promissory notes and the interest accrued thereon at an annual rate of 10% became due on December 31, 2008. In January 2009, following the closing of the 2009 Public Offering, we repaid \$45,500 of the notes, and \$29,500 of the notes were converted into common stock at \$0.70 per share (based on 70 percent of the 2009 Public Offering price). On March 19, 2009, the remaining \$37,500 promissory note and accrued interest thereon, due to Mr. James Davis, was refinanced along with another \$150,000 promissory note due to Mr. Davis (see below).

On September 16, 2008, we received funding commitments to purchase \$325,000 of units in accordance with the terms of a unit put agreement (the "Unit Put Agreement") (such funding commitments, the "Unit Put Arrangements"). Between September 2008 and December 2008, we raised \$315,000 from the sale of convertible promissory notes and warrants pursuant to the Unit Put Arrangements.

On September 25, 2008, we borrowed \$150,000 pursuant to a promissory note issued in favor of Mr. Davis. As consideration for providing the loan, we issued an immediately exercisable, five-year warrant to purchase 100,000 shares of our common stock at \$1.50 per share to Mr. Davis. The proceeds of the loan were used to retire the \$150,000 principal amount of the Profile Note. Payment in full of the promissory notes and the interest accrued thereon at an annual rate of 10 percent was due seven days after the closing date of the 2009 Public Offering. On March 19, 2009, Mr. Davis agreed to refinance the \$150,000 debt (and \$7,291 of interest accrued thereon) along with a \$37,500 note (and \$3,646 of accrued interest thereon), another \$2,632 payable to Mr. Davis, and \$15,293 of expenses paid by Mr. Davis on our behalf. Mr. Davis also agreed to loan to us an additional \$64,638 to pay for our exhibition of the ProUroScan system at the annual American Urology Association meeting, the retention of an investor relations firm and the initiation of a clinical advisory board. He also agreed to have certain website maintenance services performed for us. Pursuant to the refinancing and the other arrangements, we issued a \$281,000 unsecured convertible promissory note to Mr. Davis. The promissory note matures on March 19, 2010, bears no interest, and is convertible into our common stock at \$0.55 per share at the option of Mr. Davis.

On January 12, 2009, we closed on the 2009 Public Offering. We expect that the \$1,880,000 net proceeds of that offering will be sufficient to fund our cash obligations under the Artann Development Agreement and the Artann License Agreement and to finance our operating expenses up to receipt of FDA 510(k) clearance, as described in "Current Operations" above, and to retire certain short-term liabilities. However, if our product development efforts experience significant unforeseen delays, we may not have sufficient funds to complete these objectives, and will require additional financing. We do not expect the funds from the 2009 Public Offering to be sufficient for us to initiate any significant market launch or scale-up manufacturing capabilities. In addition, we need funding beyond the net proceeds of the 2009 Public Offering to pay, for example, up to \$1,000,000 of future payments to Artann related to their achievement of FDA 510(k) clearance milestones.

The closing of the 2009 Public Offering triggered the automatic conversion of certain debt instruments into equity, as follows:

- \$733,334 convertible debentures together with \$143,815 of interest accrued thereon converted into 292,384 shares of our common stock.

- \$1,900,000 of convertible notes issued in the 2007 and 2008 private placements together with \$177,882 of interest accrued thereon converted into 3,058,381 Units.
- \$299,250 of convertible notes issued pursuant to the Unit Put Arrangement together with \$9,563 of interest accrued thereon converted into 441,165 shares of our common stock.

Current Financing Plans

As a result of the closing on the 2009 Public Offering and the subsequent conversion of convertible notes into Units, we have 6,108,381 redeemable warrants outstanding. These warrants have an exercise price of \$1.30 per share, which we may redeem once the last sale price of our common stock equals or exceeds \$1.82 per share for a period of ten consecutive trading days. If this event were to occur, we intend to exercise our right to redeem the warrants, which will allow all holders of warrants a period of 30 days to exercise their warrants. If all such warrant holders exercise their warrants, we could realize up to approximately \$7.9 million, depending on the number of shares actually exercised pursuant to such a redemption. There can be no assurance that we will be able to redeem the warrants, or of how much would be realized if such a redemption were made.

During the first half of 2009, we plan to identify a distribution partner to market our products (see Item 1, “**Marketing and Distribution**”). We expect such a distribution partner to provide significant financial support in the form of licensing fees, loans, equity investment or a combination of these. In addition to financial support, a successful collaboration with such a partner would allow us to gain access to down stream marketing, manufacturing, and sales support. There can be no assurance that a distribution partner can be successfully identified and engaged during the first half of 2009, or at all.

In March 2009, we renewed \$1.2 million of the secured debt to mature on March 28, 2010, and temporarily paid down \$400,000 of the secured debt. We intend to re-borrow the \$400,000 secured debt before the end of May, 2009 upon the establishment of a satisfactory guaranty of the debt with the lender.

We also have other short term liabilities, consisting of the Davis convertible promissory note describe above, accounts payable and accrued expenses, exceeding \$1,575,000 We expect to pay for these obligations from the proceeds of the exercise of the Unit warrants and license fees from a potential distribution partner. If we are unable to exercise the warrants or receive financial support from a distribution partner, we will pursue one or more additional rounds of funding in 2009 and 2010 to provide the working capital needed to fund a significant commercial launch into the urology market. If additional funds are raised by the issuance of convertible debt or equity securities, or by the exercise of outstanding warrants, then existing shareholders will experience dilution in their ownership interest. If additional funds are raised by the issuance of debt or certain equity instruments, we may become subject to certain operational limitations, and such securities may have rights senior to those of our existing holders of common stock.

If adequate funds are not available through these initiatives on a timely basis, or are not available on acceptable terms, we may be unable to fund expansion, or to develop or enhance our products. If we are forced to slow our development programs, or put them on hold, it would delay regulatory clearances or approvals needed, and thus delay market entry for our products. Ultimately, if no additional financing is obtained beyond what has been secured to date, we likely would be forced to cease operations. There can be no assurance we will be successful in raising such funds.

Off-Balance Sheet Arrangements

Not applicable.

Going Concern

We have incurred operating losses, accumulated deficit and negative cash flows from operations since inception. As of December 31, 2008, we had an accumulated shareholders' deficit of approximately \$7.3 million. These factors, among others, raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements included in this Annual Report on Form 10-K do not include any adjustments related to recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result should we be unable to continue as a going concern.

Critical Accounting Policies

Our critical accounting policies are policies which have a high impact on the reporting of our financial condition and results, and require significant judgments and estimates. Our critical accounting policies relate to (a) the valuation of stock-based compensation awarded to employees, directors, loan guarantors and consultants and (b) the accounting for debt with beneficial conversion features.

Valuation of Stock-Based Compensation

Effective as of August 17, 1999 (inception), we adopted Statement of Financial Accounting Standards ("SFAS") No. 123 "Accounting for Stock-Based Compensation" ("SFAS 123") and on January 1, 2006 adopted SFAS No. 123 (revised 2004) "Share-Based Payment" ("SFAS 123R"), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including employee stock options based on fair values. Our determination of fair value of share-based payment awards is based on the date of grant using an option-pricing model which incorporates a number of highly complex and subjective variables. These variables include, but are not limited to, the expected volatility of our stock price and estimates regarding projected employee stock option exercise behaviors and forfeitures. We recognize the expense related to the fair value of the award straight-line over the vesting period.

Debt with Beneficial Conversion Features

The beneficial conversion features of the promissory notes were valued using the Black-Scholes pricing model. The resulting original issue discount is amortized over the life of the promissory notes using the straight-line method, which approximates the interest method.

ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8: FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The following financial statements are included:

Report of Independent Registered Public Accounting Firm..... F-2

Audited Financial Statements:

Consolidated Balance Sheets F-3

Consolidated Statements of Operations F-4

Consolidated Statement of Shareholders' Equity (Deficit) F- 5

Consolidated Statements of Cash Flows..... F- 12

Notes to Consolidated Financial Statements..... F- 14

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders, Audit Committee and Board of Directors
ProUroCare Medical Inc.
Eden Prairie, MN

We have audited the accompanying consolidated balance sheets of ProUroCare Medical Inc. (a development stage company) as of December 31, 2008 and 2007, and the related consolidated statements of operations, shareholders' equity (deficit) and cash flows for the years then ended and the period from August 17, 1999 (inception) to December 31, 2008. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of its internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of ProUroCare Medical Inc. as of December 31, 2008 and 2007 and the results of their operations and their cash flows for the years then ended and the period from August 17, 1999 (inception) to December 31, 2008, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has recurring operating losses, negative cash flows from operations and requires additional working capital to support future operations, which raises substantial doubt about its ability to continue as a going concern. Management's plans in regards to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Virchow, Krause & Company, LLP

Minneapolis, Minnesota
March 24, 2009

ProUroCare Medical Inc.
(A Development Stage Company)
Consolidated Balance Sheets

Assets	December 31, 2008	December 31, 2007
Current assets:		
Cash	\$ 3,900	\$ 400,613
Restricted cash	44,214	44,000
Other current assets	31,634	21,733
Total current assets	79,748	466,346
Equipment and furniture, net	—	605
Deferred offering expenses	729,924	132,638
Debt issuance costs, net	266,882	439,321
	\$ 1,076,554	\$ 1,038,910
Liabilities and Shareholders' Deficit		
Current liabilities:		
Notes payable, bank	\$ 1,600,000	\$ —
Notes payable	34,425	163,143
Notes payable - related parties	634,000	110,450
Convertible debt, net of original issue discount	1,033,484	—
Convertible debt - related parties, net of original issue discount	1,179,913	—
Accounts payable	1,203,549	484,375
Accrued license and development fees	1,327,835	—
Accrued expenses	937,253	801,925
Total current liabilities	7,950,459	1,559,893
Commitments and contingencies (note 7)		
Long-term bank debt	—	1,600,000
Long-term note payable - related parties	—	600,000
Long-term convertible debt, net of original issue discount	221,199	353,934
Long-term convertible debt - related parties net of original issue discount	162,759	616,666
Total liabilities	8,334,417	4,730,493
Shareholders' deficit:		
Common stock, \$0.00001 par. Authorized 50,000,000 shares; issued and outstanding 1,811,429 and 1,727,311 shares, respectively	18	17
Additional paid-in capital	13,677,932	12,586,496
Deficit accumulated during development stage	(20,935,813)	(16,278,096)
Total shareholders' deficit	(7,257,863)	(3,691,583)
	\$ 1,076,554	\$ 1,038,910

See accompanying notes to financial statements.

ProUroCare Medical Inc.
(A Development Stage Company)
Consolidated Statements of Operations

	Year ended December 31, 2008	Year ended December 31, 2007	Period from August 17, 1999 (inception) to December 31, 2008
	<u>2008</u>	<u>2007</u>	<u>2008</u>
Operating expenses:			
Research and development	\$ 597,755	\$ 143,628	\$ 5,455,307
General and administrative	<u>2,026,677</u>	<u>1,305,274</u>	<u>9,831,173</u>
Total operating expenses	<u>2,624,432</u>	<u>1,448,902</u>	<u>15,286,480</u>
Operating loss	(2,624,432)	(1,448,902)	(15,286,480)
Interest income	537	1,278	18,295
Interest expense	(1,001,551)	(872,713)	(3,814,474)
Interest expense - related parties	(908,486)	(439,507)	(1,347,993)
Debt extinguishment expense	(75,571)	(326,626)	(430,119)
Debt extinguishment expense - related parties	<u>(48,214)</u>	<u>(26,828)</u>	<u>(75,042)</u>
Net loss	<u>\$ (4,657,717)</u>	<u>\$ (3,113,298)</u>	<u>\$ (20,935,813)</u>
Net loss per common share:			
Basic and diluted	\$ (2.65)	\$ (1.98)	\$ (19.95)
Weighted average number of shares outstanding:			
Basic and diluted	1,759,607	1,572,555	1,049,158

See accompanying notes to consolidated financial statements.

ProUroCare Medical Inc.
(A Development Stage Company)
Consolidated Statements of Shareholders' Equity (Deficit)

	Common stock		Additional paid-in capital	Deficit accumulated during the development stage	Total shareholders' equity (deficit)
	Shares	Amount			
Balance at inception, August 17, 1999					
Net loss for the period from inception to December 31, 1999	—	\$ —	\$ —	\$ —	\$ —
Balance, December 31, 1999	—	—	—	—	—
Net loss for the year ended December 31, 2000	—	—	—	—	—
Balance, December 31, 2000	—	—	—	—	—
Issuance of common stock to founders at \$33.33 per share on March 1, 2001	1.0	—	20	—	20
Cancellation of founders' shares, March 6, 2001	(1.0)	—	(20)	—	(20)
Recapitalization and transfer of common stock to Clinical Network, Inc. July 6, 2001	300,000	3	(3)	—	—
Issuance of common stock to CS Medical Technologies, LLC as consideration for technology license agreement on July 6, 2001, valued at \$1.58 per share	300,000	3	474,997	—	475,000
Net loss for the year ended December 31, 2001	—	—	—	(612,533)	(612,533)
Balance, December 31, 2001	600,000	6	474,994	(612,533)	(137,533)
Issuance of common stock valued at \$4.29 per share to Profile LLC for technology license, January 14, 2002	400,000	4	1,713,596	—	1,713,600
Issuance of common stock at \$23.33 per share for services rendered, November 14, 2002	4,421	—	103,166	—	103,166
Issuance of common stock for cash at \$23.33 per share on November 22, 2002, net of costs of \$193,386	45,335	1	864,418	—	864,419
Options to purchase 90,000 shares issued to officers and directors, valued at \$4.60 per share, granted March 19, 2002; portion vested in 2002	—	—	124,583	—	124,583
Options to purchase 6,000 shares issued to consultants for services rendered, valued at \$4.60 per share, granted March 19, 2002; portion vested in 2002	—	—	18,400	—	18,400
Warrant for 3,000 shares valued at \$4.60 per share, issued to a director on April 19, 2002; portion vested in 2002	—	—	4,025	—	4,025
Warrant for 150 shares valued at \$3.33 per share issued for services rendered, November 11, 2002	—	—	490	—	490
Net loss for the year ended December 31, 2002	—	—	—	(3,613,003)	(3,613,003)
Balance, December 31, 2002	1,049,756	11	3,303,672	(4,225,536)	(921,853)
Stock issued in lieu of cash for accounts payable, valued at \$23.33 per share, February 25, 2003	545	—	12,705	—	12,705
Warrants for 19,286 shares valued at \$3.00 per share, issued to bank line of credit guarantors, March 1, 2003	—	—	57,858	—	57,858
Warrant for 2,143 shares valued at \$3.00 per share, issued to director as a bank line of credit guarantor, March 1, 2003	—	—	6,429	—	6,429
Warrant for 9,215 shares issued for services rendered, valued at \$20.30 per share, June 30, 2003	—	—	187,060	—	187,060
Warrants for 22,501 shares valued at \$3.60 per share, issued to bank line of credit guarantors, August 5, 2003	—	—	81,003	—	81,003
Warrant for 2,143 shares valued at \$3.60 per share, issued to director as a bank line of credit guarantor, August 5, 2003	—	—	7,714	—	7,714
Warrants for 6,429 shares valued at \$3.40 per share, issued to bank line of credit guarantors, September 11, 2003	—	—	21,858	—	21,858
Warrant for 11,789 shares valued at \$3.50 per share, issued to bank line of credit guarantor, December 22, 2003	—	—	41,250	—	41,250

ProUroCare Medical Inc.
(A Development Stage Company)

Consolidated Statements of Shareholders' Equity (Deficit) (Continued)

	<u>Common stock</u>		<u>Additional paid-in capital</u>	<u>Deficit accumulated during the development stage</u>	<u>Total shareholders' equity (deficit)</u>
	<u>Shares</u>	<u>Amount</u>			
Options to purchase 90,000 shares issued to officers and directors, valued at \$4.60 per share, granted March 19, 2002; portion vested in 2003	—	—	133,400	—	133,400
Options to purchase 6,000 shares issued to consultants for services rendered, valued at \$4.60 per share, granted March 19, 2002; portion vested in 2003	—	—	6,900	—	6,900
Warrant for 3,000 shares valued at \$4.60 per share, issued to a director on April 19, 2002; portion vested in 2003	—	—	6,900	—	6,900
Net loss for the year ended December 31, 2003	—	—	—	(1,632,457)	(1,632,457)
Balance, December 31, 2003	1,050,301	11	3,866,749	(5,857,993)	(1,991,233)
Options to purchase 3,000 shares issued to a consultant valued at \$6.70 per share, granted February 1, 2004, portion vested in 2004	—	—	10,100	—	10,100
Options to purchase 45,000 shares issued to officer valued at \$6.70 per share, granted February 1, 2004; portion vested in 2004	—	—	84,173	—	84,173
Repurchase of 90,000 shares pursuant to the exercise of dissenters' rights at time of merger, April 5, 2004 in connection with \$750,000 note payable	(90,000)	(1)	(749,999)	—	(750,000)
Issuance of shares to shareholders of Global Internet Communications, Inc. pursuant to merger April 5, 2004	209,700	2	(2)	—	—
Issuance of common stock for cash at \$20.00 per share during 2004, net of costs of \$139,493	220,500	2	4,270,505	—	4,270,507
Cost associated with Global Internet Communications, Inc. reverse merger effective April 5, 2004	—	—	(162,556)	—	(162,556)
Effect of anti-dilution and price-protection provisions of warrants issued to loan guarantors in 2003, triggered by April 5, 2004 closing of private placement; shares subject to warrants increased by 37,501; exercise price reduced from \$23.33 to \$16.67 per share (see note 10)	—	—	320,974	—	320,974
Issuance of common stock valued at \$20.00 per share for accrued expenses in lieu of cash, May 21, 2004	3,861	—	77,225	—	77,225
Warrants for 10,000 shares issued for services rendered valued at \$11.50 per share on July 19, 2004	—	—	114,914	—	114,914
Options to purchase 20,000 shares issued to officer valued at \$15.00 per share, granted July 21, 2004; portion vested in 2004	—	—	41,670	—	41,670
Issuance of common stock valued at \$20.00 per share for accrued interest in lieu of cash, October 12, 2004	4,444	—	88,882	—	88,882
Warrants for 20,000 shares issued for services rendered valued at \$8.30 per share on December 2, 2004	—	—	166,172	—	166,172
Options to purchase 90,000 shares issued to officers and directors, valued at \$4.60 per share, granted March 19, 2002; portion vested in 2004	—	—	82,452	—	82,452
Warrant for 3,000 shares valued at \$4.60 per share, issued to a director on April 19, 2002; portion vested in 2004	—	—	1,150	—	1,150
Net loss for the year ended December 31, 2004	—	—	—	(2,318,896)	(2,318,896)
Balance, December 31, 2004	1,398,806	14	8,212,409	(8,176,889)	35,534

ProUroCare Medical Inc.
(A Development Stage Company)

Consolidated Statements of Shareholders' Equity (Deficit) (Continued)

	<u>Common stock</u>		<u>Additional paid-in capital</u>	<u>Deficit accumulated during the development stage</u>	<u>Total shareholders' equity (deficit)</u>
	<u>Shares</u>	<u>Amount</u>			
Options to purchase 90,000 shares issued to officers and directors, valued at \$4.60 per share, granted March 19, 2002; portion vested in 2005	—	—	5,734	—	5,734
Options to purchase 45,000 shares issued to officer valued at \$6.70 per share, granted February 1, 2004; portion vested in 2005	—	—	111,108	—	111,108
Options to purchase 20,000 shares issued to officer valued at \$15.00 per share, granted July 21, 2004; portion vested in 2005	—	—	100,008	—	100,008
Options to purchase 15,000 shares issued to officer valued at \$16.20 per share, granted January 3, 2005; portion vested in 2005	—	—	74,256	—	74,256
Options to purchase 15,000 shares issued to officer valued at \$6.70 per share, granted September 6, 2005; portion vested in 2005	—	—	6,625	—	6,625
Issuance of common stock for services rendered at \$10.20 per share on May 13, 2005	5,000	—	51,000	—	51,000
Issuance of common stock for cash at \$7.60 per share on June 15, 2005	6,579	—	50,001	—	50,001
Issuance of common stock for deferred offering costs at \$7.10 per share on September 1, 2005	2,500	—	17,750	—	17,750
Issuance of common stock in lieu of cash for accrued expenses at \$8.90 per share on December 31, 2005	4,541	—	40,418	—	40,418
Warrants for 2,500 shares valued at \$6.30 per share, issued to bank loan guarantor, September 14, 2005	—	—	15,750	—	15,750
Warrants for 2,500 shares valued at \$5.30 per share, issued in connection with notes payable on September 21, 2005	—	—	13,250	—	13,250
Warrants for 20,000 shares valued at \$4.80 per share, issued to bank loan guarantors, October 19, 2005	—	—	106,000	—	106,000
Net loss for the year ended December 31, 2005	—	—	—	(2,028,056)	(2,028,056)
Balance, December 31, 2005	1,417,426	14	8,804,309	(10,204,945)	(1,400,622)
Options to purchase 45,000 shares issued to officer valued at \$6.70 per share, granted February 1, 2004; portion vested in 2006	—	—	101,008	—	101,008
Options to purchase 20,000 shares issued to officer valued at \$15.00 per share, granted July 21, 2004; portion vested in 2006	—	—	100,008	—	100,008
Options to purchase 15,000 shares issued to officer valued at \$16.20 per share, granted January 3, 2005; portion vested in 2006	—	—	81,006	—	81,006
Options to purchase 15,000 shares issued to officer valued at \$6.70 per share, granted September 6, 2005; portion vested in 2006	—	—	8,834	—	8,834
Options to purchase 17,500 shares issued to officers and an employee valued at \$5.60 per share, granted March 1, 2006; portion vested in 2006	—	—	48,215	—	48,215

ProUroCare Medical Inc.
(A Development Stage Company)

Consolidated Statements of Shareholders' Equity (Deficit) (Continued)

	<u>Common stock</u>		<u>Additional paid-in capital</u>	<u>Deficit accumulated during the development stage</u>	<u>Total shareholders' equity (deficit)</u>
	<u>Shares</u>	<u>Amount</u>			
Options to purchase 3,000 shares issued to a director valued at \$5.90 per share, granted May 30, 2006; portion vested in 2006	—	—	5,163	—	5,163
Original issue discount on convertible debt issued on February 16, 2006	—	—	400,000	—	400,000
Warrants for 5,000 shares valued at \$4.60 per share, issued in connection with notes payable on January 25, 2006	—	—	23,000	—	23,000
Issuance of common stock for deferred offering costs at \$9.10 per share on February 22, 2006	2,500	—	22,750	—	22,750
Original issue discount on convertible debt issued on February 29, 2006	—	—	333,334	—	333,334
Issuance of common stock for services rendered at \$6.40 per share on April 21, 2006	7,000	—	44,800	—	44,800
Warrants for 3,750 shares valued at \$6.80 per share, issued in connection with notes payable on June 1, 2006	—	—	25,500	—	25,500
Warrants for 375 shares valued at \$5.40 per share, issued in connection with notes payable on July 21, 2006	—	—	2,025	—	2,025
Warrants for 500 shares valued at \$4.60 per share, issued in connection with notes payable on August 30, 2006	—	—	2,300	—	2,300
Issuance of common stock for cash at \$4.30 per share on September 7, 2006	11,628	—	50,000	—	50,000
Issuance of common stock for services rendered at \$6.30 per share on September 8, 2006	1,415	—	8,938	—	8,938
Warrants for 5,000 shares valued at \$4.50 per share, issued in connection with notes payable on November 30, 2006	—	—	22,500	—	22,500
Warrants for 5,171 shares valued at \$5.40 per share, accrued for issuance in connection with a note payable as of December 31, 2006	—	—	27,922	—	27,922
Net loss for the year ended December 31, 2006	—	—	—	(2,959,853)	(2,959,853)
Balance, December 31, 2006	1,439,969	14	10,111,612	(13,164,798)	(3,053,172)
Options to purchase 45,000 shares issued to officer valued at \$6.70 per share, granted February 1, 2004; portion vested in 2007	—	—	16,811	—	16,811
Options to purchase 20,000 shares issued to officer valued at \$15.00 per share, granted July 21, 2004; portion vested in 2007	—	—	58,314	—	58,314
Warrants for 5,000 shares valued at \$4.50 per share, issued in connection with debt extinguishment on January 3, 2007	—	—	22,500	—	22,500
Options to purchase 15,000 shares issued to officer valued at \$16.20 per share, granted January 3, 2005; portion vested in 2007	—	—	81,007	—	81,007
Options to purchase 17,500 shares issued to officers and an employee valued at \$5.60 per share, granted March 1, 2006; portion vested in 2007	—	—	33,245	—	33,245
Issuance of investment units consisting of common stock and warrants for 62,500 shares issued for cash at \$4.00 per share on January 18, January 23, February 28 and May 1, 2007, net of costs of \$52,388	125,000	2	447,610	—	447,612

ProUroCare Medical Inc.
(A Development Stage Company)

Consolidated Statements of Shareholders' Equity (Deficit) (Continued)

	Common stock		Additional paid-in capital	Deficit accumulated during the development stage	Total shareholders' equity (deficit)
	Shares	Amount			
Options to purchase 20,000 shares issued to officer valued at \$3.40 per share, granted February 1, 2007; portion vested in 2007	—	—	32,857	—	32,857
Warrants for 5,000 shares valued at \$3.60 per share, issued in connection with debt extinguishment on February 1, 2007	—	—	18,000	—	18,000
Issuance of common stock in lieu of cash for a loan from a director at \$4.10 per share on February 9, 2007	1,707	—	7,000	—	7,000
Modification of warrant term of warrant to purchase 30,000 shares pursuant to separation agreement of employee dated March 15, 2007, valued at \$3.20 per share	—	—	96,000	—	96,000
Issuance of common stock in lieu of cash for accrued expenses at \$4.00 per share on March 21, 2007	12,478	—	49,911	—	49,911
Warrants for 6,240 shares issued pursuant to amendment of convertible debt valued at \$4.30 per share on March 21, 2007	—	—	26,829	—	26,829
Issuance of common stock for accounts payable \$5.00 per share on April 2, 2007	4,141	—	20,704	—	20,704
Warrants for 20,000 shares issued for services rendered valued at \$3.60 per share on April 16, 2007	—	—	72,000	—	72,000
Modification of option term to purchase 45,000 shares pursuant to separation agreement of officer dated May 11, 2007, valued at \$2.30 per share	—	—	103,500	—	103,500
Modification of option term to purchase 45,000 shares pursuant to separation agreement of officer dated May 11, 2007, valued at \$2.60 per share	—	—	117,000	—	117,000
Options to purchase 3,000 shares issued to a director valued at \$5.90 per share, granted May 30, 2006; portion vested in 2007	—	—	8,850	—	8,850
Options to purchase 3,000 shares issued to a director valued at \$2.40 per share, granted June 14, 2007; portion vested in 2007	—	—	1,800	—	1,800
Issuance of common stock in lieu of cash for director's fees at \$3.00 per share on September 10, 2007	20,694	—	62,082	—	62,082
Issuance of common stock in lieu of cash for loans from directors at \$3.00 per share on September 10, 2007	1,100	—	3,300	—	3,300
Issuance of common stock as debt issuance cost at \$2.00 per share on November 7, 2007	33,333	—	66,666	—	66,666
Warrants for 6,050 shares valued at \$2.80 per share, issued in connection with notes payable on December 27, 2007	—	—	16,940	—	16,940
Warrants for 5,800 shares valued at \$1.70 per share, issued in connection with notes payable on December 27, 2007	—	—	9,860	—	9,860
Warrants for 700 shares valued at \$2.20 per share, issued in connection with notes payable on December 27, 2007	—	—	1,540	—	1,540
Original issue discount on convertible debt issued on December 27, 2007	—	—	595,666	—	595,666
Original issue discount attributable to warrants for 240,000 shares issued on December 27, 2007	—	—	88,576	—	88,576
Issuance of common stock as compensation for loan guarantees at \$1.00 per share on December 28, 2007	88,889	1	88,888	—	88,889
Warrants for 15,400 shares valued at \$4.00 per share, accrued for issuance in addition to interest on a note payable as of December 31, 2007	—	—	61,600	—	61,600

ProUroCare Medical Inc.
(A Development Stage Company)

Consolidated Statements of Shareholders' Equity (Deficit) (Continued)

	Common stock		Additional paid-in capital	Deficit accumulated during the development stage	Total shareholders' equity (deficit)
	Shares	Amount			
Warrants for 51,010 shares valued at \$3.60 per share, accrued for issuance in connection with debt extinguishment as of December 31, 2007	—	—	183,637	—	183,637
Warrants for 15,221 shares valued at \$5.40 per share, accrued for issuance in connection with debt extinguishment as of December 31, 2007	—	—	82,191	—	82,191
Net loss for the year ended December 31, 2007	—	—	—	(3,113,298)	(3,113,298)
Balance, December 31, 2007	1,727,311	17	12,586,496	(16,278,096)	(3,691,583)
Original issue discount on convertible debt issued between Jan 4, 2008 and July 30, 2008	—	—	350,873	—	350,873
Warrants for 160,000 shares valued at \$0.47 to \$1.10 per share issued in connection with convertible debt between Jan 4, 2008 and July 30, 2008	—	—	65,160	—	65,160
Warrants for 14,500 shares valued at \$1.00 per share issued to former employee pursuant to a termination agreement on January 4, 2008	—	—	14,500	—	14,500
Warrants for 52,357 shares valued at \$3.60 per share, connection with debt extinguishment on January 16, 2008; portion expensed in 2008	—	—	4,848	—	4,848
Rounding of common stock due to reverse stock split on February 14, 2008	39	—	—	—	—
Warrants for 75,000 shares valued at \$0.92 per share, issued in connection with notes payable on April 3, 2008	—	—	42,768	—	42,768
Options to purchase 20,000 shares issued to officers valued at \$0.79 per share, granted July 11, 2008	—	—	15,800	—	15,800
Cancellation of an officer's options to purchase 20,000 shares valued at \$0.27 per share on July 11, 2008	—	—	(5,400)	—	(5,400)
Cancellation of an officer's options to purchase 15,000 shares valued at \$0.31 per share on July 11, 2008	—	—	(4,650)	—	(4,650)
Options to purchase 3,000 shares issued to directors valued at \$0.71 per share, granted July 11, 2008	—	—	2,130	—	2,130
Issuance of common stock valued at \$1.00 per share in lieu of cash for directors' fees on July 11, 2008	59,634	1	59,633	—	59,634
Extension of note payable modified with a conversion feature added and recorded as debt extinguishment on September 12, 2008	—	—	48,214	—	48,214
Original issue discount on convertible debt issued between September 16, 2008 and December 11, 2008	—	—	145,743	—	145,743
Warrants for 95,500 shares valued at \$0.89 to \$1.31 per share issued in connection with convertible debt between September 16, 2008 and December 11, 2008	—	—	75,819	—	75,819
Original issue discount attributable to warrants for 100,000 shares valued at \$0.47 per share, issued on September 25, 2008	—	—	46,604	—	46,604
Warrants for 31,817 shares valued at \$5.40 per share, issued on September 30, 2008 in connection with debt extinguishment expensed and accrued from previous years; portion expensed in 2008	—	—	61,700	—	61,700
Warrants for 3,000 shares valued at \$1.32 per share, issued in connection with debt extinguishment on October 24, 2008	—	—	3,960	—	3,960
Issuance of common stock as compensation for loan guarantees at \$1.00 per share on October 31, 2008	17,778	—	17,778	—	17,778
Warrants for 44,445 shares valued at \$0.77 per share issued as compensation for loan guarantees on October 31, 2008	—	—	34,223	—	34,223

ProUroCare Medical Inc.
(A Development Stage Company)

Consolidated Statements of Shareholders' Equity (Deficit) (Continued)

	Common stock		Additional paid-in capital	Deficit accumulated during the development stage	Total shareholders' equity (deficit)
	Shares	Amount			
Issuance of common stock valued at \$1.00 per share for debt issuance cost on October 31, 2008	6,667	—	6,667	—	6,667
Warrants for 16,667 shares valued at \$0.77 per share issued as debt issuance costs on October 31, 2008	—	—	12,834	—	12,834
Warrants for 3,836 shares valued at \$1.32 per share, accrued for issuance in connection with debt extinguishment as of December 31, 2006	—	—	5,063	—	5,063
Options to purchase 17,500 shares issued to officers and an employee valued at \$5.60 per share, granted March 1, 2006; portion vested in 2008	—	—	9,663	—	9,663
Options to purchase 3,000 shares issued to a director valued at \$5.90 per share, granted May 30, 2006; portion vested in 2008	—	—	3,687	—	3,687
Options to purchase 3,000 shares issued to a director valued at \$2.40 per share, granted June 14, 2007; portion vested in 2008	—	—	3,600	—	3,600
Options to purchase 5,000 shares issued to officer valued at \$3.40 per share, granted February 1, 2007; portion vested in 2008	—	—	8,869	—	8,869
Options to purchase 15,000 shares issued to officer valued at \$16.20 per share, granted January 3, 2005; portion vested in 2008	—	—	6,731	—	6,731
Options to purchase 85,000 shares issued to officers valued at \$0.85 per share, granted July 11, 2008; portion expensed in 2008	—	—	12,042	—	12,042
Reversal of expense associated with performance-based option of an officer that did not vest	—	—	(7,727)	—	(7,727)
Warrants for 12,576 shares valued at \$4.00 per share, accrued for issuance in addition to interest on a note payable; portion expensed in 2008	—	—	50,304	—	50,304
Net loss for the year ended December 31, 2008	—	—	—	(4,657,717)	(4,657,717)
Balance, December 31, 2008	1,811,429	\$ 18	\$ 13,677,932	\$ (20,935,813)	\$ (7,257,863)

See accompanying notes to consolidated financial statements.

ProUroCare Medical Inc.
(A Development Stage Company)
Consolidated Statements of Cash Flows

	Year Ended December 31, 2008	Year Ended December 31, 2007	Period from August 17, 1999 (inception) to December 31, 2008
Cash flows from operating activities:			
Net loss	\$ (4,657,717)	\$ (3,113,298)	\$ (20,935,813)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	605	3,134	20,797
Gain on sale of furniture and equipment	—	—	(2,200)
Stock-based compensation	59,245	549,384	1,764,347
Common stock issued for services rendered	50,467	—	207,371
Common stock issued for debt guarantees	17,778	88,889	106,667
Common stock issued for debt issuance cost	6,667	—	6,667
Notes payable issued for intangibles expensed as research and development	150,000	—	150,000
Warrants issued for services	—	72,000	540,636
Warrants issued for debt guarantees	34,223	—	355,197
Warrants issued for debt extinguishment	75,571	283,829	359,400
Warrants issued for debt extinguishment-related parties	—	26,828	26,828
Warrants issued for debt issuance cost	12,834	—	12,834
Amortization of note payable-original issue discount	—	23,162	152,247
Amortization of note payable-related parties original issue discount	50,304	89,940	140,244
Amortization of convertible debt-original issue discount	428,430	272	638,685
Amortization of convertible debt-related parties original issue discount	505,217	244,587	749,804
Amortization of debt issuance costs	421,564	506,639	1,705,733
Bargain conversion option added to note payable-related parties for debt extinguishment	48,214	—	48,214
Write-off debt issuance cost for debt extinguishment	—	42,797	42,797
Write-off of deferred offering cost	—	—	59,696
License rights expensed as research and development, paid by issuance of common stock to CS Medical Technologies, LLC	—	—	475,000
License rights expensed as research and development, paid by issuance of common stock to Profile, LLC	—	—	1,713,600
Changes in operating assets and liabilities:			
Deposits	—	—	(189,554)
Other current assets	44,603	36,311	133,892
Accounts payable	199,379	(46,520)	929,834
Accrued development expense	1,327,835	—	1,327,835
Other accrued expenses	129,808	229,042	1,139,796
Net cash used in operating activities	(1,094,973)	(963,004)	(8,319,446)
Cash flows from investing activities:			
Purchases of equipment and furniture	—	—	(20,797)
Deposit into a restricted cash account	(214)	(44,000)	(44,214)
Net cash used in investing activities	(214)	(44,000)	(65,011)

ProUroCare Medical Inc.
(A Development Stage Company)

Consolidated Statements of Cash Flows (Continued)

	Year Ended December 31, 2008	Year Ended December 31, 2007	Period from August 17, 1999 (inception) to December 31, 2008
Cash flows from financing activities:			
Proceeds of note payable, bank	—	—	500,000
Payments of note payable, bank	—	—	(500,000)
Proceeds of notes payable	—	—	340,500
Payment of notes payable	(333,222)	(54,442)	(1,370,518)
Proceeds of notes payable - related parties	112,500	432,150	560,100
Payments of notes payable - related parties	(76,450)	(126,850)	(203,300)
Proceeds from long-term notes payable and bank debt	923,337	684,000	3,807,337
Proceeds from long-term notes payable, related parties	254,500	866,000	1,120,500
Payments on long-term bank debt	—	(600,000)	(600,000)
Proceeds from warrants	54,500	50,000	104,500
Payments for debt issuance costs	(148,211)	(293,260)	(673,437)
Payment for rescission of common stock	—	—	(100,000)
Payments for deferred offering expenses	(88,480)	—	(117,307)
Cost of reverse merger	—	—	(162,556)
Net proceeds from issuance of common stock	—	447,612	5,682,538
Net cash provided by financing activities	698,474	1,405,210	8,388,357
Net increase (decrease) in cash	(396,713)	398,206	3,900
Cash, beginning of the period	400,613	2,407	—
Cash, end of the period	\$ 3,900	\$ 400,613	\$ 3,900
Supplemental cash flow information:			
Cash paid for interest	\$ 123,073	\$ 235,355	\$ 716,409
Non-cash investing and financing activities:			
Deferred offering costs included in accounts payable	461,456	109,988	571,444
Deferred offering costs included in accrued expenses	47,350	22,650	70,000
Debt issuance costs included in accounts payable	58,339	55,817	114,156
Warrants issued pursuant to notes payable	139,677	112,440	463,864
Warrants issued for debt issuance costs	55,409	—	298,021
Prepaid expenses financed by note payable	54,504	42,585	165,526
Convertible debt issued in lieu of cash for accrued expenses	31,413	—	31,413
Common stock issued in lieu of cash for accrued expenses	9,167	111,993	238,803
Common stock issued for debt issuance cost	6,667	66,666	164,834
Warrants issued in lieu of cash for accrued expenses	1,250	—	1,250
Conversion of notes payable, related parties into convertible debentures	—	200,000	200,000
Common stock issued in lieu of cash for accounts payable	—	20,704	122,291
Common stock issued in lieu of cash for notes payable-related parties	—	10,300	10,300
Convertible debt issued as debt issuance costs related to guarantee of long-term debt (recorded as a beneficial conversion in additional paid-in capital) applied to accounts payable	—	—	733,334
Issuance of note payable for redemption of common stock	—	—	650,000
Conversion of accounts payable to note payable	—	—	241,613
Deposits applied to note payable and accrued interest	—	—	142,696
Deposits applied to accounts payable	—	—	45,782
Assumption of liabilities in the Profile, LLC transaction	—	—	25,000
Proceeds from sale of furniture and equipment	—	—	2,200
Deposits applied to accrued expenses	—	—	1,076

See accompanying notes to financial statements.

ProUroCare Medical Inc.
A Development Stage Company

Notes to Consolidated Financial Statements

**December 31, 2008 and 2007 and the period from
August 17, 1999 (inception) to December 31, 2008**

(1) Description of Business and Summary of Significant Accounting Policies

(a) Description of Business, Development Stage Activities, and Basis of Presentation

ProUroCare Medical Inc. (“ProUroCare,” the “Company,” “we” or “us”) is a development stage company engaged in the business of developing for market innovative products for the detection and characterization of male urological prostate disease. The primary focus of the Company is currently the ProUroScan™ prostate imaging system, designed for use as an aid to the physician in visualizing and documenting tissue abnormalities in the prostate that have been previously detected by a digital rectal exam. The Company’s developmental activities, conducted by its wholly owned operating subsidiary ProUroCare Inc. (“PUC”), have included the acquisition of several technology licenses, the purchase of intellectual property, the development of a strategic business plan and a senior management team, product development and fund raising activities.

PUC had no activities from its incorporation in August 1999 until July 2001, when it acquired a license to certain microwave technology from CS Medical Technologies, LLC (“CS Medical”). In January 2002, PUC acquired a license to certain prostate imaging technology from Profile, LLC (“Profile”).

Pursuant to a merger agreement effective April 5, 2004 (the “Merger”), PUC became a wholly owned operating subsidiary of Global Internet Communications, Inc. (“Global”), which changed its name to ProUroCare Medical Inc. on April 26, 2004. In connection with the Merger, the Company completed a private placement of 220,500 shares, as adjusted for the Reverse Split (as defined below), of common stock (the “2004 Private Placement”) pursuant to Rule 506 under the Securities Act of 1933, as amended (the “Securities Act”).

On December 27, 2007, the Company’s shareholders approved a one-for-ten reverse split of the Company’s common stock without a corresponding reduction in the number of authorized shares of the Company capital stock (the “Reverse Split”). The Reverse Split became effective on February 14, 2008. The exercise price and the number of shares of common stock issuable under the Company’s outstanding convertible debentures, options and warrants were proportionately adjusted to reflect the Reverse Split for all periods presented.

On January 12, 2009, the Company closed a public offering of 3,050,000 units at \$1.00 per unit (the “2009 Public Offering”)(see Note 14). Each unit sold (the “2009 Units”) consisted of one share of common stock and one redeemable warrant to purchase one share of common stock at an exercise price of \$1.30 per share.

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, PUC. Significant inter-company accounts and transactions have been eliminated in consolidation.

(b) *Restatement of Share Data*

All share data has been restated to give effect to the Reverse Split.

At the effective time of the Merger, all 350,100 shares of common stock of PUC that were outstanding immediately prior to the Merger and held by PUC shareholders were cancelled, with one share of ProUroCare common stock issued to Global. Simultaneously, the non-dissenting shareholders of PUC received an aggregate of 960,300 shares of common stock of Global in exchange for their aggregate of 320,100 shares of PUC. The share data in this paragraph has been restated to give effect to the Reverse Split, as noted above.

All share data has been restated to give effect to the Merger under which each PUC share was converted into three shares of Global.

(c) *Accounting Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. The Company's significant estimates include the determination of the fair value of its common stock and stock-based compensation awarded to employees, directors, loan guarantors and consultants and the accounting for debt with beneficial conversion features. Actual results could differ from those estimates.

Valuation of Stock-Based Compensation. Effective as of August 17, 1999 (inception), the Company adopted Statement of Financial Accounting Standards ("SFAS") No. 123 "Accounting for Stock-Based Compensation" ("SFAS 123") and on January 1, 2006 adopted SFAS No. 123 (revised 2004) "Share-Based Payment" ("SFAS 123R"), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including employee stock options based on fair values. The Company's determination of fair value of share-based payment awards is based on the date of grant using an option-pricing model which incorporates a number of highly complex and subjective variables. These variables include, but are not limited to, the Company's expected stock price volatility and estimates regarding projected employee stock option exercise behaviors and forfeitures. The Company recognizes the expense related to the fair value of the award straight-line over the vesting period.

Debt with Beneficial Conversion Features. The beneficial conversion features of the promissory notes were valued using the Black-Scholes pricing model, which is considered the Company's equivalent to the fair value of the conversion. The resulting original issue discount is amortized over the life of the promissory notes (generally no more than 24 months) using the straight-line method, which approximates the interest method.

(d) *Net Loss Per Common Share*

Basic and diluted loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding for the reporting period. These calculations reflect the effects of the Company's Reverse Split (see Note 1(a)). Dilutive common-equivalent shares have not been included in the computation of diluted net loss per share because their inclusion would be antidilutive. Antidilutive common equivalent shares issuable based on future exercise of stock options or warrants could potentially dilute basic loss per

common share in subsequent years. All options and warrants outstanding were antidilutive for the years ended December 31, 2008 and 2007 and the period from August 17, 1999 (inception) to December 31, 2008 due to the Company's net losses. 1,603,994 and 1,167,686 shares of common stock issuable under our stock options, warrants, convertible debt and contingent shares and warrants issuable under agreements with loan guarantors were excluded from the computation of diluted net loss per common share for the years ended December 31, 2008 and 2007, respectively. Also excluded were the undetermined number of shares issuable pursuant to the convertible notes and warrants issued in connection with our private placements, unit put arrangements and certain convertible notes, whose terms of conversion were based on the price of the equity securities offered in the Company's anticipated public offering, as described and defined in Note 14. The number of such shares was determined on the January 7, 2009 effective date of the 2009 Public Offering to be 6,937,177 and 3,432,622 shares as of December 31, 2008 and 2007, respectively.

(e) Comparative Figures

Certain comparative figures have been reclassified to conform to the financial statement presentation adopted in the current year, including the reclassification of transactions with related parties.

(f) Cash

The Company maintains its cash in high quality financial institutions. The balances, at times, may exceed federally insured limits.

(g) Equipment and Furniture

Equipment and furniture are stated at cost and depreciated using the straight-line method over the estimated useful lives ranging from three to seven years. Maintenance, repairs, and minor renewals are expensed as incurred.

(h) License Agreements

The costs associated with acquisition of licenses for technology are recognized at the fair value of stock and cash used as consideration.

Costs of acquiring technology which has no alternative future uses are expensed immediately as research and development expense.

(i) Impairment of Long-lived Assets and Long-lived Assets to be Disposed Of

The Company reviews long-lived assets and certain identifiable intangibles for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

During the years ended December 31, 2008 and 2007, and the period from August 17, 1999 (inception) to December 31, 2008, the Company did not record any impairment charges.

(j) Stock-Based Compensation

Effective August 17, 1999, the Company adopted the fair value recognition provisions of Financial Accounting Standards Board (“FASB”) SFAS No. 123, “Accounting for Stock-Based Compensation” (“SFAS 123”), to record option and warrant issuances, including stock-based employee compensation. The Company’s policy is to grant stock options at fair value at the date of grant, and to record the expense at fair value as required by SFAS 123, using the Black-Scholes pricing model.

Effective January 1, 2006, the Company adopted SFAS 123R, that focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. This statement replaced SFAS 123, and supersedes Accounting Principles Board (“APB”) Opinion No. 25, “Accounting for Stock Issued to Employees.” SFAS 123R requires all companies to expense the fair value of employee stock options and similar awards, which has been the Company’s policy to date. Stock-based employee and non-employee compensation cost related to stock options and warrants was \$59,245, \$621,384, and \$2,304,983 for the years ended December 31, 2008 and 2007, and the period from August 17, 1999 (inception) to December 31, 2008, respectively, or \$0.03, \$0.40, and \$2.19 on a per share basis. The Company estimates the amount of future stock-based compensation expense related to currently outstanding options to be approximately \$30,600, \$24,000 and \$12,000 for the years ending December 31, 2009, 2010, and 2011, respectively. The Company recognizes the expense related to the fair value of the award straight-line over the vesting period.

The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option pricing models require the input of highly subjective assumptions. Because the Company’s employee and consultant stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, the existing models may not necessarily provide a reliable single measure of the fair value of the Company’s employee stock options.

In determining the compensation cost of the options granted during the years ended December 31, 2008 and 2007, as specified by SFAS 123R, the fair value of each option grant has been estimated on the date of grant using the Black Scholes pricing model and the weighted average assumptions used in these calculations are summarized as follows:

	For the years ended December 31,	
	2008	2007
Risk-free Interest Rate	3.13%	4.90%
Expected Life of Options Granted	4.3years ¹	4.0 years ¹
Expected Volatility	131.2%	133.4%
Expected Dividend Yield	0	0

¹ Calculated as the average of the vesting periods and the contractual term of the options.

The expected life of the options is determined using a simplified method, computed as the average of the option vesting periods and the contractual term of the option. For performance-based options that vest upon the occurrence of an event, the Company uses an estimate of when the event will occur as the vesting period used in the Black-Scholes calculation for each option grant. Because of the limited trading history of the Company’s stock, the expected volatility is based on a simple average of weekly price data since the date of the Merger on April 5, 2004. Management expects and estimates that substantially all employee stock options will vest, and therefore the forfeiture rate used was zero. The

risk-free rates for the expected terms of the stock options and awards are based on the U.S. Treasury yield curve in effect at the time of grants.

(k) Warrants

In accordance with Emerging Issues Task Force (“EITF”) Issue No. 96-18, “Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods and Services” and EITF Issue No. 98-5, “Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios” (“EITF 98-5”), the Company has elected to utilize the fair-value method of accounting for warrants issued to non-employees as consideration for goods or services received, including warrants issued to lenders and guarantors of Company debt (see Notes 9, 10 and 11). The weighted-average fair value of the warrants granted during the years ended December 31, 2008 and 2007 was \$1.37 and \$3.80, respectively, and such warrants are immediately vested and exercisable on the date of grant.

The fair value of stock warrants is the estimated present value at grant date using the Black-Scholes pricing model with the following weighted average assumptions:

	For the years ended December 31,	
	2008	2007
Risk-free Interest Rate	3.23%	4.68%
Expected Life of Warrants Issued ¹	5.0 years	4.9 years
Expected Volatility	129.5%	135.0%
Expected Dividend Yield	0	0

¹ The contractual term of the warrants.

The expected volatility is based on weekly price data since the date of the Merger on April 5, 2004. Based on the lack of history to calculate a forfeiture rate, the Company has not adjusted the calculated value of the warrants. The risk-free rates for the expected terms of the stock warrants are based on the U.S. Treasury yield curve in effect at the time of grants.

(l) Financial Instruments

The carrying amount for all financial instruments approximates fair value. The carrying amounts for cash, notes payable, accounts payable and accrued liabilities approximate fair value because of the short maturity of these instruments. The carrying amounts for long-term debt, and other obligations approximates fair value as the interest rates and terms are substantially similar to rates and terms which could be obtained currently for similar instruments.

(m) Research and Development

Expenditures for research and product development costs, including certain upfront license fees for technologies under development, are expensed as incurred.

(n) Debt Issuance Costs

Debt issuance costs are amortized over the term of the related debt as interest expense using the straight-line method, which approximates the interest method.

The costs related to the Company’s \$2.2 million Crown Bank promissory notes issued in February 2006 were recorded as debt issuance cost, and were amortized over the approximately two-year term of the notes using the straight-line method until October 14, 2007. At that time, \$600,000 of the notes were

retired, and approximately \$42,800 of debt issuance cost related to that portion of the notes was expensed as debt extinguishment expense. The debt issuance cost associated with the remaining Crown Bank notes were amortized as interest expense until December 28, 2007, when the notes were modified to extend the maturity date of the notes to February 28, 2009. The Company evaluated this modification in accordance with EITF Issue No. 96-19 "Debtor's Accounting for a Modification or Exchange of Debt Instruments" "EITF (6-19)". The change in the agreement did not qualify as an extinguishment of debt; therefore, debt issuance cost from the old debt is carried forward. The remaining \$39,370 of unamortized debt issuance cost, together with \$12,000 of bank fees associated with the extension, is being amortized over the new term of the notes as interest expense.

On October 15, 2007, the Company borrowed \$600,000 pursuant to a promissory note issued to the Phillips W. Smith Family Trust (the "Smith Trust") that matured on February 28, 2009. In consideration for this loan, on November 7, 2007 the Company agreed to issue 33,333 shares of its common stock to the Smith Trust. The \$66,666 value of this consideration was recorded as debt issuance cost and is being amortized over the term of the loan.

On December 27, 2007, the Company held its first closing on a private placement of investment units consisting of convertible debentures and warrants (the "2007 Private Placement") (see Note 11(b)). Direct costs of the offering totaling \$337,077, including underwriting fees, legal and accounting expenses, and printing costs were recorded as a debt issuance cost asset.

During the year ended December 31, 2008, the Company incurred additional debt issuance costs related to a second closing on the 2007 Private Placement, the closings on an aggregate of \$720,000 of units consisting of unsecured, subordinated, convertible promissory notes and common stock purchase warrants in additional private placements (the "2008 Private Placements") (see Note 11(b)) and the closing on a \$315,000 unit put financing facility (see Note 11(c)). Included in this debt issuance cost was the issuance of warrants to acquire 32,500 shares of our common stock valued at \$42,575 related to the origination of the unit put financing facility (see Note 12(f)).

Debt issuance costs are summarized as follows:

	2008	2007
Debt issuance costs, gross	\$ 701,238	\$ 452,113
Less amortization	(434,356)	(12,792)
Debt issuance costs, net	<u>\$ 266,882</u>	<u>\$ 439,321</u>

Amortization expense related to debt issuance costs was \$421,564, \$506,639, and \$1,705,733 for the years ended December 31, 2008 and 2007 and the period from August 17, 1999 (inception) to December 31, 2008, respectively. The unamortized debt issuance cost as of December 31, 2008 will either be amortized in 2009 or expensed as interest expense upon the automatic conversion of the related debt into the Company's equity securities upon the effective date of the 2009 Public Offering (see Note 14).

(o) *Deferred Offering Costs*

The legal, accounting, printing and certain other expenses directly related to the 2009 Public Offering that became effective on January 7, 2009 were recorded as a deferred offering cost asset as of December 31, 2008 and 2007. The deferred offering costs were recorded as a cost of the offering and a reduction of additional paid-in capital upon its closing on January 12, 2009.

(p) *Restricted Cash*

Pursuant to the renewal of the Crown Bank promissory notes (see Note 10), the Company agreed to deposit with Crown Bank four months worth of future interest payments due under the notes. The funds on deposit are not available to the Company for any purpose other than for debt service on the Crown Bank promissory notes. On March 19, 2009, pursuant to the renewal of a Crown Bank promissory note, this restriction was removed (see Note 14).

(q) *Income Taxes*

The Company utilizes the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences attributable to temporary differences between the financial statement and income tax reporting bases of assets and liabilities. Deferred tax assets are reduced by a valuation allowance to the extent that realization is not assured.

(r) *Recently Issued Accounting Pronouncements*

During May, 2008, FASB issued SFAS 162, "The Hierarchy of Generally accepted Accounting Principles ("SFAS 162"). SFAS 162 identifies the sources of accounting principles and the framework for selecting principles that are in conformity with generally accepted accounting principles in the United States of America. SFAS 162 became effective during November 2008. The adoption of SFAS 162 did not have a material effect on the Company's results of operations, financial position or cash flows.

(2) *Going Concern; Management's Plan to Fund Working Capital Needs*

The Company incurred net losses of \$4,657,717, \$3,113,298 and \$20,935,813 and negative cash flows from operating activities of \$1,094,973, \$963,004, and \$8,319,446 for the years ended December 31, 2008 and 2007 and for the cumulative period from August 17, 1999 (inception) to December 31, 2008, respectively. From July 2001 through January 2002, the Company entered into several license arrangements to develop the licensed technologies into diagnostic equipment and treatments for enlarged prostates and other male urological conditions. Since January 2002, the Company's efforts to develop the licensed technologies have been significantly delayed at times due to a lack of sufficient capital resources. The Company anticipates materially increasing its expenditures for technology development activities and building the Company's infrastructure over the near term. Implementation of the Company's business plan is dependent upon the successful transition of its product development program into a viable product with market penetration and profitability and obtaining sufficient capital to fund these developmental activities.

Management believes that the Company has sufficient funds to complete clinicals of its ProUroScan System, submit a premarket notification application to FDA and obtain FDA clearance of a 510(k) for a basic mapping and data maintenance labeling claim. However, the Company does not currently have sufficient funds to make a significant commercial launch into the urology market. As of February 28, 2009, the Company had approximately \$774,000 cash on hand and current liabilities of approximately \$3.5 million, including \$2.2 million of secured debt that was due on that date. In March 2009, the Company renewed \$1.8 million of the secured debt to mature on March 28, 2010, and temporarily paid down \$400,000 of the secured debt. The Company intends to re-borrow the \$400,000 secured debt before the end of May, 2009 upon the establishment of a satisfactory guaranty of the debt with the lender. Management believes that over the next 12 months the Company will need approximately \$8 million of working capital to fund operations through FDA clearance and subsequent commercial launch.

As a result of the closing on the 2009 Public Offering and the subsequent conversion of convertible notes into the Company's equity Units, there are 6,108,381 redeemable warrants outstanding. These warrants have an exercise price of \$1.30 per share, which the Company may redeem once the last sale price of our common stock equals or exceeds \$1.82 per share for a period of ten consecutive trading days. If this event were to occur, the

Company intends to exercise its right to redeem the warrants, which will allow all holders of warrants a period of 30 days to exercise their warrants. If all such warrant holders exercise their warrants, the Company could realize up to approximately \$7.9 million, depending on the number of shares actually exercised pursuant to such a call. There can be no assurance that the Company will be able to call the warrants, or of how much would be realized if such a call were made.

During the first half of 2009, the Company plans to identify a distribution partner to market its products. The Company expects such a distribution partner to provide significant financial support in the form of licensing fees, loans, equity investment or a combination of these. In addition to financial support, a successful collaboration with such a partner would allow access to down stream marketing, manufacturing, and sales support. There can be no assurance that a distribution partner can be successfully identified and engaged during the first half of 2009, or at all.

If the Company is unable to obtain sufficient funding through the exercise of the warrants or from financial support from a distribution partner, it will pursue one or more additional rounds of funding in 2009 and 2010 to provide the working capital needed to fund a significant commercial launch into the urology market. If additional funds are raised by the issuance of convertible debt or equity securities, or by the exercise of outstanding warrants, then existing shareholders will experience dilution in their ownership interest. If additional funds are raised by the issuance of debt or certain equity instruments, the Company may become subject to certain operational limitations, and such securities may have rights senior to those of its existing holders of common stock.

If adequate funds are not available through these initiatives on a timely basis, or are not available on acceptable terms, the Company may be unable to fund expansion, or to develop or enhance our products. If the Company is forced to slow our development programs, or put them on hold, it would delay regulatory clearances or approvals needed, and thus delay market entry for its products. Ultimately, if no additional financing is obtained beyond what has been secured to date, the Company likely would be forced to cease operations. There can be no assurance the Company will be successful in raising such funds.

(3) Equipment and Furniture

Equipment and furniture consisted of the following at December 31:

	<u>2008</u>	<u>2007</u>
Computer equipment	\$ 11,563	\$ 11,563
Furniture	4,279	4,279
	<u>15,842</u>	<u>15,842</u>
Less accumulated depreciation	(15,842)	(15,237)
	<u>\$ 0</u>	<u>\$ 605</u>

Depreciation expense was \$605, \$3,134, and \$20,797 for the years ended December 31, 2008 and 2007 and the period from August 17, 1999 (inception) to December 31, 2008, respectively.

(4) Accrued Expenses

Accrued expenses consisted of the following at December 31:

	<u>2008</u>	<u>2007</u>
Accrued interest	\$ 169,985	\$ 69,134
Accrued compensation, benefits, and related taxes	350,836	535,537
Accrued interest-related party	263,522	87,088
Public offering costs	70,000	22,650
Audit fees	47,000	21,250
Directors' fees	20,249	9,166
Consulting fees	15,000	15,000
Other	662	–
Contracted development	–	35,000
Legal fees	–	7,100
	<u>\$ 937,253</u>	<u>\$ 801,925</u>

(5) Agreements with Artann Laboratories Inc.

The Company has developed its ProUroScan System under contracts with Artann Laboratories, Inc. (“Artann”), a scientific technology company based in Trenton, New Jersey, that is focused on early-stage technology development.

Artann 2004 Development Agreement

In July 2004, the Company entered into a development agreement with Artann and Dr. Armen Sarvazyan under which Artann and Dr. Sarvazyan developed two working, pre-clinical ProUroScan™ systems. These systems were delivered to the Company in late November 2004. The Company paid Artann \$180,000 for this development work, which was expensed as research and development cost during the year ended December 31, 2004.

Artann 2004 Research and Development Agreement

In July 2004, the Company entered into a research and development agreement with Artann (the “Research and Development Agreement”) for the further development of the ProUroScan™ system. Under this agreement, Artann was a research and development partner to the Company, supporting the further development of the ProUroScan™ system. For its role, Artann received a payment of \$50,000 and warrants for the purchase of 10,000 shares of the Company’s common stock upon the execution of the agreement, and \$110,000 and warrants for the purchase of 20,000 shares of the Company’s common stock following the shipment of the ProUroScan™ pre-clinical systems in accordance with the development agreement in December 2004. The warrants were fully vested, five-year warrants at a per share exercise price of \$20.00 per share value. The total value of these warrants computed using the Black-Scholes pricing model was \$281,086. All payments and the value of the warrants were recorded as research and development expense in the year ended December 31, 2004.

Artann 2007 Cooperation Agreement

On April 16, 2007, the Company entered into a cooperation agreement with Artann (the “Cooperation Agreement”) in which the parties agreed to terminate the existing Research and Development agreement and to use their best efforts to finalize a new development agreement within a reasonable period of time. The

Cooperation Agreement released each party from all undischarged obligations and liabilities under that agreement.

Under the terms of the Cooperation Agreement, the Company paid \$60,000 in fees originally due to Artann under the Research and Development Agreement, related to submission of two patents and associated patent attorney fees. Further, the Company issued to Artann five-year warrants (immediately exercisable) to acquire 20,000 shares of its common stock at \$4.10 per share, thus fulfilling another obligation under the Research and Development Agreement. The warrants were valued at \$72,000 by the Black-Scholes pricing model and were recorded as research and development expense. The Company also agreed to pay Artann \$35,000 as a first payment for work already completed under the proposed development agreement. This payment was made on January 16, 2008.

Artann 2008 License Agreement

On July 25, 2008, the Company entered into two agreements with Artann. Under the first agreement, the “License Agreement,” Artann granted to the Company an exclusive, worldwide, sublicensable license to certain patent applications, trade secrets and technology to make, use and market certain mechanical imaging products in the diagnosis or treatment of urologic disorders of the prostate, kidney or liver field of use. Artann also agreed to transfer possession of five fully functional prostate imaging systems to the Company and grant the Company full access to all relevant documentation thereto. The License Agreement became effective on December 23, 2008. As consideration, the Company agreed to pay, on the effective date of the agreement, an upfront cash license fee of \$600,000 and shares of the Company’s common stock valued at \$500,000. The total \$1,100,000 license fee was recorded as a general and administrative expense in the year ended December 31, 2008. In addition, the Company agreed to pay Artann a royalty equal to four percent of the first \$30 million of net cumulative sales of licensed products, three percent of the next \$70 million of net cumulative sales and two percent of net cumulative sales over \$100 million. Further, the Company will pay Artann a technology royalty of one percent of net sales on prostate imaging system products through December 31, 2016. The combined royalties are subject to a minimum annual royalty equal to \$50,000 per year for each of the first two years after clearance from the Food and Drug Administration (“FDA”) for commercial sale and \$100,000 per year for each year thereafter until termination or expiration of the License Agreement. The Company also agreed to grant Artann a non-exclusive fully paid up, sublicensable, royalty-free and worldwide license for Artann to make, use or sell any mechanical imaging system for the diagnosis or treatment of disorders of the female human breast. The License Agreement will terminate upon the expiration of all royalty obligations, by failure of either party to cure a breach of the agreement within a 60-day cure period, if the Company fails to make a payment to Artann and such failure is not cured within a 30-day cure period or should one of the parties become insolvent, go into liquidation or receivership or otherwise lose legal control of its business.

Artann 2008 Development Agreement

Under the second Artann agreement, the “Development and Commercialization Agreement,” the parties intend to collaborate together to develop, commercialize and market prostate mechanical imaging systems. Artann will conduct and complete all pre-clinical activities and testing on the prostate imaging system, conduct clinical trials, prepare and submit FDA regulatory submissions and provide hardware and software development, refinement and debugging services to ready the prostate imaging system for commercial sale. For these development services, the Company will make cash milestone payments to Artann of \$250,000 upon initiation of an FDA approved clinical study, \$250,000 upon completion of that FDA approved clinical study and submission of an FDA regulatory approval application on the prostate imaging system and \$750,000 upon FDA clearance to allow the prostate imaging system to be commercially sold in the United States. As of the December 23, 2008 effective date of the Development and Commercialization Agreement, the FDA approved clinical study milestone had been initiated, and the Company has expensed \$250,000 on the consolidated statement of operations. In addition, the Company will issue to Artann shares of common

stock of the Company having a value of \$1 million upon completion of the FDA approved clinical study and submission of an FDA regulatory approval application on the prostate imaging system and, as a success bonus, the Company will issue to Artann shares of its common stock having a value of \$1 million upon FDA clearance. The success bonus will be reduced by ten percent for each month that FDA clearance is delayed following 15 months from the effective date of the Development and Commercialization Agreement. The Company will also pay a monthly retainer fee for technical advice and training by Artann personnel. The monthly fee retainer shall be \$30,000 per month for each of the first nine months following the effective date of the Development and Commercialization Agreement and \$15,000 per month for the next 12 months.

Additionally, Artann will supply to the Company such quantities of the prostate imaging system as is reasonably required for pre-commercial testing, evaluation, marketing and clinical study and to facilitate the transfer of commercial production to a third party. Artann also agrees to use best reasonable efforts to provide a limited number of commercial systems, if requested by the Company. The pre-commercial and commercial systems will be sold to the Company at prices yet to be determined. Qualified Artann personnel shall provide manufacture and scale-up services to the Company or a third party manufacturer designated by the Company to facilitate the commercial manufacture of the prostate imaging systems at a cost of \$1,200 per day per individual for such services.

The initial term of the Development and Commercialization Agreement is for three years and may thereafter be renewed for additional one year terms upon mutual agreement of the parties. The Development and Commercialization Agreement may also terminate if the Company fails to make a payment to Artann and such failure is not cured within a 60-day cure period or should one of the parties become insolvent, go into liquidation or receivership or otherwise lose legal control of its business.

Accrued License and Development Fees

As of December 31, 2008, accrued license and development fees consisted of the following amounts due to Artann under the License and Development and Commercialization Agreements:

	Amount accrued
Upfront license fee payable in cash	\$600,000
Upfront license fee payable in equity	500,000
First milestone cash payment due under the Development and Commercialization Agreement	250,000
Less: Advances	(22,165)
Accrued license and development fees at December 31, 2008	<u>\$1,327,835</u>

(6) License Agreements

(a) Profile LLC

In January 2002, Profile granted the Company an exclusive license for prostate imaging systems in exchange for 323,077 shares of the Company's common stock and the assumption of \$25,000 of Profile net liabilities. On March 22, 2002, in exchange for eliminating certain covenants of the license agreement, the Company issued to Profile an additional 76,923 shares of its common stock. The 400,000 shares of common stock were valued at \$1,713,600. The aggregated stock and cash consideration for the Profile license was \$1,738,600, which was expensed as research and development.

On April 3, 2008, the Company purchased certain patents, patent applications and know-how from Profile (the "Profile Assets") pursuant to an asset purchase agreement. The purchase of the Profile

Assets effectively terminated the license agreement. The technology encompassed by the Profile Assets provides the basis for the ProUroScan™ system, the Company's initial product currently in the final stages of development. The purchase price of the Profile Assets was \$300,000, of which \$150,000 was paid in cash and \$150,000 was financed under the Profile Note (see Note 9). As indicated by SFAS No. 2, "Accounting for Research and Development Costs," regarding costs of intangibles that are purchased from others for a particular research and development project and that have no alternative future uses, the entire \$300,000 purchase price was expensed as research and development expense for the year ended December 31, 2008.

(b) CS Medical

In July 2001, the Company licensed certain microwave technology from CS Medical. The worldwide, exclusive license is limited to the field of use of the treatment of enlarged prostates, prostatitis, prostate cancer and other urological disorders, and terminates with the expiration of the last patent to expire that is the subject of the license and requires defined royalty payments. As consideration for the license, the Company exchanged 300,000 shares of its common stock valued at \$475,000. This consideration was expensed as research and development. Under the terms of the license agreement, royalty payments are to be made quarterly in an amount equal to 0.5 percent of the amount that net sales of the Company's products that incorporate the licensed technology exceed \$500,000 in that quarter. The Company has no current plans to develop the licensed technology due to resource limitations. In the absence of revenues, the Company is not obligated to make any royalty payments to CS Medical.

(c) RPI Agreement

In July 2001, the Company entered into a license agreement with Rensselaer Polytechnic Institute ("RPI") to allow the Company to use Electrical Impedance Tomography ("EIT") technology developed and patented by RPI, on a worldwide, exclusive basis for the diagnosis and treatment of urological conditions. Consideration for the license was \$50,000, paid in two \$25,000 installments, which were expensed as research and development in fiscal 2001. On July 27, 2005, the Company and RPI entered into Amendment No. 1 to the RPI license. Subsequently, the license became non-exclusive. The Company intends to abandon the EIT technology due to resource limitations.

(7) Commitments and Contingencies

(a) Lease

Effective March 1, 2009, the Company began renting approximately 500 square feet of office space on a month-to-month basis at a cost of approximately \$550 per month. From March 1, 2007 to February 28, 2009, the Company rented executive offices within the offices of a former Company director, Mr. Nazarenko. Our rental cost for these offices was approximately \$2,129 per month, which is the market price for similar office space in Minneapolis, Minnesota.

Rent expense for the years ended December 31, 2008 and 2007, and the period from August 17, 1999 (inception) to December 31, 2008 was \$23,062, \$21,286 and \$256,206, respectively.

(b) Employment Agreements

On July 16, 2008, PUC entered into an employment agreement with Richard Carlson, its Chief Executive Officer. The agreement provides for a minimum annual salary of \$150,000, a cash incentive bonus potential of up to 40 percent of Mr. Carlson's base pay and eligibility to participate in an annual grant of options to purchase shares of common stock, as determined by the Company's Board of Directors. The agreement provides for severance payments if the Company terminates Mr. Carlson without cause or if Mr. Carlson terminates the agreement for good reason that includes nine months of base salary plus one month of base salary for each year of service (up to a maximum of 12 months of

base salary), payment of earned bonuses, continued payment of existing health and life insurance benefits for a period of nine months and immediate vesting of all unvested stock options then held by Mr. Carlson. In addition, within a one-year period following a “change in control” of the Company, upon termination without cause, unacceptable demotion or reduction in responsibilities or a relocation of more than 100 miles, Mr. Carlson will receive as severance, nine months of base salary plus one month of base salary for each year of service (up to a maximum of 12 months of base salary) and immediate vesting of all unvested stock options then held by Mr. Carlson. The agreement prohibits Mr. Carlson from directly or indirectly participating in the ownership, management, operation or control of a competitive business for a period of one year after his employment with the Company terminates. The agreement will expire on December 31, 2009.

On July 21, 2007, PUC entered into an employment agreement with its Chief Financial Officer, Richard Thon. The agreement extends through June 30, 2009. The agreement provides for a minimum annual salary of \$140,000, a cash incentive bonus potential of up to 30 percent of Mr. Thon’s base pay and eligibility to participate in an annual grant of options to purchase shares of common stock, as determined by the Company’s Board of Directors. The agreement provides for severance payments if the Company terminates Mr. Thon without cause or if Mr. Thon terminates the agreement for good reason, including four months of base salary plus one month of base salary for each year of service (up to a maximum of nine months of base salary), payment of earned bonuses, continued payment of existing health and life insurance benefits for a period of four months and immediate vesting of all unvested stock options then held by Mr. Thon. In addition, within a one-year period following a “change in control” of the Company, upon termination without cause, unacceptable demotion or reduction in responsibilities or a relocation of more than 100 miles, Mr. Thon will receive as severance, six months of base salary plus one month of base salary for each year of service (up to a maximum of 12 months of base salary), and immediate vesting of all unvested stock options then held by Mr. Thon. The agreement prohibits Mr. Thon from directly or indirectly participating in the ownership, management, operation or control of a competitive business for a period of one year after his employment with the Company terminates.

At December 31, 2008, approximately \$269,000 of our current senior management’s salaries and bonuses had not been paid, and were recorded as an accrued expense.

(c) Legal proceedings

The Company is involved in routine legal proceedings in the conduct of the ordinary course of its business.

(8) Income Taxes

The Company has generated net operating loss carryforwards of approximately \$5.0 million which, if not used, will begin to expire in 2021. Federal and state tax laws impose significant restrictions on the utilization of net operating loss carryforwards in the event of a change in ownership of the Company that constitutes an “ownership change,” as defined by Section 382 of the Code. The Company has analyzed the 2009 Public Offering along with previous changes and believes that such an ownership change has not occurred, and that the Company’s use of its net operating loss carryforwards is not subject to such restrictions.

The Company has recorded a full valuation allowance against its deferred tax assets and deferred tax liability due to the uncertainty of realizing the related benefits and costs as follows:

	<u>2008</u>	<u>2007</u>
Deferred tax assets		
Net operating loss carryforwards	\$ 1,916,000	\$ 1,566,000
Capitalized start up costs	2,921,000	2,450,000
Expenses paid with options and warrants	724,000	836,000
Capitalized licenses	893,000	416,000
Other	164,000	149,000
Deferred tax liability		
Beneficial conversion feature of convertible debentures	(212,000)	(347,000)
Less: valuation allowance	<u>(6,406,000)</u>	<u>(5,070,000)</u>
Net deferred tax assets	<u>\$ 0</u>	<u>\$ 0</u>

The change in the valuation allowance was \$1,336,000, \$795,000 and \$6,406,000 for the years ended December 31, 2008 and 2007 and the period from August 17, 1999 (inception) to December 31, 2008, respectively. In September 2005, the FASB approved EITF Issue No. 05-8, "Income Tax Consequences of Issuing Convertible Debt with a Beneficial Conversion Feature" ("EITF 05-8"). EITF 05-8 provides: (i) that the recognition of a beneficial conversion feature creates a difference between book basis and tax basis of a convertible debt instrument, (ii) that basis difference is a temporary difference for which a deferred tax liability should be recorded and (iii) the effect of recognizing the deferred tax liability should be charged to equity in accordance with SFAS No. 109 "Accounting for Income Taxes." EITF 05-8 was effective for financial statements for periods beginning after December 15, 2005. The Company applied EITF 05-8 to the 2008 and 2007 issuances of convertible debt and the remaining deferred tax liability at December 31, 2008 and 2007 was \$212,000 and \$347,000, respectively. Pursuant to EITF 05-8 Issue Summary No. 1 dated August 29, 2005, paragraph 15, the Company offset the deferred tax liability against the deferred tax valuation allowance at December 31, 2008 and 2007.

Reconciliation between the federal statutory rate and the effective tax rates for the years ended December 31, 2008 and 2007 and the period from August 17, 1999 (inception) to December 31, 2008 is as follows:

	<u>2008</u>	<u>2007</u>	<u>Period from August 17, 1999 (inception) to December 31, 2008</u>
Federal statutory tax rate	(34.0) %	(34.0) %	(34.0) %
State taxes, net of federal benefit	(4.5)	(4.5)	(4.5)
Employee incentive stock options	0.3	2.5	1.9
Expired warrants and options	4.6	2.6	1.5
Capitalized license fees	-	-	0.9
Change in valuation allowance	<u>33.6</u>	<u>33.4</u>	<u>34.2</u>
Effective tax rate	<u>0.0 %</u>	<u>0.0 %</u>	<u>0.0 %</u>

The Company has adopted the policy of classifying interest in interest expense and penalties in general and administrative expense.

The Company had no significant unrecognized tax benefits as of December 31, 2008 or December 31, 2007 and, likewise, no significant unrecognized tax benefits that, if recognized, would affect the effective tax rate.

The Company had no positions for which it deemed that it is reasonably possible that the total amounts of the unrecognized tax benefit will significantly increase or decrease.

The tax years that remain subject to examination by major tax jurisdictions currently are:

Federal 2005 - 2007

State of Minnesota 2005 - 2007

(9) Notes Payable

- On June 1, 2006, PUC borrowed \$75,000 from Mr. Roman Pauly, and in connection therewith issued to Mr. Pauly a promissory note to mature on August 30, 2006. The promissory note and amendments thereto bore an interest at the Prime Rate. On August 24, 2006, the promissory note was amended to mature on October 29, 2006. On January 22, 2007, the Company repaid \$25,000 of the promissory note. On March 20, 2007, the promissory note was amended for a second time to extend the due date of the remaining balance until the Company closed on an aggregate of \$750,000 or more of additional financing following the date of the amendment. On January 3, 2008 and February 29, 2008, the Company repaid \$33,000 and \$7,650 of the principal of the promissory note, respectively. On October 24, 2008, the promissory note was further amended to extend the maturity date to the earlier of the Company's closing of its anticipated public offering or November 30, 2008. In connection with the promissory note and the amendments thereto, the Company issued several warrants to Mr. Pauly (see Note 12(f)). The note balance outstanding at December 31, 2008 and 2007 was \$9,350 and \$50,000.

On January 9, 2009, the Company repaid the remaining \$9,350 principal amount of the Pauly loan and issued a warrant to acquire 4,295 shares of the Company's common stock as described above (see Note 14).

- On November 30, 2006, the Company borrowed \$100,000 from Adron Holdings, LLC ("Adron"). In connection therewith, the Company issued to Adron an unsecured promissory note that bore an annual interest rate of 60 percent and was set to mature on January 2, 2007 (the "Adron Note"). On each of March 20, 2007 and August 8, 2007, the Company amended the Adron Note, resulting in a change of the annual interest rate to 42 percent, the extension of its due date to September 15, 2007 and an agreement to issue to Adron five-year warrants to acquire 167 shares at \$5.00 per share for each day the principal remained unpaid on and after March 1, 2007 (see Note 12(f)). The Company repaid the principal in January, 2008. The note balance outstanding at December 31, 2008 and 2007 was \$0 and \$100,000.
- On May 25, 2007, the Company borrowed \$42,585 from a commercial lender pursuant to an insurance policy financing agreement. The financing agreement called for ten monthly installment payments of \$4,453 beginning July 1, 2007, with an imputed annual interest rate of 9.85 percent. The proceeds were paid directly to an insurance company as a prepayment on an insurance policy. The note was paid in full during 2008.
- On July 31, 2007, the Company borrowed for working capital purposes \$100,000 from the Smith Trust pursuant to a promissory note. On January 3, 2008, the Company repaid \$66,000 of this note. On March 11, 2008, the Company amended the promissory note with the Smith Trust. Under the terms of the amendment, unpaid principal and interest will be payable upon the Company's closing of an aggregate of \$500,000 or more of financing following the date of the amendment. The note bore interest at the Prime Rate (3.25 percent and 7.25 percent at December 31, 2008 and 2007, respectively). In addition, the Company agreed to issue a five-year warrant to the Smith Trust to acquire one share of the Company's common stock at \$5.00 per share for each \$1,000 of principal amount outstanding for each day the promissory note remained unpaid (see Note 12(f)). On January 20, 2009, the Company repaid the Smith

Trust promissory note and issued 28,656 warrants according to the above terms (see Note 14). The note balance outstanding at December 31, 2008 and 2007 was \$34,000 and \$100,000.

- On August 29, October 31 and November 30, 2007, the Company borrowed for working capital needs \$50,000, \$100,000 and \$25,000, respectively, from James Davis pursuant to promissory notes. Each note bore interest at the Prime Rate (3.25 percent and 7.25 percent at December 31, 2008 and 2007, respectively). Upon the December 27, 2007 conversion of these notes into the convertible debentures of the Company (see Note 11(b)), pursuant to the terms of the promissory note, the Company issued to Mr. Davis a warrant to acquire 12,550 shares of its common stock that was valued at \$28,340 using the Black-Scholes pricing model and expensed as interest expense. The conversion resulted in there not being an outstanding balance at December 31, 2007.
- On October 31, 2007, the Company issued a promissory note for \$600,000 in favor of the Smith Trust effective as of October 15, 2007. The proceeds were used to retire \$600,000 of the Crown Bank promissory notes. The promissory note issued to the Smith Trust matures on February 28, 2009, bears interest at 1.0 percent over the Prime Rate, but never less than 6.50 percent (6.50 percent and 8.25 percent at December 31, 2008 and 2007, respectively), and has a subordinated security interest in all of the Company's assets. As consideration to the Smith Trust for making this loan, the Company issued shares of its common stock and warrants to acquire shares of its common stock (see Note 12(f)). On March 11, 2008, the Company amended the promissory note with the Smith Trust. Under the terms of the first amendment, interest accrued pursuant to the promissory note is payable on the maturity date, rather than payable monthly. The note balance outstanding at both December 31, 2008 and 2007 was \$600,000. On March 19, 2009, the Company again amended the promissory note with the Smith Trust to extend the maturity date to March 28, 2010 (see Note 14).
- On May 27, 2008, the Company borrowed \$43,860 from a commercial lender pursuant to an insurance policy financing agreement. The financing agreement calls for ten monthly installment payments of \$4,554 beginning July 1, 2008, with an imputed annual interest rate of 8.26 percent. The proceeds were paid directly to an insurance company as a prepayment on an insurance policy. On September 16, 2008, the Company borrowed an additional \$10,644 from the same commercial lender pursuant to an increase in its insurance coverage, resulting in an increase in the remaining monthly payments of \$1,823 beginning November 1, 2008. The note balance outstanding at December 31, 2008 was \$25,075.
- On April 3, 2008, the Company purchased the Profile Assets from Profile (see Note 6(a)). \$150,000 of the purchase price was financed under a secured promissory note issued in favor of Profile (the "Profile Note"). Pursuant to the terms of the Profile Note, the principal and interest accrued thereon was to become due and payable five business days following the close of a public offering of the Company's equity securities or August 29, 2008, whichever occurred first (the "Maturity Date"). Interest accrued at an annual rate of 10 percent prior to the Maturity Date and 18 percent thereafter. On September 10, 2008, the Company amended the Profile Note such that it became due on September 25, 2008. On September 25, 2008, the Company repaid the principal amount the Profile Note and the accrued interest thereon.
- At various times during the years ended December 31, 2008 and 2007, the Company received short-term, unsecured loans from certain officers and directors solely for short-term working capital needs. These loans were made without any interest or other consideration accruing to the officers and directors, and had no defined terms. As of December 31, 2008 and 2007, the Company had total outstanding borrowings of \$0 and \$10,450 from one director, respectively.

See Note 13 for information regarding related party transactions and loans.

(10) Notes Payable - Bank

In February 2006, the Company completed two closings of senior debt financing. Pursuant to the two closings, on February 16, 2006, the Company issued a promissory note to Crown Bank in the amount of \$1,200,000 at an interest rate of the Prime Rate plus one percent, but never less than 6.50 percent (6.50 and 8.25 percent at December 31, 2008 and 2007, respectively). On February 28, 2006, the Company issued a second promissory note to Crown Bank in the amount of \$1,000,000, at an interest rate of the Prime Rate plus one percent (4.25 percent and 8.25 percent at December 31, 2008 and 2007, respectively). The average interest rate of the notes was 6.60 and 9.05 percent for the years ended December 31, 2008 and 2007, respectively. The promissory notes were secured by a pledge of all Company assets, including two technology licenses that were assigned to Crown Bank, and were guaranteed by Bruce Culver, James Davis, William Reiling and the Smith Trust. In consideration for their guarantees, the Company issued 10 percent unsecured convertible subordinated debentures totaling \$733,334 to the four guarantors (see Note 11(a)).

On October 15, 2007, the Company retired \$600,000 of the Crown Bank promissory notes, and on October 31, 2007, the Company renewed the remaining notes to mature on February 28, 2009. In connection with the renewal, and as a condition to the effectiveness of the terms and conditions of the renewal of the notes, the Company agreed to deposit into an escrow with Crown Bank four months worth of future interest payments due under the notes. On December 28, 2007, the Company deposited \$44,000 into Crown Bank as the four months' interest requirement, thereby making effective the terms of the renewed notes. The guidance provided by EITF 96-19 indicates that a substantial modification of debt terms should be accounted for as an extinguishment of debt. The present value of the cash flows under the modification of the Crown Bank notes was less than 10 percent different from the cash flows of the original agreement. Accordingly, the extension of the maturity date of the notes was not deemed to be a substantial modification.

As a condition to the renewal of the notes, Crown Bank required that the guarantors extend their guarantees to cover the longer note terms and increase the amount each guaranteed. As consideration to Messrs. Culver, Davis and Reiling for extending their guarantees through February 28, 2009, the Company issued to each shares of its common stock and warrants to acquire its common stock (see Note 12(f)).

On March 19, 2009, the Company renewed the \$1,200,000 Crown Bank note, and temporarily paid down the \$400,000 note (see Note 14).

(11) Convertible Debt

(a) Convertible Debentures

As consideration to the guarantors to provide their guarantees for the Crown Bank promissory notes (see Note 10), the Company issued \$733,334 of unsecured convertible 10 percent debentures. All of the debentures mature three years from the date of issue (coincident with the closing dates of the promissory notes as noted above) and are convertible into Company common stock at a price of \$3.00 per share. The face value of the convertible debentures was recorded as long-term convertible debentures liability for \$733,334 (before the impact of the calculation of the beneficial conversion feature – see below) with the offset of the cost of the debentures recorded as a debt issuance cost asset.

The debt issuance cost asset is being amortized as interest expense over the term of the underlying bank note payable. The convertible debentures are being treated as debt issuance cost because they represent the costs directly attributable to the bank promissory note financing.

The embedded conversion feature of the convertible debentures does not meet all the characteristics of a derivative instrument as described in SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133"), and therefore was not separated from the host contract and accounted for as a derivative. The embedded conversion feature does not provide for net settlement, the shares to be issued pursuant to the exercise of the conversion feature will be unregistered and, due to the large number of shares involved and the thinly traded market for the Company's shares, cannot

be readily settled net by a means outside the contract. The value of the beneficial conversion feature was computed as the difference between the fair market value of the shares at the transaction dates and the lowest possible conversion price during the debenture term (\$3.00 per share), multiplied by the number of conversion shares that would be issued at that conversion price (244,445 shares). The value so computed was in excess of the face value of the convertible debentures issued, and was therefore limited to the face value of the debentures issued (\$733,334). The beneficial conversion feature was recorded as an original issue discount as defined in EITF 98-5 against the convertible debt liability and is also being amortized as interest expense over the term of the convertible debentures. See Note 8 for the deferred income tax effects of the beneficial conversion feature.

On March 21, 2007, the Company and the four guarantors agreed to amend the debenture agreements. Pursuant to the revised debenture agreements, among other things, the Company issued a total of 12,478 shares of its Investment Units to the four guarantors in lieu of \$49,911 of accrued interest. Each Investment Unit consists of one share of the Company's common stock and a 3-year warrant (immediately exercisable) to acquire 0.5 shares of the Company's common stock for \$2.50 (\$5.00 per share). The guidance provided by EITF 96-19 indicates that a substantial modification of debt terms should be accounted for as an extinguishment of debt, as the present value of the cash flows under the March 20, 2007 modification was greater than 10 percent different from the present value of the cash flows under the original agreement. Accordingly, the warrants issued, valued at \$26,829 using the Black-Scholes method, were recorded as debt extinguishment expense. No other gain or loss was recorded.

On December 27, 2007, the holders of the unsecured convertible 10 percent debentures issued by the Company agreed to further amend the terms of their debentures to provide for automatic conversion of the principal amount of the debentures and the unpaid interest accrued thereon into shares of the Company's common stock at \$3.00 per share upon the closing of an underwritten public offering by the Company. The \$733,334 outstanding principal amount of the debentures will convert into 244,445 shares of the Company's common stock. As of December 31, 2008, \$142,604 of unpaid accrued interest related to the debentures was outstanding. Interest will continue to accrue on the debentures until they are converted or otherwise retired. The balance outstanding at both December 31, 2008 and 2007 was \$733,334.

On January 12, 2009, the Company closed on its 2009 Public Offering, which triggered the automatic conversion of the convertible debentures along with the interest accrued thereon into shares of the Company's common stock (see Note 14).

(b) *Convertible Notes – 2007 and 2008 Private Placements*

On December 27, 2007, the Company closed on the sale of \$1,050,000 of units consisting of unsecured, subordinated, convertible promissory notes (the "2007 Notes") and common stock purchase warrants (the "2007 Warrants") in the 2007 Private Placement. Net cash proceeds to the Company were \$712,923, after deducting \$337,077 of expenses of the offering (including \$105,000 of commissions paid to the placement agent) and excluding from the cash proceeds the conversion into units of \$25,000 of loans made to the Company by James Davis and \$25,000 of certain loans from the Company's directors.

At the closing, the Company issued \$997,500 in principal amount of 2007 Notes and 2007 Warrants to purchase 210,000 shares of common stock. The 2007 Notes bore interest at 10 percent per year and would have matured on June 27, 2009. As a result of the 2009 Public Offering, the 2007 Notes converted into the Company's 2009 Units at \$0.70 per unit. The 2007 Warrants became exercisable

upon the closing of the 2009 Public Offering and will remain exercisable until December 31, 2012 (see Note 12(f)). The exercise price is \$0.50 per share.

On December 27, 2007, the Company also converted \$150,000 of existing loans from James Davis into a note (the "Davis Note") and warrants similar to those described above. The principal amount of the note issued to Mr. Davis was \$142,500. Mr. Davis also received warrants to purchase 30,000 shares of the Company's common stock. The terms of the note and warrants issued to Mr. Davis are the same as those issued in the 2007 Private Placement, except that his note is converted into the Company's 2009 Units at \$0.50 per unit. In addition, Mr. Davis agreed that the 2009 Units issued upon conversion of his note and the common stock issued upon exercise of his warrant will not be transferable for a period of one year from January 7, 2009.

On January 4, 2008, the Company closed on the sale of \$80,000 of additional units as part of the 2007 Private Placement with the same terms as noted above. Net cash proceeds to the Company were \$69,600, after deducting \$10,400 of commissions paid to the placement agent. At closing, the Company issued \$76,000 in principal amount of 2007 Notes and 2007 Warrants to purchase 16,000 shares of common stock.

On February 13, February 28, May 2, July 15 and July 30, 2008, the Company closed on the 2008 Private Placements, selling an aggregate of \$720,000 of investment units. Net cash proceeds to the Company were \$539,716, after deducting \$180,284 of expenses of the offerings (including \$93,600 of commissions paid to the placement agent). Each \$10,000 unit consists of a note in the principal amount of \$9,500 (the "2008 Notes") and a warrant to purchase 2,000 shares of our common stock (the "2008 Warrants"). In aggregate, the Company issued \$684,000 in principal amount of 2008 Notes and 2008 Warrants to purchase 144,000 shares of common stock. The terms of the 2008 Notes and 2008 Warrants are identical to the 2007 Notes and 2007 Warrants, respectively, except with regard to the eligible periods of prepayment.

The embedded conversion features of the 2007 Notes, the Davis Note and the 2008 Notes do not meet all the characteristics of a derivative instrument as described in SFAS 133, and therefore were not separated from the host contracts and accounted for as derivatives. The embedded conversion features are indexed to the Company's common stock, and would be classified in shareholders' equity under the guidance of EITF Issue No. 00-19 "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock" ("EITF 00-19"), if they were freestanding derivatives. The embedded conversion feature contains an explicit limit on the number of shares to be delivered, the Company has sufficient authorized and unissued shares available to settle the maximum number of shares and the debenture agreement does not contain a net cash settlement feature. The beneficial conversion features of the 2007 Notes, the Davis Note and the 2008 Notes, valued at \$946,539 using the Black-Scholes pricing model, along with the \$153,735 relative fair value of the 2007 Warrants, the Davis Warrants and the 2008 Warrants, were recorded as an original issue discount as defined in EITF 98-5 against the convertible debt liability, and are being amortized as interest expense over the term of the convertible debentures. \$612,689, \$417 and \$613,106 of the original issue discount was amortized as interest expense during the years ended December 31, 2008 and 2007 and the period from August 17, 1999 (inception) to December 31, 2008, respectively. See Note 8 for the deferred income tax effects of the beneficial conversion feature.

The aggregate balance outstanding of the 2007 Notes, the Davis Note and the 2008 Notes at December 31, 2008 and 2007 was \$1,900,000 and \$1,140,000, respectively. On the January 7, 2009 effective date of the Company's 2009 Public Offering, the 2007 Notes, the Davis Note and the 2008 Notes along with the interest accrued thereon automatically converted into units identical to those sold in the 2009 Public Offering (see Note 14).

(c) Convertible Notes – Unit Put Arrangement

On September 16, 2008, the Company secured \$325,000 of future funding through commitments to purchase units in accordance with the terms of a unit put agreement (the “Unit Put Agreement,” such future funding commitments, the “Unit Put Arrangements”). In consideration of each purchaser’s future funding commitment, each purchaser received an origination warrant to purchase 1,000 shares of the Company’s common stock for each \$10,000 unit an investor committed to purchase (each, an “Origination Warrant”) (see Note 12(f)).

Each unit consists of a note in the principal amount of \$9,500 (the “Unit Put Notes”) and a warrant to purchase 2,000 shares of the Company’s common stock (the “Unit Put Warrants”)(see Note 12(f)). The purchase price of the warrant portion of each unit was \$500. The Unit Put Notes bore interest at 10 percent per year, were to mature on March 16, 2010 and, as a result of the January 12, 2009 closing of 2009 Public Offering, converted into common stock at \$0.70 per share.

On September 16, 2008, the Company exercised \$162,500 of its put options under the Unit Purchase Agreement, and upon the September 24, 2008 closing thereof, issued Unit Put Notes in the principal amount of \$154,375 and 32,500 Unit Put Warrants. On October 17, 2008, the Company exercised the remaining \$162,500 of its put option under the Unit Put Agreement and on October 28, 2008 and December 11, 2008, closed on \$127,500 and \$25,000 of this exercise, respectively. \$10,000 of the put option was not closed. Pursuant to these closings, the Company issued Unit Put Notes in the principal amount of \$144,875 and 30,500 Unit Put Warrants. Cash proceeds from all closings were \$282,339, while \$32,661 of the Unit Put Notes and Warrants were paid for by the reduction of accrued interest due to one of the investors. Legal, accounting and other direct costs related to the offering totaling \$13,002 were recorded as debt issuance cost and are being amortized as interest expense over the term of the Unit Put Agreement.

The embedded conversion feature of the Unit Put Notes does not meet all the characteristics of a derivative instrument as described in SFAS 133, and therefore was not separated from the host contracts and accounted for as derivatives. The embedded conversion feature is indexed to the Company’s common stock and would be classified in shareholders’ equity under the guidance of EITF 00-19 if it was a freestanding derivative. The embedded conversion feature contains an explicit limit on the number of shares to be delivered, the Company has sufficient authorized and unissued shares available to settle the maximum number of shares and the debenture agreement does not contain a net cash settlement feature. The beneficial conversion features of the Unit Put Notes, valued at \$145,743 using the Black-Scholes pricing model, along with the \$17,493 relative fair value of the Unit Put Warrants, were recorded as an original issue discount as defined in EITF 98-5 against the convertible debt liability, and are being amortized as interest expense over the term of the convertible debentures. \$24,797 of the original issue discount was amortized as interest expense during the year ended December 31, 2008. See Note 8 for the deferred income tax effect of the beneficial conversion feature.

The \$299,250 of Unit Put Notes outstanding at December 31, 2008 and the interest accrued thereon automatically converted into shares of the Company’s common stock on February 6, 2009 (see Note 14).

(d) Other Convertible Notes

- On April 3, 2008, the Company borrowed an aggregate of \$112,500 pursuant to three promissory notes, each in the amount of \$37,500, issued in favor of James Davis, William Reiling and the Smith Trust. The proceeds from the promissory notes were used toward the purchase of the Profile Assets (see Note 6(a)). Payment in full of the promissory notes and the interest accrued thereon at an annual rate of 10 percent was due on September 1, 2008. As consideration for providing the

loans, the Company issued immediately exercisable, five-year warrants to purchase 25,000 shares of the Company's common stock at \$1.50 per share to each lender. The gross proceeds were allocated between the note and the warrants based on the relative fair value at the time of issuance. The \$42,769 relative fair value of the warrants was recorded as original issue discount on the related promissory notes and expensed as interest expense over the term of the promissory notes. On September 12, 2008, the Company amended the three promissory notes. Under the terms of the amendments, the maturity date of each \$37,500 note was changed from September 1, 2008 to the earlier of the seven days after the date the Company closed on an underwritten public offering of equity securities or December 31, 2008. In addition, each note holder was given the option of converting the principal and interest into shares of the Company's common stock at price equal to 70 percent of the price of the securities sold in that underwritten public offering, in lieu of cash. EITF Issue No. 06-6 "Debtor's Accounting for a Modification (or Exchange) of Convertible Debt Instruments" requires that a modification or exchange of debt instruments be accounted for as debt extinguishment if a substantive conversion option is added to the new or modified debt instrument. Under the guidance of EITF Issue No. 05-1 "Accounting for the Conversion of an Instrument That Became Convertible upon the Issuer's Exercise of a Call Option," the added conversion option was deemed to be substantive. Accordingly, the amendments were treated as a debt extinguishment. No gain or loss was recognized. The \$48,214 fair value of the beneficial conversion feature was recorded as original issue discount, and was amortized as debt extinguishment expense over the term of the notes. The principal balance outstanding at December 31, 2008 was \$112,500.

In January 2009, following the closing of the 2009 Public Offering, the Company repaid \$45,500 of the notes, and \$29,500 of the notes were converted into common stock at \$0.70 per share (see Note 14). On March 19, 2009, the remaining \$37,500 promissory note, due to Mr. Davis, was refinanced along with another \$150,000 promissory note due to Mr. Davis (see Note 14).

- On September 25, 2008, the Company borrowed \$150,000 pursuant to a convertible promissory note issued in favor of James Davis. The proceeds of the loan were used to retire the \$150,000 principal balance of the Profile Note. Payment in full of the promissory notes and the interest accrued thereon at an annual rate of 10 percent was due on the earlier of seven days after the date the Company closed an underwritten public offering of equity securities or March 25, 2010. Under the terms of the promissory note, following the closing of the 2009 Public Offering, Mr. Davis has the option to convert the principal and accrued interest into shares of the Company's common stock at \$0.70 per share. As consideration for providing the loan, the Company issued an immediately exercisable, five-year warrant to purchase 100,000 shares of the Company's common stock at \$1.50 per share to Mr. Davis. The gross proceeds were allocated between the note, the warrants and the bargain conversion feature of the note based on the relative fair value at the time of issuance. The \$46,604 relative fair value of the warrants was recorded as original issue discount and is being expensed as interest expense over the term of the promissory note. As the holder's ability to exercise the conversion feature of the note is contingent upon an event outside the control of the holder, the bargain conversion feature valued at \$103,396 was not recorded until January 2009 when the contingency was removed (see Note 14). The principal balance outstanding at December 31, 2008 was \$150,000.

Any unamortized original discount will be expensed upon a conversion of the promissory note. On March 19, 2009, the \$150,000 debt (and \$6,542 of interest accrued thereon) was refinanced by Mr. Davis (see Note 14).

See Note 13 for related party information concerning convertible notes.

(e) *Future maturities of long-term debt*

Future maturities of long-term convertible notes for the years succeeding December 31, 2008 are as follows:

<u>Year</u>	<u>Paid in Cash</u>	<u>Original Issue Discount</u>	<u>Total</u>
2009	\$ —	\$ (197,166)	\$ (197,166)
2010	615,500	(34,376)	581,124
Total	\$ 615,500	\$ (231,542)	\$ 383,958

(12) **Shareholders' Equity (Deficit)**

(a) *Common stock issued related to formation and licensing activities*

The Company issued 300,000 shares to Clinical Network Inc. in July 2001. In connection with the Company's license agreements with CS Medical and Profile, the Company issued 300,000 and 400,000 shares of common stock in 2001 and 2002, respectively.

(b) *Common Stock and Warrants issued related to 2002 Private Placement*

In connection with a private placement to accredited investors, the Company issued 45,335 shares of common stock in 2002. In addition, the Company issued warrants to purchase 4,535 shares of common stock to three individuals related to services rendered in connection with the private placement. These warrants expired unexercised.

(c) *Common Stock and Warrants issued related to Merger and 2004 Private Placement*

Merger Agreement

Prior to the April 5, 2004 Merger (see Note 1(a)), Profile had notified the Company of a possible breach of its license agreement with the Company, and had also dissented from the Merger proposal as the registered holder of securities beneficially owned by certain shareholders holding, in the aggregate, 30,847 (pre-merger) shares of PUC's common stock. Effective on April 4, 2004, the parties reached an agreement pursuant to which Profile waived any existing defaults under the Profile license agreement, and the Company agreed to purchase 30,000 of the 30,847 (pre-conversion) shares with respect to which dissenters' rights were exercised for an aggregate purchase of \$750,000. Of that amount, \$100,000 was paid upon the initial closing of the private placement (described below) and the balance of \$650,000 was paid pursuant to the delivery of a promissory note, which was paid in full in October 2004. The remaining 847 (pre-conversion) shares with respect to which dissenters' rights were originally exercised withdrew their dissents and participated in the Merger.

At the effective time of the Merger all 350,100 (pre-conversion) shares of common stock of PUC that were outstanding immediately prior to the Merger and held by PUC shareholders were cancelled, with one share of PUC common stock issued to Global. Simultaneously, the former shareholders of PUC common stock received an aggregate of 960,300 shares of common stock of Global, representing approximately 82.1 percent of Global's common stock outstanding immediately after the Merger.

Global was a non-operating public shell company at the time of the Merger. Accordingly, the Merger transaction was recorded as a recapitalization rather than a business combination. The assets and liabilities resulting from the reverse acquisition were the former PUC assets and liabilities (at historical

cost) plus a \$13,500 accrued Global liability (assumed at historical cost). There were no other assets or liabilities on Global's books at the time of the Merger. The Company recorded costs associated with the Merger totaling \$162,556 during 2004.

2004 Private Placement of Common Stock

In connection with the Merger, the Company completed a private placement offering of 220,500 shares of common stock pursuant to Rule 506 promulgated under the Securities Act. The initial closing occurred on April 5, 2004, at which time the Company issued 198,000 shares at \$20.00 per share, aggregating to gross proceeds of \$3.96 million. Subsequent to April 5, 2004, the Company issued an additional 22,500 shares at \$20.00 per share, aggregating to gross proceeds of \$450,000. Costs associated with the private placement (including the subsequent registration costs) were \$139,493.

As part of the private placement, the Company engaged a consultant to provide financial-advisory services. Under terms of the arrangement, the consultant was paid \$27,000 and was issued a warrant for 30,000 shares of common stock upon the first closing of the private placement. The warrant had a three-year term and was exercisable at \$20.00 per share.

(d) *Private sales of Common Stock*

- On June 15, 2005, the Company sold 6,579 shares of its common stock to an accredited investor in a non-public offering. The per share selling price of \$7.60 was based on the last selling price prior to this sale as reported on the Over-the-Counter Bulletin Board. Net proceeds received from this placement were \$50,000.
- On September 7, 2006, the Company sold 5,814 shares of its common stock to Scott Smith, a director of the Company, and 5,814 shares of our common stock to an investor. The per share selling price of \$4.30 was based on the last selling price prior to this sale as reported on the Over-the-Counter Bulletin Board. Net proceeds received from these investments were \$50,000.
- During the year ended December 31, 2007, the Company sold 125,000 of the Company's Investment Units at a price of \$4.00 per unit, with total gross proceeds of \$500,000. The Investment Units were sold in tranches of 31,250 Units each to four investors on January 18, January 23, February 28 and May 1, 2007. Each Investment Unit consists of one share of the Company's common stock and a 3-year warrant (immediately exercisable) to acquire 0.5 shares of the Company's common stock for \$2.50 (\$5.00 per share). Costs of this sale totaled \$52,388.
- On February 12, 2007, the Company sold 1,707 shares of its common stock to Scott Smith, a director of the Company. The per share selling price of \$4.10 was based on the last selling price prior to this sale as reported on the Over-the-Counter Bulletin Board. The subscription price was paid by the conversion of a \$7,000 loan to the Company from Mr. Smith.
- On March 21, 2007, the Company and the four guarantors of the Company's Crown Bank promissory notes (see Note 10) agreed to amend the related debenture agreements. Pursuant to the revised debenture agreements, among other things, the Company issued a total of 12,478 shares of its Investment Units to the four guarantors in lieu of \$49,911 of accrued interest. The 6,240 warrants were valued at \$26,829 using the Black-Scholes method and were recorded as debt extinguishment expense.
- On September 10, 2007, the Company sold a total of 1,100 shares of its common stock to Mr. Carlson and Mr. Smith. The per share selling price of \$3.00 was based on the last selling price prior to this sale as reported on the Over-the-Counter Bulletin Board. The subscription price was paid by the conversion of a \$3,300 of loans to the Company from Mr. Carlson and Mr. Smith.

(e) Common Stock and Warrants issued for services and liabilities

- In March 2002, the Company granted a warrant to purchase 3,000 shares of common stock to a former director that was exercisable at \$11.33 per share. This warrant expired unexercised. An aggregate of \$12,075 of stock-based compensation expense related to this warrant was recognized in the period from August 17, 1999 (inception) to December 31, 2008.
- In November 2002, the Company granted a warrant to purchase 150 shares of common stock at an exercise price of \$23.33 per share to a consultant, for services rendered. This warrant expired unexercised. An aggregate of \$490 of stock-based compensation expense related to this warrant was recognized in the period from August 17, 1999 (inception) to December 31, 2008.
- In February 2003, the Company issued 545 common shares to a consultant, in lieu of \$12,705 cash for accounts payable.
- In June 2003, under the terms of an agreement with a supplier, the Company issued a warrant to purchase 9,215 shares of common stock at an exercise price of \$3.33 per share. This warrant expired unexercised. The value of \$187,060 related to this warrant was recognized as research and development expense in the year ended December 31, 2003.
- In May 2004, a vendor was issued 3,861 shares of the Company's common stock as payment for product development work valued at \$77,225.
- In July 2004, the Company entered into a research and development agreement with Artann for the further development of the ProUroScan™ system (see Note 5). Under this agreement, warrants for the purchase of 10,000 shares of the Company's common stock upon the execution of the agreement and warrants for the purchase of 20,000 shares of the Company's common stock in December 2004. The warrants were fully vested, five-year warrants at a per share exercise price of \$20.00 per share value. The total value of these warrants computed using the Black-Scholes pricing model was \$281,086. The value of the warrants was recorded as research and development expense in the year ended December 31, 2004.
- In October 2004, another vendor was issued 4,444 shares of the Company's common stock in lieu of \$88,882 cash for accounts payable.
- On April 11, 2005, the Company entered into a placement agency agreement with Stonegate Securities Inc. to raise working capital for the Company. Pursuant to the agreement, on May 13, 2005 the Company issued 5,000 shares of the Company's common stock to the placement agent. The 5,000 shares were valued at \$51,000 using the stock price on the date of grant and were recorded as general and administrative expense during the year ended December 31, 2005.
- On December 30, 2005, the Company issued 4,541 shares of common stock to our current and former directors in satisfaction of accrued director's fees in the amount of \$40,418.
- On April 21, 2006, the Company issued 7,000 shares of its common stock to Alan Haggerty, our former Vice-President of Engineering, upon his resignation, pursuant to his employment agreement. The shares were valued at \$44,800 based on the average closing share price during the five days before and after the issuance date, and were recorded as compensation expense during the year ended December 31, 2006.
- On September 8, 2006, the Company issued 1,415 shares of its common stock to a vendor, as payment for product development work valued at \$8,938.

- On April 2, 2007, the Company issued 4,141 shares of its common stock to a vendor, as payment for product development work valued at \$20,704.
- On April 16, 2007, the Company issued to Artann five-year warrants (immediately exercisable) to acquire 20,000 shares of its common stock at \$4.10 per share pursuant to an agreement with Artann (see Note 5). The warrants were valued at \$72,000 by the Black-Scholes pricing model and recorded as research and development expense during the year ended December 31, 2007.
- On September 10, 2007, the Company issued a total of 20,694 shares of its common stock to its directors Mr. Smith, Mr. Rudelius, Mr. Koenig and former directors as payment for \$62,082 of accrued directors' fees.
- On January 4, 2008, pursuant to a final separation agreement with a former employee of the Company, the Company issued to the former employee five-year warrants (immediately exercisable) to acquire up to 14,500 shares of the Company's common stock at an exercise price of \$5.00 per share, and amended a previously issued warrant to acquire up to 30,000 shares of the Company's common stock to provide for cashless exercise thereof. The warrants, valued at \$14,500 using the Black-Scholes pricing model, were recorded as compensation expense during the year ended December 31, 2008.
- On July 11, 2008, the Company's directors received 21,667 of shares of the Company's common stock in lieu of cash for \$21,667 of unpaid director's fees accrued through June 30, 2008. The shares were valued at \$1.00 per share and expensed during the period of service.
- On July 11, 2008, the Company issued a total of 37,967 shares of the Company's common stock to its directors in recognition of extraordinary amount of time and effort they have spent on the Company's restructuring and refocusing efforts since January 2007. The shares were valued at \$1.00 per share and expensed on the date of issuance.

(f) Common Stock and Warrants issued pursuant to loans and loan guarantees

Each warrant listed below was valued using the Black-Scholes pricing model; however, the recorded value of warrants issued to lenders and guarantors of Company debt is limited to the corresponding amount loaned or guaranteed (see Note 1(k)).

- During the year ended December 31, 2003, the Company issued warrants to purchase a total of 64,287 shares of common stock at \$23.33 per share to nine individuals, including 4,286 shares to David Koenig, a Company director, in exchange for their guaranteeing a bank line of credit. An aggregate of \$216,112 of debt issuance cost related to these warrants was recorded and amortized over the life of the bank line of credit. Upon the closing of the Company's 2004 private placement and Merger on April 5, 2004, certain exercise price protections and anti-dilution provisions of these warrants became effective. Under the terms of these provisions, the holders of these warrants became eligible to purchase a total of 101,788 shares at \$16.67 per share. The additional warrants and revaluation of the existing warrants were valued at \$320,974 using the Black Scholes pricing model, and were recorded as interest expense at the time of issuance. The warrants expired unexercised.
- In September 2005, the Company engaged Venture Law Resources, PLLC ("VLR") to assist with the introduction of strategic investors to the Company. Under this agreement, on September 1, 2005 and February 22, 2006, the Company issued a total of 5,000 shares of common stock valued at \$40,500 on the grant dates to VLR. Upon the closing of the Company's Crown Bank notes on February 16, 2006, the \$43,000 aggregate value of the shares and initial retainer were recorded as debt issuance cost and are being amortized over the term of the notes (see Note 10).

- On September 14, 2005, in connection with a commercial guaranty of a \$100,000 bank loan, the Company issued two five-year warrants (immediately exercisable) to James Murphy to acquire a total of 5,000 shares of the Company's common stock at \$5.00 per share. The warrants, valued at \$29,000 using the Black-Scholes pricing model, were recorded as debt issuance costs and expensed over the term of the loan as interest expense. The Company recorded \$29,000 of expense related to the value of the warrants during the period from August 17, 1999 (inception) to December 31, 2008.
- On September 21, 2005, in connection with \$100,000 loan from Roman Pauly, the Company issued two five-year warrants (immediately exercisable) to the lender to acquire a total of 5,000 shares of the Company's common stock at \$5.00 per share. The gross proceeds of \$100,000 were allocated between the promissory note and the common stock warrants based on the relative fair values of the securities at the time of issuance. The warrants, valued at \$26,500 using the Black-Scholes pricing model, were recorded as original issue discount as defined in EITF 98-5 and expensed on a straight-line basis over the term of the promissory note as interest expense. The Company recorded \$0, \$12,187 and \$26,500 of expense related to the value of the warrants during the years ended December 31, 2008 and 2007, and the period from August 17, 1999 (inception) to December 31, 2008, respectively.
- On October 19, 2005, in connection with commercial guaranties of a \$300,000 loan from Venture Bank, the Company issued five-year warrants (immediately exercisable) to Ron Musich and Adrian Johnson to acquire up to 7,500 shares (15,000 shares in total) of the Company's common stock at \$5.00 per share. The warrants, valued at \$79,500 using the Black-Scholes pricing model, were recorded as debt issuance costs and expensed over the term of the loan as interest expense. The Company recorded \$79,500 of expense related to the value of the warrants during the period from August 17, 1999 (inception) to December 31, 2008.
- On January 25, 2006, in connection with a \$23,000 loan, the Company issued a five-year warrant (immediately exercisable) to Adron to acquire 5,000 shares of Company common stock at \$5.00 per share. The gross proceeds of \$23,000 were allocated between the promissory note and the common stock warrant based on the relative fair values of the securities at the time of issuance. The fair value of the warrant estimated at grant date using the Black-Scholes pricing model exceeded the amount of the loan. Accordingly, the warrant was valued at \$23,000 and recorded as original issue discount as defined in EITF 98-5. The Company recorded \$23,000 of expense related to the value of the warrants during the period from August 17, 1999 (inception) to December 31, 2008.
- On June 1, 2006, the Company borrowed \$75,000 from Roman Pauly, and in connection therewith issued to Mr. Pauly a promissory note to mature on August 30, 2006 (see Note 9). Under the terms of the loan agreement, the Company issued a five-year warrant (immediately exercisable) to Mr. Pauly to acquire 3,750 shares of Company common stock at \$5.00 per share. The fair value of the warrant at the grant date was estimated using the Black-Scholes pricing model to be \$25,500 and was recorded as original issue discount as defined in EITF 98-5 and subsequently expensed as interest expense over the 90-day term of the loan.

On August 24, 2006 the promissory note was amended to mature on October 29, 2006 and the Company agreed to issue a five-year warrant to Mr. Pauly to acquire 41.7 shares of the Company's common stock at \$5.00 per share for each day the promissory note was outstanding after August 30, 2006 upon repayment of the promissory note. These warrants were valued at \$5.40 per share using the Black-Scholes pricing model. In connection with amendments to the promissory note, the Company issued to Mr. Pauly 31,817 warrants accrued between August 30, 2006 and October 1,

2008 along with a warrant to acquire 3,000 shares of its common stock and agreed to continue to accrue 41.7 warrants per day to be issued upon the Company's repayment of the promissory note. The warrants issued and accruing on and after October 1, 2008 are five-year warrants with an exercise price of \$1.50 per share, and were valued at \$1.32 per share using the Black-Scholes pricing model.

The guidance provided by EITF Issue 96-19 indicates that a substantial modification of debt terms should be accounted for as an extinguishment of debt. The present value of the cash flows under both amendments was greater than 10 percent different from the present value of the cash flows under the original agreement. Accordingly, the warrants issued and the accrual of warrants to be issued pursuant to the amended note were recorded as debt extinguishment expense. The total debt extinguishment expense recorded for the 15,262, 5171 and 35,653 warrants accrued for issuance during the years ended December 31, 2008 and 2007, and the period from August 17, 1999 (inception) to December 31, 2008 was \$70,723, \$82,191 and \$180,836, respectively.

- On July 21, 2006, in connection with a \$7,500 loan from Michael Wright, the Company issued a five-year warrant (immediately exercisable) to Mr. Wright to acquire 375 shares of Company common stock at \$5.00 per share. The gross proceeds of \$7,500 were allocated between the promissory note and the common stock warrant based on the relative fair values of the securities at the time of issuance. The warrant, valued at \$2,025 using the Black-Scholes pricing model, was recorded as original issue discount as defined in EITF 98-5 and was expensed as interest expense during the year ended December 31, 2006.
- On August 30, 2006, in connection with a \$10,000 loan from Leslie Pearson, the Company issued a five-year warrant (immediately exercisable) to Ms. Pearson to acquire 500 shares of Company common stock at \$5.00 per share. The gross proceeds of \$10,000 were allocated between the promissory note and the common stock warrant based on the relative fair values of the securities at the time of issuance. The warrant, valued at \$2,300 using the Black-Scholes pricing model, was recorded as original issue discount as defined in EITF 98-5 and was expensed as interest expense during the year ended December 31, 2006.
- On November 30, 2006, the Company borrowed \$100,000 from Adron, and in connection therewith issued to Adron a promissory note to mature on January 2, 2007 (see Note 9). Pursuant to the terms of the promissory note, the Company issued five-year warrants (immediately exercisable) to Adron's partners to acquire 5,000 shares of Company common stock at \$5.00 per share. In addition, pursuant to the terms of the promissory note, the Company issued an additional five-year warrant (immediately exercisable) to Adron's partners to acquire 5,000 shares of Company common stock at \$5.00 per share, when the loan was not repaid on January 2, 2007. The first warrant, valued at \$22,500 using the Black-Scholes pricing model, was recorded as original issue discount as defined in EITF 98-5 and was expensed as interest expense over the term of the promissory note. The second warrant, also valued at \$22,500, was expensed immediately as interest expense in January 2007. The Company recorded interest expense of \$23,162 and \$45,000 related to the warrants issued pursuant to the original agreement during the year ended December 31, 2007, and the period from August 17, 1999 (inception) to December 31, 2008, respectively.

On each of March 20, 2007 and August 8, 2007, the Company amended the Adron Note, resulting in an extension of its due dates, the issuance of a third warrant to acquire 5,000 shares of Company common stock at \$5.00 per share on February 1, 2007 and an agreement to issue to Adron five-year warrants to acquire 167 shares at \$5.00 per share for each day the principal remained unpaid on and after March 1, 2007. The guidance provided by EITF 96-19 indicates that a substantial modification of debt terms should be accounted for as an extinguishment of debt. The present

value of the cash flows under the modifications was greater than 10 percent different from the present value of the cash flows under the existing agreement. Accordingly, the accrual of warrants to be issued and the warrants issued on February 1, 2007 pursuant to the Adron Note were recorded as debt extinguishment expense. The Company expensed as debt extinguishment cost \$4,848, \$201,637 and \$206,485 related to the accrual of 1,347, 51,010 and 52,357 warrants to be issued of warrants pursuant to the amended terms of the promissory note during the years ended December 31, 2008 and 2007, and the period from August 17, 1999 (inception) to December 31, 2008, respectively. On January 16, 2008, the Company repaid the outstanding principal amount of the Adron Note and issued the 52,357 accrued warrants.

- On March 14, 2007, upon the termination of employment of an employee, and in consideration for an agreement to defer payment of accrued salaries until the Company is able to make such payments, the Company agreed to extend by three years the expiration date of 30,000 warrants beneficially held by the employee. The modification of the warrant resulted in the recording of an immediate incremental compensation expense totaling \$96,000, computed as the increase in the fair value of the warrant as determined under the provisions of SFAS 123R over the fair value so determined immediately before the modification.
- On July 31, 2007, the Company borrowed \$100,000 for short-term working capital needs pursuant to a promissory note issued to the Smith Trust (see Note 9). During the years ended December 31, 2008 and 2007, and the period from August 17, 1999 (inception) to December 31, 2008, the Company accrued for the issuance of warrants to acquire 12,576, 15,400 and 27,976 shares of the Company's common stock, respectively, and recorded interest expense of \$50,304, \$61,600 and \$111,904, respectively, related thereto. On January 20, 2009, the Company repaid the promissory note and issued 28,656 warrants related to this note (see Note 14).
- On August 29, October 31, and November 30, 2007, the Company borrowed for working capital needs \$50,000, \$100,000 and \$25,000, respectively, from James Davis (see Note 9). Upon the December 27, 2007 conversion of these notes into the convertible debentures of the Company (see Note 11(b)), pursuant to the terms of the promissory note the Company issued to Mr. Davis 12,550 warrants that were valued at \$28,340 using the Black-Scholes pricing model, which were expensed as interest expense during the year ended December 31, 2007.
- On October 15, 2007, the Company borrowed \$600,000 pursuant to a promissory note issued to the Smith Trust (see Note 9). In consideration for this loan, on November 7, 2007 the Company agreed to issue 33,333 shares of its common stock to the Smith Trust. The \$66,666 value of this consideration was recorded as debt issuance cost and is being amortized over the term of the loan using the straight-line method, which approximates the interest method. The Company recorded \$48,473, \$10,358 and \$58,831 of interest expense related to the amortization of this debt issuance cost during the years ended December 31, 2008 and 2007, and the period from August 17, 1999 (inception) to December 31, 2008, respectively. On October 31, 2008, pursuant to the terms of the loan when the loan remained unpaid on that date, the Company issued to the Smith Trust 6,667 shares of its common stock and a five-year immediately exercisable warrant to acquire 16,667 shares of its common stock at an exercise price of \$2.00. The \$6,667 value of the shares issued and the \$12,834 value of the warrants was recorded as interest expense during the year ended December 31, 2008.
- On December 27, 2007, the Company closed on the sale of \$1,050,000 of units under its 2007 Private Placement (see Note 11(b)). At the closing, the Company issued 2007 Warrants to purchase 210,000 shares of common stock. On the same day, the Company also converted \$150,000 of existing loans from James Davis into similar units, and issued warrants to purchase 30,000 shares of the Company's common stock. On January 4, 2008, the Company closed on the sale of \$80,000

of additional units as part of the 2007 Private Placement with the same terms as noted above. At closing, the Company issued 2007 Warrants to purchase 16,000 shares of common stock.

On February 13, February 28, May 2, July 15 and July 30, 2008, the Company closed on an aggregate \$720,000 of units under its 2008 Private Placements (see Note 11(b)). Pursuant to these closings, the Company issued 2008 Warrants to purchase 144,000 shares of common stock.

The \$153,735 relative fair value of the aggregate 400,000 2007 Warrants, Davis Warrants and 2008 Warrants issued were recorded as an original issue discount as defined in EITF 98-5 against the convertible debt liability, and are being amortized as interest expense over the term of the convertible debentures.

The exercise price of the 2007 Warrants, the Davis Warrants, and the 2008 Warrants was set upon the January 7, 2009 effective date of the Company's 2009 Public Offering at \$0.50 per share (based on 50 percent of the offering price) (see Note 14). All of these warrants became exercisable upon the January 12, 2009 closing of the 2009 Public Offering and will remain exercisable until December 31, 2012. Mr. Davis agreed that the equity securities issued upon exercise of the Davis Warrant will not be transferable until January 7, 2010. The unamortized original issue discount relating to the warrants was expensed as interest expense upon the January 12, 2009 closing of the 2009 Public Offering.

- On December 28, 2007, the terms and conditions of the renewed Crown Bank notes became effective (see Note 10). Pursuant to the terms of the guarantees the Company issued to the three guarantors of the Crown Bank notes an aggregate of 88,889 shares of the Company's common stock. The \$88,889 value of the shares was recorded as interest expense during the year ended December 31, 2007. On October 31, 2008, pursuant to the terms of the loan when the loan remained unpaid on that date, the Company issued to the three guarantors an aggregate amount of 17,778 shares of our common stock and five-year immediately exercisable warrants to acquire an aggregate of 44,445 shares of our common stock at an exercise price of \$2.00 per share. The \$17,778 value of the shares issued and the \$34,223 value of the warrants was recorded as interest expense during the year ended December 31, 2008.
- On April 3, 2008, as consideration to James Davis, William Reiling and the Smith Trust for providing certain loans to the Company, the Company issued five-year warrants (immediately exercisable) to purchase a total of 75,000 shares of the Company's common stock at \$1.50 per share (see Note 11(d)). The gross proceeds were allocated between the note and the warrants based on the relative fair value at the time of issuance. The relative fair value of warrants was recorded as original issue discount on the related promissory notes and was expensed as interest expense over the term of the promissory notes. During the year ended December 31, 2008, original issue discounts of \$42,768 were expensed as interest expense.
- On September 16, 2008, pursuant to the Company's Unit Put Agreement (see Note 11(c)), the Company issued Origination Warrants to purchase an aggregate 32,500 shares of our common stock. Of these, 31,500 Origination Warrants became exercisable when the Company exercised its put options and closed on \$315,000 of the Unit Put Arrangement, while 1,000 Origination Warrants were forfeited when an investor failed to meet a \$10,000 unit put obligation. The Origination Warrants are exercisable until December 31, 2012 at an exercise price of \$1.00 per share. The Origination Warrants, valued at \$42,575 using the Black-Scholes pricing model, were recorded as a debt issuance cost asset and are being amortized as interest expense over the term of the Unit Put Agreement. During the year ended December 31, 2008, debt issuance cost of \$10,891 was recorded as interest expense.

Each unit issued in the Unit Put Agreement included a Unit Put warrant (see Note 11(c)). The purchase price of the warrant portion of each unit was \$500. The Unit Put Warrants will remain exercisable until December 31, 2012 at an exercise price of \$1.00 per share. On September 16, 2008, the Company exercised \$162,500 of its put options under the Unit Purchase Agreement, and upon the September 24, 2008 closing thereof, issued 32,500 Unit Put Warrants. On October 17, 2008, the Company exercised the remaining \$162,500 of its put option under the Unit Put Agreement and on October 28, 2008 and December 11, 2008, closed on \$127,500 and \$25,000 of this exercise, respectively. Pursuant to these closings, the Company issued 30,500 Unit Put Warrants. The \$17,493 relative fair value of the Unit Put Warrants was recorded as an original issue discount as defined in EITF 98-5 against the convertible debt liability, and is being amortized as interest expense over the term of the convertible debentures.

Under the terms of the Unit Put Arrangement, the promissory notes issued along with interest accrued thereon automatically converted into shares of the Company's common stock on February 6, 2009 (see Note 14). The unamortized original issue discount and unamortized debt issuance cost was expensed as interest cost upon this conversion.

- On September 25, 2008, the Company borrowed \$150,000 pursuant to a convertible promissory note issued in favor of James Davis (see Note 11(d)). As consideration for providing the loan, the Company issued an immediately exercisable, five-year warrant to purchase 100,000 shares of the Company's common stock at \$1.50 per share to Mr. Davis. The \$46,604 relative fair value of the warrant was recorded as original issue discount and is being expensed as interest expense over the term of the promissory note. During the year ended December 31, 2008, original issue discount of \$8,280 was expensed as interest expense. Any unamortized original issue discount relating to the warrants will be expensed immediately in the event that the promissory note is converted into common stock.
- On March 19, 2009, pursuant to the renewal of its \$600,000 Smith Trust promissory note and guaranties received relating to the Company's renewal of its \$1,200,000 Crown Bank promissory note, the Company issued an aggregate 200,001 shares of its common stock as consideration to the Smith Trust, James Davis, and William Reiling, and will issue a further 33,333 shares per month for each month the notes remain outstanding after August 31, 2009 (see Note 14).

(g) Warrants summary

Warrant activity was as follows for the years ended December 31:

	Warrants		Weighted-Average Exercise Price	
	2008	2007	2008	2007
Outstanding, January 1	639,504	215,949	\$ 10.18	\$ 14.61
Granted	538,297	432,920	1.66	4.91
Exercised	-	-	-	-
Expired	(103,787)	(9,365)	16.37	3.62
Outstanding, December 31	1,074,014	639,504	\$ 4.45	\$ 10.18

The fair value of stock warrants is the estimated present value at grant date using the Black-Scholes pricing model (see Note 1(k)). The weighted-average fair value of the warrants granted during the years ended December 31, 2008 and 2007 was \$1.37 and \$3.80, respectively. The expense related to warrants issued to lenders and debt guarantors was \$262,305, \$423,096 and \$1,097,185 for the years ended December 31, 2008 and 2007, and the period from August 17, 1999 (inception) to December 31, 2008, respectively (excluding warrants issued in connection with the 2007 and 2008 Private Placement

and Unit Put Agreements). Stock-based compensation cost related to warrants issued to the Company's consultants and suppliers was \$14,500, \$168,000 and \$651,136 for the years ended December 31, 2008 and 2007, and the period from August 17, 1999 (inception) to December 31, 2008, respectively. Stock-based compensation cost related to warrants issued to directors (in lieu of stock options) was \$0, \$0 and \$12,075 for the years ended December 31, 2008 and 2007, and the period from August 17, 1999 (inception) to December 31, 2008, respectively.

(h) Stock Options

Stock Option Plans

In April 2002, the Company's Board of Directors passed a resolution adopting the ProUroCare Medical Inc. 2002 Stock Plan (the "2002 Plan"), reserving 150,000 shares of the Company's common stock for issuance.

In July 2004, the Company's Board of Directors passed a resolution adopting the ProUroCare Medical Inc. 2004 Stock Option Plan (the "2004 Plan"), which was approved by the Company's shareholders in July 2005. The Company has reserved 150,000 shares of common stock for issuance under the 2004 Plan.

The plans permit the Company to grant incentive and nonqualified options, stock appreciation rights, stock awards, restricted stock awards, performance shares and cash awards to Company employees and independent contractors. The exercise price for all options granted under the plans shall be determined by the Board of Directors. The term of each stock option and period of exercisability will also be set by the Board of Directors, but will not exceed a period of ten years and one day from grant date. The agreements also include provisions for anti-dilution of options.

Stock Option Grants

Each of the options granted below were valued using the Black-Scholes pricing model (see Note 1(j)) and are being expensed over the vesting period as general and administrative expense.

- In March 2002, the Company granted an aggregate of 90,000 employee stock options to officers and directors that were exercisable at \$11.33 per share. The officers' options vested ratably over a 36-month period through December 2004, while the directors' options vested ratably over a 24-month period through April 2004. An aggregate \$342,782 of stock-based compensation expense related to these options was recognized in the period from August 17, 1999 (inception) to December 31, 2008.

In October 2003, an officer resigned from the Company and 15,000 of his unvested options were forfeited and in October 2004 his remaining 21,000 options expired. In February 2004, a director resigned from the Board of Directors, and 375 of his unvested options were forfeited, and in October 2005 his remaining 2,625 options expired. Effective May 1, 2007, Maurice Taylor, the Company's former Chairman and Chief Executive Officer, retired from the Company. Pursuant to a May 11, 2007 agreement to defer payment of his unpaid salary, the Company extended the date through which Mr. Taylor may exercise 45,000 options (including options gifted to his children) following his separation to April 1, 2012. The Company recorded stock-based compensation expense of \$103,500 related to the extension of the exercise date in the year ended December 31, 2007.

- In April 2002, the Company issued a nonqualified stock option to a consultant to acquire 3,000 shares of common stock at \$11.33 per share. This option expired unexercised. At the same time, the Company also issued a nonqualified stock option to another consultant to acquire 3,000 shares

of common stock at \$11.33 per share. This option vested ratably over a two-year period through April 2004. An aggregate of \$27,600 of stock-based compensation expense related to these options was recognized in the period from August 17, 1999 (inception) to December 31, 2008.

- In February 2004, the Company issued 45,000 employee stock options to Michael Grossman, our former President and Chief operating Officer. These options were valued at \$6.70 per share, vested ratably over a three-year period and are exercisable at \$20.00 per share. The Company expensed, \$16,811 and \$303,000 related to these options during the year ended December 31, 2007 and the period from August 17, 1999 (inception) to December 31, 2008, respectively. Pursuant to a May 11, 2007 separation agreement, the Company extended the date through which Mr. Grossman may exercise 45,000 options (including options gifted to his children) following his separation until February 1, 2012. The Company recorded stock-based compensation expense of \$117,000 related to the extension of the exercise date in the year ended December 31, 2007.
- In February 2004, the Company issued 3,000 nonqualified stock options to a consultant in consideration of services rendered. The options were valued at \$6.70 per share, and vested as to 1,500 shares upon issuance and as to the remaining 1,500 shares on January 1, 2005. These options are exercisable at \$20.00 per share through February 2014. The Company expensed \$20,200 related to these options during the period from August 17, 1999 (inception) to December 31, 2008.
- In July 2004, the Company issued 20,000 employee stock options to Mr. Thon in connection with his employment agreement. These options were valued at \$15.00 per share, vested ratably over a three-year period, and are exercisable at \$25.00 per share through July 2014. The Company expensed \$58,314 and \$300,000 related to these options during the year ended December 31, 2007 and the period from August 17, 1999 (inception) to December 31, 2008, respectively. On July 11, 2008, in connection with the issuance of new options to Mr. Thon (see below), these options were cancelled.
- In January 2005, the Company issued 15,000 stock options to Mr. Carlson, who at the time was the Company's Vice President of Marketing and Sales. The options were valued at \$16.20 per share, vest ratably over a three-year period, and are exercisable at \$23.50 per share through January 2015. The Company expensed \$6,729, \$81,006, and \$243,000 related to these options during the years ended December 31, 2008 and 2007 and the period from August 17, 1999 (inception) to December 31, 2008, respectively. On July 11, 2008, in connection with the issuance of new options to Mr. Carlson (see below), these options were cancelled.
- In September 2005, the Company issued 15,000 stock options exercisable at \$6.00 per share to Mr. Haggerty. The options were valued at \$5.30 per share and expired unexercised. The Company expensed \$15,460 related to these options during the period from August 17, 1999 (inception) to December 31, 2008.
- On March 1, 2006, the Company issued to five of its employees five-year stock options to acquire a total of up to 20,000 shares of common stock at \$7.50 per share. The options, valued at \$5.60 per share, vest upon the Company securing FDA approval of its ProUroScan™ system. 10,000 of these options were awarded to employees who subsequently left the Company and have been forfeited. The remaining options are being expensed over the vesting period (estimated by the Company as forty-one months) as general and administrative expense. The Company expensed \$9,663, \$33,245 and \$91,184 related to these options during the years ended December 31, 2008 and 2007, and the period from August 17, 1999 (inception) to December 31, 2008, respectively.

- On May 30, 2006, the Company issued 3,000 nonqualified stock options to Mr. Smith, a director, upon his appointment to the Board of Directors. The options were valued at \$5.90 per share, and vested over a two year period. These options are exercisable at \$7.00 per share through May 2013. The Company expensed \$3,688, \$8,850 and \$17,700 related to these options during the years ended December 31, 2008 and 2007, and the period from August 17, 1999 (inception) to December 31, 2008, respectively.
- On February 1, 2007, the Company granted to Mr. Carlson, a seven-year option to acquire up to 20,000 shares of the Company's common stock at a price of \$5.00 per share. The options were valued at \$3.40 per share using the Black-Scholes pricing model and will be expensed over the vesting period as general and administrative expense. The options vested as follows:
 - (a) 5,000 shares vested immediately.
 - (b) 5,000 shares vest upon the Company's closing on new equity financing arrangements aggregating to \$3,000,000 or more after February 1, 2007 and prior to December 31, 2007. This objective was not met, and these options did not vest and were forfeited.
 - (c) 5,000 shares vest if the Company records gross product revenues of \$1,000,000 or more in the Company's 2008 fiscal year. This objective was not met, and these options did not vest and were forfeited.
 - (d) 5,000 shares vested on December 31, 2008.

The Company expensed \$1,143, \$32,857 and \$34,000 related to these options during the year ended December 31, 2008 and 2007, and the period from August 17, 1999 (inception) to December 31, 2008, respectively.

- On June 14, 2007, the Company issued 3,000 nonqualified stock options to Mr. Rudelius, upon his appointment to the Board of Directors. The options were valued at \$2.40 per share, and vest ratably over a 24-month period through June 14, 2009. These options are exercisable at \$2.90 per share through May 2014. The Company expensed \$3,600, \$1,800 and \$5,400 related to these options during the year ended December 31, 2008 and 2007, and the period from August 17, 1999 (inception) to December 31, 2008, respectively.
- On July 11, 2008, the Company issued incentive stock options to acquire 70,000 shares of its common stock to Mr. Carlson. The options are exercisable for a period of seven years at an exercise price of \$1.00 per share. Of the options, 10,000 shares vest immediately and 20,000 shares will vest on July 1 of each of 2009, 2010 and 2011. At the same time, Mr. Carlson agreed to cancel existing, fully-vested stock options to acquire 15,000 shares of common stock at an exercise price of \$23.50 per share. SFAS 123R requires that options that are cancelled and reissued simultaneously be accounted for as a modification of the terms of the original option. Accordingly, the incremental compensation cost of the fully vested portion of the newly issued options, valued at \$0.79 per share using the Black-Scholes pricing model, over the \$0.31 per share value of the cancelled options on the cancellation date will be expensed immediately as general and administrative expense. The value of the unvested portion will be recorded as general and administrative expense over the three-year vesting period. The Company expensed \$11,750 related to these options during the year ended December 31, 2008.
- On July 11, 2008, the Company issued incentive stock options to acquire 35,000 shares of its common stock to Mr. Thon. The options are exercisable for a period of seven years at an exercise price of \$1.00 per share. Of the options, 10,000 shares vest immediately and 8,333 shares will vest on July 1 of each of 2009, 2010 and 2011. At the same time, Mr. Thon agreed to cancel existing, fully-vested stock options to acquire 20,000 shares of common stock at an exercise price of \$25.00

per share. SFAS 123R requires that options that are cancelled and reissued simultaneously be accounted for as a modification of the terms of the original option. Accordingly, the incremental compensation cost of the fully vested portion of the newly issued options, valued at \$0.79 per share using the Black-Scholes pricing model, over the \$0.27 per share value of the cancelled options on the cancellation date will be expensed immediately as general and administrative expense. The value of the unvested portion will be recorded as general and administrative expense over the three-year vesting period. The Company expensed \$6,042 related to these option during the year ended December 31, 2008.

- On August 11, 2008, the Company issued 1,000 non-qualified stock options (immediately exercisable) to each of its three outside directors, Mr. Koenig, Mr. Smith and Mr. Rudelius, pursuant to its standard annual option award program, upon their re-election to the Company's Board of Directors. The options are exercisable for a period of seven years at an exercise price of \$0.90 per share, and were valued at \$0.71 per share. The Company expensed \$2,130 related to these option during the year ended December 31, 2008.
- On March 3, 2009, the Company granted at total of 215,000 options to its officers and directors (see Note 14).

(i) **Stock options summary**

Stock option activity was as follows for the years ended December 31:

	Options		Weighted-Average Exercise Price	
	2008	2007	2008	2007
Outstanding, January 1	175,500	160,417	\$ 15.16	\$ 16.17
Granted	108,000	23,000	1.00	4.73
Exercised	—	—	—	—
Forfeited	(50,500)	(7,917)	19.16	5.37
Expired	—	—	—	—
Outstanding, December 31	233,000	175,500	\$ 7.73	\$ 15.16
Exercisable, December 31	132,250	152,210	\$ 12.20	\$ 16.54

The following table summarizes information about stock options outstanding as of December 31, 2008:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Number of Options	Weighted Average Exercise Price
\$0.90-\$7.50	134,000	\$1.96	6.28	33,250	\$2.26
\$11.33	51,000	\$11.33	3.26	51,000	\$11.33
\$20.00	48,000	\$20.00	3.21	48,000	\$20.00
	233,000	\$7.73	4.99	132,250	\$12.20

The aggregate intrinsic value of the options outstanding and exercisable at December 31, 2008 was \$5,700 and \$1,450, respectively. The average fair value of each option granted during the years ended December 31, 2008 and 2007, and the period from August 17, 1999 (inception) to December 31, 2008, as determined using the Black-Scholes pricing model (see Note 1(j)) was \$0.84, \$3.27 and \$4.83, respectively. The stock-

based employee and non-employee compensation cost related to stock options was \$44,745, \$453,384 and \$1,641,772 for the years ended December 31, 2008 and 2007, and the period from August 17, 1999 (inception) to December 31, 2008, respectively.

(13) Related Parties

The Company considers its directors, executives and beneficial shareholders of more than five percent of its common stock to be related parties. During the years ended December 31, 2008 and 2007, the following significant transactions were made between the Company and those parties that were related parties at the time of each transaction:

From March 1, 2007 to January 31, 2009, the Company rented executive offices within the offices of a former Company director, Mr. Alex Nazarenko. Our rental cost for these offices was approximately \$2,129 per month, which is the market price for similar office space in Minneapolis, Minnesota.

On April 17, 2007, the Company borrowed \$75,000 from Mr. Nazarenko. In consideration, the Company executed and delivered to Mr. Nazarenko a \$75,000 unsecured demand promissory note. The note bore interest at an annual rate of the Prime Rate plus one percent, and was repaid on May 8, 2007.

As consideration to Mr. James Davis, Mr. William Reiling, the Smith Trust and Mr. Bruce Culver to provide their guarantees for the Crown Bank promissory notes (see Note 10), in 2006 the Company issued \$733,334 of unsecured convertible 10 percent debentures. On March 21, 2007, the Company and the four guarantors agreed to amend the debenture agreements. Pursuant to the revised debenture agreements, among other things, the Company issued a total of 12,478 shares of its Investment Units to the four guarantors in lieu of \$49,911 of accrued interest. On December 27, 2007, the holders of the 10 percent unsecured convertible subordinated debentures agreed to further amend the terms of their debentures to provide for automatic conversion of the principal amount of the debentures and the unpaid interest accrued thereon into shares of the Company's common stock at \$3.00 per share (see Note 11(a)).

On June 12, 2007, the Company borrowed \$10,000 from Mr. Nazarenko. The loan bore no interest. On June 25, 2007, the Company borrowed an additional \$27,000 from Mr. Nazarenko. In consideration of these two loans, the Company executed and delivered to Mr. Nazarenko a \$37,000 unsecured demand promissory note. The note bore interest at an annual rate of the Prime Rate plus one percent. The principal amounts of these loans were repaid to Mr. Nazarenko on December 28, 2007.

On July 3, 2007, the Company borrowed \$10,000 from Mr. Nazarenko (see Note 9) and was repaid in 2007.

On July 31, 2007, the Company borrowed \$100,000 from the Smith Trust (see Note 9).

On August 29, October 31, and November 30, 2007, the Company borrowed for working capital needs \$50,000, \$100,000 and \$25,000, respectively, from James Davis pursuant to promissory notes (see Note 9).

Effective October 15, 2007, the Company borrowed \$600,000 from the Smith Trust pursuant to a long-term promissory note (see Note 9). The proceeds were used to retire bank notes payable.

On September 28, 2007, the Company borrowed for working capital purposes \$15,000 from Mr. Smith and \$10,000 from Mr. Rudelius, both directors of the Company (see Note 9). Upon the first closing of the 2007 Private Placement, these loans were converted into investment units under that offering (see Note 11(b)).

On December 27, 2007, the Company closed on its 2007 Private Placement (see Note 11(b)). Mr. Davis acquired \$225,000 of the units sold in the 2007 Private Placement, including the conversion into units of \$25,000 of loans made to the Company. In addition, the Company converted \$150,000 of existing loans from

Mr. Davis into a note (the “Davis Note”) and warrants similar to those sold in the 2007 Private Placement, except that his note was convertible into the type of equity securities offered by the Company in an underwritten public offering at 50 percent of the public offering price. In addition, Mr. Davis agreed that the equity securities issued upon conversion of the Davis Note and the common stock issued upon exercise of his warrant will not be transferable for a period of one year beginning on the effective date of the public offering triggering conversion of the note. On the same date, Mr. Reiling acquired \$50,000 of the units sold in the 2007 Private Placement.

On February 28, 2008, Mr. Rudelius acquired \$10,000 of the units sold in the 2008 Private Placement.

On April 3, 2008, in connection with the Company’s purchase of the Profile Assets, the Company borrowed an aggregate of \$112,500 pursuant to three promissory notes each in the amount of \$37,500 (see Note 11(d)). The promissory notes were issued in favor of Mr. Davis, Mr. Reiling and the Smith Trust. On September 12, 2008, these three promissory notes were amended to extend their due dates to the earlier of seven days following the close of an underwritten public offering or December 31, 2008, and to give the holders an option to convert their notes into shares of our common stock at a conversion price equal to 70% of the price of the Units sold in such offering.

On September 16, 2008, Mr. Davis agreed to purchase \$100,000 of the puts pursuant to the Unit Put Agreement (see Note 11(d)). On September 24, 2008, we closed on \$50,000 of Mr. Davis’ put commitment, and issued a \$47,500 convertible note and a warrant to acquire 10,000 shares of our common stock at an exercise price of \$1.00 per share. On October 28, 2008, we closed on the remaining \$50,000 of Mr. Davis’ put commitment, and issued a \$47,500 convertible note and a warrant to acquire 10,000 shares of our common stock at an exercise price of \$1.00 per share.

On September 25, 2008, we borrowed \$150,000 pursuant to a promissory note issued in favor of Mr. Davis and used the proceeds to retire the \$150,000 principal amount of the Profile Note (see Note 11(d)). As consideration for providing the loan, we issued an immediately exercisable, five-year warrant to purchase 100,000 shares of our common stock at \$1.50 per share to Mr. Davis.

On March 19, 2009, pursuant to the renewal of its \$600,000 Smith Trust promissory note and guaranties received relating to the Company’s renewal of its \$1,200,000 Crown Bank promissory note, the Company issued an aggregate 200,001 shares of its common stock as consideration to the Smith Trust, James Davis, and William Reiling, and will issue a further 33,333 shares per month for each month the notes remain outstanding after August 31, 2009 (see Note 14).

On March 19, 2009, a \$37,500 convertible promissory note and a \$150,000 convertible promissory note due to Mr. Davis were refinanced and combined with other loans and advances on behalf of the Company from Mr. Davis in a \$281,000 convertible promissory note (see Note 14).

(14) Subsequent Events

On January 7, 2009, the Company’s 2009 Public Offering was declared effective by the United States Securities and Exchange Commission, and January 12, 2009 the 2009 Public Offering was closed. In the offering, the Company sold 3,050,000 units at \$1.00 per unit, with each unit consisting of one share of common stock and one redeemable warrant to purchase one share of common stock at an exercise price of \$1.30 per share resulting in net cash of \$1,883,626, after costs of \$1,666,374.

On the January 7, 2009 effective date of the Company’s 2009 Public Offering, the \$1,757,500 aggregate amount of the 2007 Notes and the 2008 Notes, along with \$162,959 of interest accrued thereon, automatically converted into 2,743,535 units identical to those sold in the 2009 Public Offering (based on 70 percent of the

offering price, or \$0.70 per share). On the same date, the \$142,500 of Davis Note, along with \$14,923 of interest accrued thereon, automatically converted into 314,846 units identical to those sold in the 2009 Public Offering (based on 50 percent of the offering price, or \$0.50 per share).

The exercise price of the 2007 Warrants, the Davis Warrants and the 2008 Warrants was set upon the January 7, 2009 effective date of the Company's 2009 Public Offering at \$0.50 per share (based on 50 percent of the offering price). All of these warrants became exercisable upon the January 12, 2009 closing of the 2009 Public Offering and will remain exercisable until December 31, 2012. Mr. Davis agreed that the equity securities issued upon exercise of the Davis Warrant will not be transferable until January 7, 2010.

Unamortized original issue discount relating to the warrants and the beneficial conversion feature of the notes totaling \$387,169 and unamortized debt issuance cost of \$207,575 was expensed as interest expense upon the conversion.

As consideration to the guarantors to provide their guarantees for the Crown Bank promissory notes (see Note 10), the Company issued \$733,334 of unsecured convertible 10 percent debentures (see Note 11(a)). On January 12, 2009, the Company closed on its 2009 Public Offering, which triggered the automatic conversion of the \$733,334 convertible debentures along with \$143,815 interest accrued thereon into 292,384 shares of the Company's common stock.

On June 1, 2006, the Company borrowed \$75,000 from Roman Pauly pursuant to a promissory note (see Note 9). The Company had repaid a total of \$65,650 of the note through December 31, 2008. In January 2009, following the closing of the 2009 Public Offering, the Company repaid the remaining \$9,350 principal amount of the Pauly loan and issued an immediately exercisable five-year warrant to acquire 4,295 shares of the Company's common stock at \$1.50 per share pursuant to the terms of the note.

On July 31, 2007, the Company borrowed \$100,000 from the Smith Trust pursuant to a promissory note. The Company had repaid a total of \$66,000 of the note through December 31, 2008. In January 2009, following the closing of the 2009 Public Offering, the Company repaid the remaining \$34,000 principal balance and issued to the Smith Trust a five-year, immediately exercisable warrant to acquire 28,656 shares of the Company's common stock at \$5.00 per share pursuant to the terms of the note.

On February 6, 2009 (30 days after the effective dates of the Company's 2009 Public Offering), the \$299,250 outstanding Unit Put Notes (see Note 11(c)) along with the \$9,563 interest accrued thereon automatically converted into 441,165 shares of the Company's common stock on February 6, 2009. The notes and accrued interest converted at 70 percent of the 2009 Public Offering price, or \$0.70 per share. Unamortized original issue discount relating to the warrants and the beneficial conversion feature of the notes totaling \$138,440 and unamortized debt issuance cost of \$44,686 was expensed as interest expense upon the conversion.

On April 3, 2008, the Company borrowed \$112,500 pursuant to three convertible promissory notes (see Note 11(d)). In January 2009, following the closing of the 2009 Public Offering, the Company repaid \$45,500 of the notes, and \$29,500 of the notes were converted into common stock at \$0.70 per share (based on 70 percent of the 2009 Public Offering price). On March 19, 2009, the remaining \$37,500 promissory note, due to Mr. James Davis, was refinanced along with another \$150,000 promissory note due to Mr. Davis (see below).

On September 25, 2008, the Company borrowed \$150,000 pursuant to a convertible promissory note issued in favor of Mr. Davis (see Note 11(b)). The note was convertible upon the Company's closing of an underwritten public offering, at 70 percent of the public offering price. As the holder's ability to exercise the conversion feature of the note was contingent upon an event outside the control of the holder, the bargain conversion feature valued at \$103,396 was not recorded until the January 12, 2009 closing of the Company's 2009 Public Offering when the contingency was removed. On March 19, 2009, Mr. Davis agreed to refinance

the \$150,000 debt (and \$7,291 of interest accrued thereon) along with the \$37,500 note noted above (and \$3,646 of accrued interest thereon), another \$2,632 payable to Mr. Davis and \$15,293 of expenses paid by Mr. Davis on behalf of the Company. Mr. Davis also agreed to loan to the Company an additional \$64,638 to pay for the exhibition of the ProUroScan system at the annual American Urology Association meeting, the retention of an investor relations firm and the initiation of a clinical advisory board. He also agreed to have certain website maintenance services performed for the Company. Pursuant to the refinancing and the other arrangements, the Company issued a \$281,000 unsecured convertible promissory note to Mr. Davis. The promissory note matures on March 19, 2010, bears no interest, and is convertible into our common stock at \$0.55 per share at the option of Mr. Davis. The guidance provided by EITF Issue 96-19 indicates that a substantial modification of debt terms should be accounted for as an extinguishment of debt. As the present value of the cash flows under the new convertible promissory note was greater than 10 percent different from the present value of the cash flows under the original note, the issuance of the new note will be treated as a debt extinguishment. Accordingly, the \$123,000 value of the bargain conversion option as computed using the Black-Scholes pricing model will be recorded as original issue discount at the inception of the loan and amortized as debt extinguishment expense over the term of the note. Interest imputed on the new convertible note, using a 6.0 percent assumed interest rate, of \$16,000 will be recorded as a note discount and amortized as interest expense over the term of the note.

On March 3, 2009, the Company issued non-qualified stock options to acquire an aggregate of 70,000 shares of its common stock to its non-employee directors, and incentive options to acquire 45,000 shares of its common stock to Richard Thon. The options are fully vested and are exercisable for a period of seven years at an exercise price of \$0.85 per share. The 115,000 options will be valued at \$0.68 per share using the Black-Scholes pricing model and immediately expensed as general and administrative expense.

Also on March 3, 2009, the Company granted incentive stock option to acquire an aggregate of 100,000 shares of its common stock to Richard Carlson. Of the options, 90,000 shares vest immediately and 10,000 shares will vest on January 2, 2010. At the same time, Mr. Carlson agreed to cancel existing, unvested stock options to acquire 5,000 shares of common stock at an exercise price of \$7.50 per share. SFAS 123R requires that options that are cancelled and reissued simultaneously be accounted for as a modification of the terms of the original option. Accordingly, the incremental compensation cost of the fully vested portion of the newly issued options valued at \$0.68 per share using the Black-Scholes pricing model over the \$0.07 per share value of the cancelled options on the cancellation date, or \$67,850, will be expensed immediately as general and administrative expense.

On March 19, 2009, the Company renewed the \$1,200,000 Crown Bank promissory note, and temporarily paid down the \$400,000 Crown Bank promissory note (see Note 10) pending the Company obtaining a satisfactory guaranty of that amount. The renewed note matures on March 28, 2010 and bears interest at the Prime Rate plus one percent, but never less than 6.00 percent. No other note terms were changed. The note remains collateralized by all Company assets and continues to be guaranteed by James Davis and William Reiling.

On March 19, 2009, the Company amended the \$600,000 Smith Trust promissory note (see Note 9). Under the terms of the amendment, the note's maturity date was extended to March 28, 2010, and the interest rate floor was lowered from 6.50 percent to 6.00 percent. No other terms were changed.

On March 19, 2009, pursuant to the renewal of its \$600,000 Smith Trust promissory note and guaranties received relating to the Company's renewal of its \$1,200,000 Crown Bank promissory note, the Company issued an aggregate 200,001 shares of its common stock as consideration to the Smith Trust, James Davis and William Reiling, and will issue a further 33,333 shares per month for each month the related notes remain outstanding after August 31, 2009. The guidance provided by EITF Issue 96-19 indicates that a substantial modification of debt terms should be accounted for as an extinguishment of debt. As the present value of the

cash flows under both loan renewals was greater than 10 percent different from the present value of the cash flows under the original agreements, the renewals of the notes will be treated as debt extinguishments. Accordingly, the \$100,000 value of the initial 200,001 shares issued will be recorded as original issue discount and expensed as debt extinguishment expense on a straight-line basis through August 31, 2009. Additional accruals of stock to be issued if the promissory notes remain outstanding after August 31, 2009 will be expensed each month as debt extinguishment expense. In addition, the \$12,000 loan origination fee will be recorded as original issue discount and expensed as debt extinguishment expense over the term of the promissory notes.

ITEM 9: CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A(T): CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission. As of December 31, 2008, the end of the period covered by this Annual Report on Form 10-K, we carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective.

Management's Annual Report on Internal Control Over Financial Reporting

The financial statements, financial analyses and all other information included in this Annual Report on Form 10-K were prepared by the Company's management, which is responsible for establishing and maintaining adequate internal control over financial reporting.

The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. The Company's internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition and use or disposition of the Company's assets that could have a material effect on the financial statements.

There are inherent limitations in the effectiveness of any internal control, including the possibility of human error and the circumvention or overriding of controls. Accordingly, even effective internal controls can provide only reasonable assurances with respect to financial statement preparation. Further, because of changes in conditions, the effectiveness of internal controls may vary over time.

Management assessed the design and effectiveness of the Company's internal control over financial reporting as of December 31, 2008. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control—Integrated Framework*. Based on management's assessment using this framework, it believes that, as of December 31, 2008, the Company's internal control over financial reporting is effective.

This Annual Report on Form 10-K does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to

attestation by the Company's independent registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this Annual Report on Form 10-K

Changes in Internal Control Over Financial Reporting

During the quarter ended December 31, 2008, there has been no change in the Company's internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B: OTHER INFORMATION

On March 19, 2009, we renewed our \$1,200,000 Crown Bank promissory note. The renewed note matures on March 28, 2010 and bears interest at the Prime Rate plus 1.0 percent, but never less than 6.00 percent. No other note terms were changed. The note remains secured by all Company assets and continues to be guaranteed by James Davis and William Reiling. At the same time, we temporarily paid down the \$400,000 Crown Bank promissory note pending our obtaining a satisfactory guaranty of that amount. It is our intent to renew the \$400,000 promissory note within 60 days; however, there can be no assurance that such a guarantee can be provided. Assuming we are successful in identifying such guarantors, we expect to issue additional consideration to guarantors of the \$400,000 Crown Bank promissory note upon its renewal.

On March 19, 2009, we amended our \$600,000 promissory note with the Smith Trust. Under the terms of the amendment, the note's maturity date was extended to March 28, 2010, and the interest rate floor was lowered from 6.50 percent to 6.00 percent. No other terms were changed.

On March 19, 2009, pursuant to the renewal of the \$600,000 Smith Trust promissory note and guaranties received relating to renewal of our \$1,200,000 Crown Bank promissory note, we issued an aggregate 200,001 shares of our common stock as consideration to the Smith Trust, James Davis and William Reiling, and will issue a further 33,333 shares per month for each month the related notes remain outstanding after August 31, 2009.

PART III

ITEM 10: DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

The following information sets forth the names of our executive officers and directors, their ages and their present positions with the Company as of March 23, 2009. The directors serve for a term of one year or until the next annual meeting of the shareholders. Each officer serves at the discretion of the Board of Directors.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Richard C. Carlson.....	57	Chief Executive Officer and Acting Chairman
Richard B. Thon.....	53	Chief Financial Officer
David F. Koenig.....	68	Director
Robert J. Rudelius.....	53	Director
Scott E. Smith	53	Director

Richard C. Carlson was elected to our Board of Directors in December 2006 and became Acting Chairman in May 2007. Mr. Carlson was hired as our Vice President of Marketing and Sales in January 2005, and was promoted to Chief Executive Officer in November 2006. Immediately prior to joining ProUroCare, Mr. Carlson was a marketing consultant for several medical device companies. From 1998 to April 2004, Mr. Carlson held several positions with SurModics, Inc. (“SurModics”), a company that provides surface modification solutions for medical device and biomedical applications. From February 2003 until April 2004, Mr. Carlson was the Vice President of Strategic Planning for SurModics, where he structured the company’s performance targets, developed market segmentation plans and long-term strategies. Prior to that, Mr. Carlson served as the Vice President of Marketing for SurModics, where he was responsible for developing the marketing and sales organization.

Richard B. Thon was engaged as our Chief Financial Officer on a part-time consulting basis from 2002 until July 2004, when he became employed by the Company in that position on a full-time basis. From 2001 to 2004, Mr. Thon was also the part-time Chief Financial Officer of CHdiagnostics, LLC, a marketer of blood glucose diagnostic supplies.

David F. Koenig served as a director of our predecessor company, ProUroCare, Inc. (“PUC”), from 1999 until April 2004, when he became a director of the Company as a result of the Merger. From 1996 to 2005, Mr. Koenig was the Executive Vice President and Chief Operating Officer of Solar Plastics, Inc., a manufacturer of custom rotationally molded plastic parts. Mr. Koenig is Chairman of the Compensation Committee and a member of the Audit and Nominating and Governance Committees.

Robert J. Rudelius was elected to the Company’s Board of Directors in June 2007. Since 2003, Mr. Rudelius has been the Managing Director and CEO of Noble Ventures, LLC, a company he founded, providing advising and consulting services to early-stage companies in the information technology, renewable energy and loyalty marketing fields. Mr. Rudelius is also the Managing Director and CEO of Noble Logistics, LLC, a holding company he founded in 2002 to create, acquire and grow a variety of businesses in the freight management, logistics and information technology industries. Mr. Rudelius is the Chairman of the Nomination and Governance Committee and a member of the Compensation Committee.

Scott E. Smith has been a director of the Company since 2006. He is employed by F-2 Intelligence Group (“F-2”), a company engaged in providing critical insights to multinational corporations and private equity clients on a broad range of strategic issues. From 2002 to 2004, Mr. Smith served as F-2’s Director of Corporate Accounts, where he was responsible for selling strategic consulting services primarily to Fortune 500 companies. In 2004, Mr. Smith transitioned to and is currently serving as F-2’s Regional Director of Sales for Private Equity, where he sells market and competitive intelligence consulting services to private equity firms. Prior to joining F-2, Mr. Smith was employed by the accounting firm Arthur Andersen for 23 years and served the last 10 years as an audit partner. Mr. Smith is a Certified Public Accountant and a Certified Management Accountant. Mr. Smith is Chairman of the Audit Committee.

There are no family relationships among our executive officers or directors.

Audit Committee

Our Board of Directors has established a two-member Audit Committee that currently consists of Messrs. Smith, the Chairman, and Koenig. The Board of Directors has adopted a written charter for the Audit Committee, which is available on our website www.prourocare.com. The Audit Committee was formed after the Merger. Prior to the Merger, the Company had no such Audit Committee.

The board of directors has determined that both members of the Audit Committee, Mr. Smith and Mr. Koenig, are “audit committee financial experts” as that term is defined in Item 407(d)(5) of Regulation S-K promulgated under the Exchange Act. Mr. Smith was an Audit Partner for Arthur Andersen and is a Certified Public Accountant and a Certified Management Accountant. Mr. Koenig’s relevant experience includes his previous service as the Chief

Financial Officer and director of Quadion Corporation, and his past consulting experience, which involved his oversight and supervision of the performance of business enterprises respecting the preparation, audit and evaluation of financial statements. Both members of the Audit Committee qualify as “independent directors,” as such term is defined in Section 4200(a)(15) of the NASDAQ listing standards. Moreover, the board of directors has determined that each of the Audit Committee members is able to read and understand fundamental financial statements and has past employment experience in finance or accounting.

Code of Ethics Disclosure Compliance

On February 15, 2005, our Board of Directors adopted a Code of Ethics for Financial Executives, which includes our Company’s principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, as required by Sections 406 and 407 of the Sarbanes-Oxley Act of 2002. Our Code of Ethics is available on our website www.prourocare.com, and we will provide a copy, without charge, to any shareholder upon written request to Dick Thon, ProUroCare Medical Inc., 6440 Flying Cloud drive, Suite 101, Eden Prairie, MN 55344.

Section 16(a) Beneficial Ownership Reporting Compliance

The rules of the Securities and Exchange Commission require our directors, executive officers and holders of more than 10 percent of our common stock to file reports of stock ownership and changes in ownership with the Securities and Exchange Commission. Based on the Section 16 reports filed by our directors and executive officers and written representations of our directors and executive officers we believe there were no late or inaccurate filings for transactions occurring during fiscal 2008, except as follows:

<u>Name</u>	<u>Number of Late Reports</u>	<u>Number of Transactions Reported Late</u>
David Koenig	1	1
Robert Rudelius	1	1
Scott Smith	1	1
James Davis	2	2

ITEM 11: EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth the compensation earned for services rendered in all capacities by our Chief Executive Officer and Chief Financial Officer. There were no other executive officers or other individuals who earned more than \$100,000 during 2008. The individuals named in the table will be hereinafter referred to as the “Named Executive Officers.”

Summary Compensation Table

<u>Name and Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)</u>	<u>Option Awards (\$)(3)</u>	<u>All Other Compensation (\$)(4)</u>	<u>Total (\$)</u>
Richard Carlson(1)..... Chief Executive Officer and Acting Chairman of the Board	2008	\$150,000	\$—	\$25,451	\$2,103	\$177,554
	2007	\$150,000	\$—	\$120,898	\$—	\$270,898
Richard Thon(2)..... Chief Financial Officer	2008	\$136,375	\$—	\$10,873	\$4,825	\$152,073
	2007	\$140,000	\$—	\$65,348	\$1,200	\$206,548

- (1) All compensation Mr. Carlson earned is related to his duties as an officer. Due to funding limitations, \$124,335 of Mr. Carlson's salary earned in 2006, 2007 and 2008 was unpaid as of December 31, 2008. See "Executive Compensation—Employment Agreements" for the terms of Mr. Carlson's current employment arrangements with us.
- (2) Due to funding limitations, \$144,818 of Mr. Thon's salary and bonus earned in 2006, 2007 and 2008 was unpaid as of December 31, 2008. See "Executive Compensation—Employment Agreements" for the terms of Mr. Thon's current employment arrangements with us.
- (3) Option awards are valued in accordance with Statement of Financial Accounting Standards ("SFAS") No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R"). See Notes 1(j) and 10(h) to the Consolidated Financial Statements for the fiscal year ended December 31, 2007 and Notes 1(f) and 7(b) to the Consolidated Financial Statements for the fiscal year ended December 31, 2008 included in Item 8 of this Annual Report on Form 10-K for the material terms of stock option grants.
- (4) Other compensation represents insurance premiums paid by us with respect to term life insurance and long-term care policies for the benefit of the executive. There is no cash surrender value associated with the policies.

Outstanding Equity Awards at December 31, 2008

No stock options or stock-appreciation rights were exercised during fiscal year 2008, and no stock-appreciation rights were outstanding at the end of such fiscal year. The table below sets forth outstanding but unexercised options of our Named Executive Officers as of December 31, 2008.

<u>Name</u>	Number of Securities Underlying Unexercised Options		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price	Option Expiration Date
	(# Exercisable)(1)	(# Unexercisable)(1)	(#)		
Richard Carlson.....	—	—	5,000(2)	\$7.50	March 1, 2011
	10,000	—	—	\$5.00	February 1, 2017
	10,000	60,000(3)	—	\$1.00	July 11, 2015
Richard Thon	—	—	5,000(2)	\$7.50	March 1, 2011
	3,000	—	—	\$11.33	April 18, 2012
	10,000	25,000(4)	—	\$1.00	July 11, 2015

- (1) See Notes 1(j) and 12(h) to the Consolidated Financial Statements for the fiscal year ended December 31, 2008 included in Item 8 in this Annual Report on Form 10-K for the material terms of stock option grants.
- (2) Equity Incentive Plan Awards vest upon the Company securing FDA approval of its ProUroScan System.
- (3) On July 11, 2008, the Company issued incentive stock options to acquire 70,000 shares of its common stock to Mr. Carlson. The options are exercisable for a period of seven years at an exercise price of \$1.00 per share. Of the options, 10,000 shares vest immediately and 20,000 shares will vest on July 1 of each of 2009, 2010 and 2011. At the same time, Mr. Carlson agreed to cancel existing, fully-vested stock options to acquire 15,000 shares of common stock at an exercise price of \$23.50 per share.
- (4) On July 11, 2008, the Company issued incentive stock options to acquire 35,000 shares of its common stock to Mr. Thon. The options are exercisable for a period of seven years at an exercise price of \$1.00 per share. Of the options, 10,000 shares vest immediately and 8,333 shares will vest on July 1 of each 2009, 2010 and 2011. At the same time, Mr. Thon agreed to cancel existing, fully-vested stock options to acquire 20,000 shares of common stock at an exercise price of \$25.00 per share.

Director Compensation

Effective July 1, 2008, our Board of Directors established a policy that each of our non-employee directors receives an annual cash payment of \$10,000 for annual services to the Company, that the chairpersons of our Compensation, Audit and Nominating and Governance committees receive an additional annual payment of \$2,500 and that each committee member receive an annual payment of \$1,000 per committee. In addition, we have also agreed to grant to all non-employee directors a one-time non-qualified stock option upon election or appointment to the Board of Directors to purchase 3,000 shares of our common stock at fair market value and, additionally, to grant options to purchase 1,000 shares of our common stock at a fair market value to each director upon their annual re-election to the Board. These director options vest ratably over two years of service.

Prior to July 1, 2008, each of our non-employee directors received an annual cash payment of \$5,000 for services to the Company and the chairpersons of our Compensation, Audit and Nominating and Governance committees received an additional annual payment of \$2,500. All non-employee directors were granted a one-time non-qualified stock option upon appointment to the Board of Directors to purchase 3,000 shares of our common stock at fair market value. These director options vested ratably over two years of service. The options granted to Mr. Nazarenko and Mr. Koenig have a ten-year term, and to Mr. Smith and Mr. Rudelius have a seven-year term.

All directors shall be reimbursed for travel and other out-of-pocket expenses incurred in connection with attendance at meetings of the Board of Directors and its committees.

The table below sets forth director compensation earned during 2008:

<u>Name</u>	Fees Earned or Paid in			Total
	Cash	Stock	Option	
	(\$)	Awards(5) (\$)	Awards(6) (\$)	(\$)
David Koenig(1).....	\$7,250	\$13,750	\$710	\$21,710
Alexander Nazarenko(2).....	\$—	\$9,842	—	\$9,842
Scott Smith(3).....	\$6,250	\$13,750	\$4,398	\$24,398
Robert Rudelius(4).....	\$6,750	\$13,125	\$4,310	\$24,185

- (1) Chairman of the Compensation Committee as of March 14, 2008. Prior to March 14, 2008, Mr. Koenig was Chairman of the Nominating and Governance Committee.
- (2) Mr. Nazarenko resigned from the Board of Directors on March 11, 2008. Mr. Nazarenko served as Chairman of the Compensation Committee until that time.
- (3) Chairman of the Audit Committee.
- (4) Chairman of the Nominating and Governance Committee as of March 14, 2008.
- (5) On July 11, 2008, we issued a total of 12,500 shares of our common stock to our directors in lieu of cash as payment of directors' fees earned in 2008. In addition, a total of 37,967 shares of our common stock were issued to our directors in recognition of the extraordinary amount of time and effort they have put forth on the Company's restructuring and refocusing efforts since January 1, 2007. Finally, 9,167 shares of common stock were issued to our directors in lieu of cash as payment for directors' fees earned in 2007 (not included in the 2008 compensation). The dollar amount included in this column is the amount recognized for financial statement reporting purposes with respect to the fiscal year ended December 31, 2008 in accordance with SFAS 123R.
- (6) Each outside director held options to acquire 4,000 shares at December 31, 2008. Options awarded during the fiscal year are valued in accordance with SFAS 123R. See Notes 1(j) and 12(h) to the Consolidated Financial Statements for the fiscal year ended December 31, 2008 included in Item 8 of this Annual Report on Form 10-K for the material terms of stock option grants.

Employment Agreements

On July 16, 2008, we entered into an employment agreement with Mr. Carlson, our Chief Executive Officer. The agreement provides for a minimum annual salary of \$150,000, a cash incentive bonus potential of up to 40 percent of Mr. Carlson's base pay, and eligibility to participate in an annual grant of options to purchase shares of common stock, as determined by our board of directors. The agreement provides for severance payments if we terminate Mr. Carlson without cause or if Mr. Carlson terminates the agreement for good reason that includes six months of base salary plus one month of base salary for each year of service (up to a maximum of 12 months of base salary), payment of earned bonuses, continued payment of existing health and life insurance benefits for a period of six months and immediate vesting of all unvested stock options then held by Mr. Carlson. In addition, within a one-year period following a "change in control" of the Company, upon termination without cause, unacceptable demotion or reduction in responsibilities or a relocation of more than 100 miles, Mr. Carlson will receive as severance, six months of base salary plus one month of base salary for each year of service (up to a maximum of 12 months of base salary), and immediate vesting of all unvested stock options then held by Mr. Carlson. The agreement prohibits Mr. Carlson from directly or indirectly participating in the ownership, management, operation or control of a competitive business for a period of one year following termination of his employment. The agreement will extend through December 31, 2009.

On July 21, 2007, we entered into an employment agreement with our Chief Financial Officer, Richard Thon. The agreement extends through June 30, 2009. The agreement provides for a minimum annual salary of \$140,000, a cash incentive bonus potential of up to 30 percent of Mr. Thon's base pay and eligibility to participate in an annual grant of options to purchase shares of common stock, as determined by our Board of Directors. The agreement provides for severance payments if we terminate Mr. Thon without cause or if Mr. Thon terminates the agreement for good reason, including four months of base salary plus one month of base salary for each year of service (up to a maximum of nine months of base salary), payment of earned bonuses, continued payment of existing health and life insurance benefits for a period of four months and immediate vesting of all unvested stock options then held by Mr. Thon. In addition, within a one-year period following a "change in control" of the Company, upon termination without cause, unacceptable demotion or reduction in responsibilities, or a relocation of more than 100 miles, Mr. Thon will receive as severance, nine months of base salary plus one month of base salary for each year of service (up to a maximum of 12 months of base salary), and immediate vesting of all unvested stock options then held by Mr. Thon. The agreement prohibits Mr. Thon from directly or indirectly participating in the ownership, management, operation or control of a competitive business for a period of one year following termination of his employment.

From June 2006 through December 2007, the Company deferred payment of the majority of our remaining executive team's compensation. We expect to pay a portion of the balance of the deferred compensation out of the proceeds of the 2009 Public Offering, and intend to pay the balance during the course of 2009 as funding allows. As of December 31, 2008, approximately \$269,000 of our remaining executive team's compensation had not been paid, and was recorded as an accrued liability.

ITEM 12: SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information regarding beneficial ownership of our common stock as of March 23, 2009, by (i) each person known by us to be the beneficial owner of more than five percent of the outstanding common stock, (ii) each director of the Company, (iii) each executive officer of the Company and (iv) all executive officers and directors as a group.

The number of shares beneficially owned is determined under rules promulgated by the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. The definition of beneficial ownership for proxy

statement purposes includes shares over which a person has sole or shared voting power or dispositive power, whether or not a person has any economic interest in the shares. The definition also includes shares that a person has a right to acquire currently or within 60 days of March 23, 2009. Including those shares in the tables does not, however, constitute an admission that the named stockholder is a direct or indirect beneficial owner of those shares. Unless otherwise indicated, each person or entity named in the table has sole voting power and investment power (or shares that power with that person's spouse) with respect to all shares of common stock listed as owned by that person or entity. Unless otherwise indicated, the address of each of the following persons is 6440 Flying Cloud Drive, Suite 101, Eden Prairie, MN 55344.

Name	Shares Beneficially Owned	Percent of Class
Richard C. Carlson ⁽¹⁾	110,850	1.2
David F. Koenig ⁽²⁾	101,502	1.1
Robert J. Rudelius ⁽³⁾	99,056	1.1
Scott E. Smith ⁽⁴⁾	163,097	1.7
Richard B. Thon ⁽⁵⁾	58,000	*
All directors and officers as a group (5 total)⁽⁶⁾	532,505	5.5
James Davis ⁽⁷⁾⁽⁸⁾	2,955,549	26.9
William Reiling ⁽⁹⁾⁽¹⁰⁾	509,985	5.4

*Less than one percent.

- (1) Includes 850 shares held directly and currently exercisable options to purchase 110,000 shares of common stock.
- (2) Includes 1,875 shares held by Clinical Network Management Corp. and 26,572 shares held by Clinical Network, Inc. with respect to each of which Mr. Koenig is an officer and minority owner. Also includes 39,055 shares of common stock held directly and currently exercisable options to purchase up to 34,000 shares of common stock.
- (3) Includes 45,195 shares held directly, warrants to purchase 29,986 shares of common stock and options to purchase up to 23,875 shares of common stock that are currently exercisable or exercisable within 60 days of March 23, 2009.
- (4) Includes 86,622 shares held directly, warrants to purchase 52,475 shares of common stock and currently exercisable options to purchase up to 24,000 shares of common stock.
- (5) Includes currently exercisable directly held options to purchase up to 58,000 shares of common stock.
- (6) Includes Messrs. Carlson, Koenig, Rudelius, Smith and Thon.
- (7) The address of Mr. Davis is 6446 Flying Cloud Drive, Eden Prairie, MN 55344.
- (8) Shares beneficially owned includes the following directly held shares and immediately exercisable warrants and convertible notes: 1,208,468 shares of common stock, \$281,000 of convertible notes convertible into 510,909 shares of common stock, and warrants to purchase 989,530 shares of common stock. Shares beneficially owned also includes the following shares and immediately exercisable warrants held by Davis & Associates Inc., 401K PSP, of which Mr. Davis has sole voting power: 74,964 shares of common stock and warrants to purchase 91,014 shares of common stock. Shares beneficially owned also includes the following shares and immediately exercisable warrants held by Davis & Associates Inc., of which Mr. Davis has sole voting power: 37,482 shares of common stock and warrants to purchase 43,182 shares of common stock.
- (9) The address of Mr. Reiling is 200 University Avenue W., Suite 200, St. Paul, MN 55103.
- (10) Shares beneficially owned includes the following 336,027 directly held shares and immediately exercisable warrants to purchase 173,958 shares.

**Securities Authorized for Issuance under Equity Compensation Plans
as of Last Fiscal Year (December 31, 2008)**

	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by stockholders ⁽¹⁾	233,000	\$7.73	67,000
Equity compensation plans not approved by stockholders ⁽²⁾	611,514	\$3.98	--
Total	854,514	\$5.02	67,000

- (1) Includes shares of our common stock issuable under options granted under our 2002 and 2004 Plans (as defined below).
(2) Consists of warrants issued to vendors, consultants and lenders and loan guarantors.

The Board of Directors adopted the ProUroCare Inc. 2002 Stock Plan (the “2002 Plan”) and the ProUroCare Inc. 2004 Stock Option Plan (and the “2004 Plan”) to provide a means by which our employees, directors, officers and consultants may be given an opportunity to purchase our stock, to assist in retaining the services of such persons, to secure and retain the services of persons capable of filling such positions and to provide incentives for such persons to exert maximum efforts for our success. Under the 2002 and 2004 Plans, we are able to grant incentive and non-qualified options, stock appreciation rights, stock awards, restricted stock awards and performance shares. Incentive stock options granted under the 2002 Plan and 2004 Plan are intended to qualify as “incentive stock options” within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (the “Code”). Non-qualified stock options granted under the 2004 Plan will not qualify as incentive stock options under the Code. The Compensation Committee of the board of directors determines the vesting provisions of stock-based awards under the 2002 Plan and 2004 Plan on a case-by-case basis. In accordance with SFAS 123 and SFAS 123R, we have elected to utilize the fair-value method of accounting for these options. An aggregate of \$44,745, \$453,384 and \$1,626,823 of stock-based compensation related to these options was recognized in the years ended December 31, 2008, 2007 and the period from August 17, 1999 to December 31, 2008, respectively.

2002 Plan

In April 2002, PUC adopted the 2002 Stock Plan, pursuant to which PUC granted options to officers, directors, employees and independent contractors. The Company adopted the 2002 Plan as part of the Merger, and on February 15, 2005 our board of directors approved an amendment to the 2002 Stock Plan that provides for the cashless exercise of options granted under the plan, at the discretion of a committee of independent directors. On March 27, 2008, our board of directors approved a second amendment to the 2002 Plan that made certain technical changes to make it compliant with Section 409A of the Code. Following the amendment, the plan was restated to include the amendment and to reflect the effects of the Merger and the February 2008 reverse stock split and was renamed as the “Amended and Restated 2002 Stock Plan.”

As of December 31, 2008, there were options to purchase 147,000 shares of our common stock outstanding under the 2002 Plan that are exercisable at prices ranging from \$0.90 to \$20.00. All of these options are held by Company officers, former officers, consultants and directors.

2004 Plan

On July 12, 2005, our stockholders approved a resolution adopting the 2004 Plan. On March 27, 2008, our board of directors approved an amendment to the 2004 Plan that made certain technical changes to make it compliant with Section 409A of the Code. Following the amendment, the plan was restated to include the amendment and to reflect the effects of the Merger and the February 2008 reverse stock split and was renamed as the “Amended and Restated 2004 Stock Option Plan.”

We have reserved 150,000 shares of common stock for issuance under the 2004 Plan. As of December 31, 2008, there were options to purchase 86,000 shares of our common stock outstanding under the 2004 Plan that are exercisable at prices ranging from \$1.00 to \$7.00 per share. All of these options have been issued to Company officers and directors.

ITEM 13: CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Throughout 2008, we rented executive offices within the offices of a former director, Mr. Alex Nazarenko. Our rental cost for these offices was approximately \$2,129 per month, which is the market price for similar office space in Minneapolis, Minnesota.

On April 3, 2008, the Company purchased the Profile Assets from Profile pursuant to an asset purchase agreement. At the time of the transaction, Profile was a 5% beneficial owner of the Company. The purchase price of the Profile Assets was \$300,000.

On April 3, 2008, in connection with our purchase of the Profile Assets, we borrowed an aggregate of \$112,500 pursuant to three promissory notes each in the amount of \$37,500 (see Note 11(d)). The promissory notes were issued in favor of Mr. Davis, Mr. Reiling and the Smith Trust. On September 12, 2008, these three promissory notes were amended to extend their due dates to the earlier of seven days following the close of an underwritten public offering or December 31, 2008, and to give the holders an option to convert their notes into shares of our common stock at a conversion price equal to 70% of the price of the Units sold in such offering.

On July 11, 2008, our directors received 21,667 of shares of our common stock in lieu of cash for \$21,667 of unpaid director’s fees accrued through June 30, 2008.

On July 11, 2008, we issued a total of 37,967 shares of our common stock to our directors in recognition of extraordinary amount of time and effort they have spent on our restructuring and refocusing efforts since January 2007. The shares were valued at \$1.00 per share and expensed on the date of issuance.

On September 16, 2008, Mr. Davis agreed to purchase \$100,000 of the puts pursuant to the Unit Put Agreement (see Note 11(d)). On September 24, 2008, we closed on \$50,000 of Mr. Davis’ put commitment, and issued a \$47,500 convertible note and a warrant to acquire 10,000 shares of our common stock at an exercise price of \$1.00 per share. On October 28, 2008, we closed on the remaining \$50,000 of Mr. Davis’ put commitment, and issued a \$47,500 convertible note and a warrant to acquire 10,000 shares of our common stock at an exercise price of \$1.00 per share.

On September 25, 2008, we borrowed \$150,000 pursuant to a promissory note issued in favor of Mr. Davis and used the proceeds to retire the \$150,000 principal amount of the Profile Note (see Note 11(d)). As consideration for providing the loan, we issued an immediately exercisable, five-year warrant to purchase 100,000 shares of our common stock at \$1.50 per share to Mr. Davis.

Director Independence

Each of Messrs. Koenig, Rudelius and Smith qualifies as an “independent director,” as such term is defined in Section 4200(a)(15) of the NASDAQ listing standards. As an executive officer of the Company, Mr. Carlson does not qualify as an “independent director.”

ITEM 14: PRINCIPAL ACCOUNTANT FEES AND SERVICES

Principal Accountant Fees and Services

The following is a summary of the fees billed to the Company by Virchow, Krause & Company, LLP (“Virchow Krause”) for professional services rendered for the fiscal years ended December 31, 2008 and 2007, respectively:

<u>Fee Category</u>	<u>Fiscal 2008 Fees</u>	<u>Fiscal 2007 Fees</u>
Audit Fees	\$82,471	\$77,103
Audit-related Fees	--	3,750
Tax Fees	1,300	--
All Other Fees	44,790	9,825
Total Fees	\$128,561	\$90,678

Audit Fees. These consist of fees billed by our auditors for professional services rendered for the audit of our consolidated financial statements and review of the interim consolidated financial statements included in quarterly reports.

Audit-related Fees. These consist of fees billed by our auditors for professional services rendered for the review of an SEC comment letter.

Tax Fees. These consist of fees billed by our auditors for professional services for tax compliance, tax advice and tax planning.

All Other Fees. There consist of fees billed by our auditors for professional services rendered for the review of private placement memorandums and registration statement filings on Form S-1 and Form S-8.

Preapproval Policies

The policy of our Audit Committee is to review and preapprove both audit and non-audit services to be provided by the independent auditors (other than with de minimus exceptions permitted by the Sarbanes-Oxley Act of 2002). This duty may be delegated to one or more designated members of the Audit Committee with any such approval reported to the committee at its next regularly scheduled meeting. Approval of non-audit services shall be disclosed to investors in periodic reports required by Section 13(a) of the Exchange Act. 100 percent of the fees paid to Virchow Krause were pre-approved as aforesaid.

No services in connection with appraisal or valuation services, fairness opinions or contribution-in-kind reports were rendered by Virchow Krause. Furthermore, no work of Virchow Krause with respect to its services rendered to the Company was performed by anyone other than Virchow Krause.

PART IV

ITEM 15: EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Exhibit No.	Description
2.1	Agreement of Merger and Reorganization by and among Global Internet Communications, Inc., GIC Acquisition Co., and ProUroCare Inc. dated April 5, 2004 (incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K filed April 20, 2004).
2.2	Articles of Merger relating to the merger of GIC Acquisition Co., then a wholly owned subsidiary of the registrant with and into ProUroCare Inc., as filed with the Minnesota Secretary of State on April 5, 2004 (incorporated by reference to Exhibit 2.2 to our Current Report on Form 8-K filed April 20, 2004).
3.1	Amended and Restated Bylaws of ProUroCare Medical Inc. (incorporated by reference to Exhibit 3.2 to Annual Report on Form 10-KSB filed March 31, 2005).
4.1	Warrant to acquire 300,000 shares of common stock of ProUroCare Medical Inc., issued in favor of BINA Enterprises on April 5, 2004 (incorporated by reference to Exhibit 4.2 to Registration Statement on Form SB-2 filed August 3, 2004).
4.2	Form of Warrant to acquire 300,000 shares of common stock of ProUroCare Medical Inc., issued in favor of Artann Laboratories, Inc. and Vladimir Drits effective as of July 19, 2004 and December 2, 2004 (incorporated by reference to Exhibit 4.6 to Registration Statement on Form SB-2/A filed October 1, 2004).
4.3	Form of warrants issued to promissory note guarantors and a lender between September 14 and October 19, 2005 (incorporated by reference to Exhibit 4.9 to Annual Report on Form 10-KSB filed March 31, 2006).
4.4	Warrant to acquire 25,000 shares of common stock of ProUroCare Medical, Inc. issued in favor of Adron Holdings, LLC, dated January 25, 2006 (incorporated by reference to Exhibit 10.7 to Current Report on Form 8-K filed January 31, 2006).
4.5	Security Agreement between Crown Bank and ProUroCare, Inc., dated January 11, 2006 and executed February 16, 2006 (incorporated by reference to Exhibit 4.8 to Current Report on Form 8-K filed February 23, 2006).
4.6	Security Agreement between Crown Bank and ProUroCare, Inc., dated February 28, 2006 (incorporated by reference to Exhibit 4.9 to Current Report on Form 8-K filed March 3, 2006).
4.7	Security Agreement between Crown Bank and ProUroCare Medical, Inc., dated February 28, 2006 (incorporated by reference to Exhibit 4.10 to Current Report on Form 8-K filed March 3, 2006).
4.8	Warrant to acquire 37,500 shares of common stock of ProUroCare Medical, Inc. issued in favor of Roman Pauly and Maryjo Pauly, dated June 1, 2006 (incorporated by reference to Exhibit 10.7 to Current Report on Form 8-K filed June 6, 2006).
4.9	Form of warrant to acquire shares of common stock of ProUroCare Medical, Inc. issued to lenders in connection with a \$100,000 promissory note, dated November 29, 2006 and January 3, 2007 (incorporated by reference to Exhibit 4.17 to Annual Report on Form 10-KSB filed March 30, 2007).
4.10	Form of warrants to acquire shares of common stock of ProUroCare Medical Inc. issued in favor of subscribers of the Company's \$500,000 Investment Unit offering dated January 18 and January 23, 2007 (incorporated by reference to Exhibit 4.18 to Annual Report on Form 10-KSB filed March 30, 2007).
4.11	Form of revised Convertible Subordinated Debenture issued to William Reiling, James Davis, Bruce Culver, and the Phillips W. Smith Family Trust in replacement of Convertible Subordinated Debentures dated February 17, 2006 and February 28, 2006 (incorporated by reference to Exhibit 4.23 to Annual Report on Form 10-KSB filed March 30, 2007).
4.12	Amendment No. 1 to warrant to acquire 300,000 shares of common stock of ProUroCare Medical Inc., originally issued in favor of BINA Enterprises on April 5, 2004, dated April 5, 2007 (incorporated by reference to Exhibit 4.14 to Annual Report on Form 10-KSB filed March 31, 2008).

Exhibit No.	Description
4.13	Form of Amendment No. 1 to Convertible Subordinated Debentures issued to William Reiling, James Davis, Bruce Culver, and the Phillips W. Smith Family Trust, dated December 28, 2007 (incorporated by reference to Exhibit 4.15 to Annual Report on Form 10-KSB filed March 31, 2008).
4.14	Form of warrant issued pursuant to the Company's 2007 Private Placement dated December 27, 2007 (incorporated by reference to Exhibit 4.16 to Annual Report on Form 10-KSB filed March 31, 2008).
4.15	Warrant issued to James Davis dated December 27, 2007 (incorporated by reference to Exhibit 4.17 to Annual Report on Form 10-KSB filed March 31, 2008).
4.16	Form of warrant issued pursuant to the Company's 2008 Private Placement dated February 13, 2008 (incorporated by reference to Exhibit 4.18 to Annual Report on Form 10-KSB filed March 31, 2008).
4.17	Form of warrants issued to William Reiling, James Davis and the Phillips W. Smith Family Trust dated April 3, 2008 (incorporated by reference to Exhibit 4.1 to Quarterly Report on Form 10-Q filed May 8, 2008).
4.18	Form of Origination Warrant issued pursuant to the Company's Unit Put Agreement dated September 16, 2008 (incorporated by reference to Exhibit 4.22 to Registration Statement on Form S-1 filed September 19, 2008).
4.19	Form of Put Warrant issued pursuant to the Company's exercise of its put right pursuant to the Unit Put Agreement dated September 16, 2008 (incorporated by reference to Exhibit 4.23 to Registration Statement on Form S-1 filed September 19, 2008).
4.20	Warrant issued to James Davis dated September 25, 2008 (incorporated by reference to Exhibit 4.1 to Quarterly Report on Form 10-Q filed October 23, 2008).
4.21	Form of Warrant issued to James Davis, Bruce Culver, William S. Reiling and the Smith Family Trust, dated October 31, 2008 (incorporated by reference to Exhibit 4.25 to Amendment No. 1 to Registration Statement on Form S-1 filed November 10, 2008).
4.22	Form of Underwriters Warrant Agreement (incorporated by reference to Exhibit 4.26 to Amendment No. 3 to Registration Statement on Form S-1 filed December 18, 2008).
4.23	Form of Warrant Agreement between ProUroCare Medical Inc. and Interwest Transfer (incorporated by reference to Exhibit 4.27 to Amendment No. 3 to Registration Statement on Form S-1 filed December 18, 2008).
4.24	Specimen Warrant (incorporated by reference to Exhibit 4.28 to Amendment No. 3 to Registration Statement on Form S-1 filed December 18, 2008).
4.25	Form of Unit Certificate (incorporated by reference to Exhibit 4.29 to Amendment No. 3 to Registration Statement on Form S-1 filed December 18, 2008).
4.26	Form of Unit Agreement between ProUroCare Medical Inc. and Interwest Transfer (incorporated by reference to Exhibit 4.30 to Amendment No. 3 to Registration Statement on Form S-1 filed December 18, 2008).
10.1*	ProUroCare Medical Inc. Amended and Restated 2002 Stock Plan (incorporated by reference to Exhibit 4.1 to Registration Statement on Form S-8 filed March 31, 2008).*
10.2*	ProUroCare Medical Inc. Amended and Restated 2004 Stock Option Plan (incorporated by reference to Exhibit 4.2 to Registration Statement on Form S-8 filed March 31, 2008).*
10.3	Guaranty provided to Crown Bank on behalf of ProUroCare Medical Inc. dated January 10, 2006 (incorporated by reference to Exhibit 4.4 to Current Report on Form 8-K filed February 23, 2006).
10.4	Guaranty provided to Crown Bank on behalf of ProUroCare Medical Inc. dated February 28, 2006 (incorporated by reference to Exhibit 4.5 to Current Report on Form 8-K filed March 3, 2006).
10.5	Promissory Note issued in favor of Crown Bank, dated February 28, 2006 (incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed March 3, 2006).
10.6	Promissory Note issued in favor of Roman Pauly, dated June 1, 2006 (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed June 6, 2006).

Exhibit No.	Description
10.7	Amendment #1 to Promissory Note dated June 1, 2006 issued in favor of Roman Pauly, dated August 24, 2006 (incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-QSB filed September 18, 2006).
10.8	Promissory Note issued in favor of Adron Holdings, LLC, dated November 29, 2006, as amended March 21, 2007 (incorporated by reference to Exhibit 10.37 to Annual Report on Form 10-KSB filed March 30, 2007).
10.9	Amendment #2 to Promissory Note dated June 1, 2006 issued in favor of Roman Pauly, dated March 21, 2007 (incorporated by reference to Exhibit 10.38 to Annual Report on Form 10-KSB filed March 30, 2007).
10.10	Termination and Intent for Cooperation Agreement dated April 16, 2007 by and between ProUroCare Medical Inc. and Artann Laboratories, Inc. (incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-QSB filed May 15, 2007).
10.11	Promissory Note issued in favor of Alexander Nazarenko, dated April 17, 2007 (incorporated by reference to Exhibit 10.5 to Quarterly Report on Form 10-QSB filed May 15, 2007).
10.12	Maurice Taylor Agreement to Defer Payment of Accrued Salary dated May 11, 2007 (incorporated by reference to Exhibit 10.6 to Quarterly Report on Form 10-QSB filed May 15, 2007).
10.13	Michael Grossman Final Separation Agreement dated May 11, 2007 (incorporated by reference to Exhibit 10.7 to Quarterly Report on Form 10-QSB filed May 15, 2007).
10.14	Promissory Note issued in favor of Alexander Nazarenko, dated June 25, 2007 (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-QSB filed August 14, 2007).
10.15*	Employment Agreement by and between ProUroCare Inc. and Richard B. Thon, dated July 21, 2007 (incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-QSB filed August 14, 2007).
10.16	Promissory Note issued in favor of Phillips W. Smith Family Trust, dated July 31, 2007 (incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-QSB filed August 14, 2007).
10.17	Amendment # 2 to Promissory Note issued in favor of Adron Holdings, LLC on November 29, 2006, dated August 8, 2007 (incorporated by reference to Exhibit 10.5 to Quarterly Report on Form 10-QSB filed August 14, 2007).
10.18	Promissory Note issued in favor of James Davis, dated August 29, 2007 (incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-QSB filed November 14, 2007).
10.19	Promissory Note issued in favor of the Phillips W. Smith Family Trust, executed on October 31, 2007 effective as of October 15, 2007 (incorporated by reference to Exhibit 10.35 to Annual Report on Form 10-KSB filed March 31, 2008).
10.20	Security Agreement issued in favor of the Phillips W. Smith Family Trust, executed on October 31, 2007 effective as of October 15, 2007 (incorporated by reference to Exhibit 10.36 to Annual Report on Form 10-KSB filed March 31, 2008).
10.21	\$400,000 Promissory Note issued in favor of Crown Bank, executed October 31, 2007 (incorporated by reference to Exhibit 10.37 to Annual Report on Form 10-KSB filed March 31, 2008).
10.22	\$1,200,000 Promissory Note issued in favor of Crown Bank, executed October 31 2007 (incorporated by reference to Exhibit 10.38 to Annual Report on Form 10-KSB filed March 31, 2008).
10.23	Commercial Loan and Security Agreement with Crown Bank, executed October 31, 2007 and effective as of December 28, 2007 (incorporated by reference to Exhibit 10.39 to Annual Report on Form 10-KSB filed March 31, 2008).
10.24	Guaranty provided to Crown Bank on behalf of ProUroCare Medical Inc. by Bruce Culver dated October 10, 2007 (incorporated by reference to Exhibit 10.40 to Annual Report on Form 10-KSB filed March 31, 2008).
10.25	Guaranty provided to Crown Bank on behalf of ProUroCare Medical Inc. by James Davis dated October 10, 2007 (incorporated by reference to Exhibit 10.41 to Annual Report on Form 10-KSB filed March 31, 2008).

Exhibit No.	Description
10.26	Guaranty provided to Crown Bank on behalf of ProUroCare Medical Inc. by Phillips W. Smith Family Trust dated October 10, 2007 (incorporated by reference to Exhibit 10.42 to Annual Report on Form 10-KSB filed March 31, 2008).
10.27	Promissory Note issued in favor of James Davis, dated October 31, 2007 (incorporated by reference to Exhibit 10.43 to Annual Report on Form 10-KSB filed March 31, 2008).
10.28	Promissory Note issued in favor of James Davis, dated November 30, 2007 (incorporated by reference to Exhibit 10.44 to Annual Report on Form 10-KSB filed March 31, 2008).
10.29	Form of Convertible Note issued pursuant to the Company's 2007 Private Placement dated December 27, 2007 (incorporated by reference to Exhibit 10.45 to Annual Report on Form 10-KSB filed March 31, 2008).
10.30	Convertible Note issued to James Davis dated December 27, 2007 (incorporated by reference to Exhibit 10.46 to Annual Report on Form 10-KSB filed March 31, 2008).
10.31	Form of Convertible Note issued pursuant to the Company's 2008 Private Placement dated February 13, 2008 (incorporated by reference to Exhibit 10.47 to Annual Report on Form 10-KSB filed March 31, 2008).
10.32	Amendment #1 to Promissory Note dated July 31, 2007 between ProUroCare Medical, Inc. and the Phillips W. Smith Family Trust, Dated March 11, 2008 (incorporated by reference to Exhibit 10.48 to Annual Report on Form 10-KSB filed March 31, 2008).
10.33	Amendment #1 to \$600,000 Promissory Note dated October 15, 2007 between ProUroCare Medical, Inc. and the Phillips W. Smith Family Trust, dated March 11, 2008 (incorporated by reference to Exhibit 10.49 to Annual Report on Form 10-KSB filed March 31, 2008).
10.34	Asset Purchase Agreement by and between ProUroCare Medical Inc. and Profile, LLC dated April 3, 2008 (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed May 8, 2008).
10.35	Security Agreement by and between ProUroCare Medical Inc. and Profile, LLC dated April 3, 2008 (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed May 8, 2008).
10.36	Promissory Note by and between ProUroCare Medical Inc. and Profile, LLC dated April 3, 2008 (incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed May 8, 2008).
10.37	Form of Promissory Notes by and between ProUroCare Medical Inc. and each of William Reiling, James Davis and the Phillips W. Smith Family Trust dated April 3, 2008 (incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed May 8, 2008).
10.38*	Employment Agreement by and between ProUroCare Inc. and Richard Carlson dated July 16, 2008 (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed August 14, 2008).
10.39*	Form of Stock Option Agreement and Notice of Stock Option Grant for incentive stock options issued to Richard Carlson and Richard Thon on July 11, 2008 (incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed August 14, 2008).
10.40	License Agreement by and between ProUroCare Medical Inc. and Artann Laboratories Inc. dated July 25, 2008 (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed August 14, 2008).
10.41	Development and Commercialization Agreement by and between ProUroCare Medical Inc. and Artann Laboratories Inc. dated July 25, 2008 (incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed August 14, 2008).
10.42	Amendment Number 1 to Promissory Note by and between ProUroCare Medical Inc. and Profile, LLC dated April 3, 2008 (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed September 16, 2008).
10.43	Form of Amendment Number 1 to Promissory Notes by and between ProUroCare Medical Inc. and each of William Reiling, James Davis and the Phillips W. Smith Family Trust dated April 3, 2008 (incorporated by reference to Exhibit 10.2 on Form 8-K filed September 16, 2008).

Exhibit No.	Description
10.44	Unit Put Agreement dated September 16, 2008 (incorporated by reference to Exhibit 10.43 to Registration Statement on Form S-1 filed September 19, 2008).
10.45	Form of Unit Put Origination Warrant to be issued to Unit Put Agreement dated September 16, 2008 (incorporated by reference from Exhibit 4.23 to Registration Statement on Form S-1 filed September 19, 2008).
10.46	Form of Unit Put Warrant to be issued to Unit Put Agreement dated September 16, 2008 (incorporated by reference from Exhibit 4.22 to Registration Statement on Form S-1 filed September 19, 2008).
10.47	Form of Convertible Promissory Note issued pursuant to the Company's exercise of its put right pursuant to the Unit Put Agreement dated September 16, 2008 (incorporated by reference to Exhibit 10.44 to Registration Statement on Form S-1 filed September 19, 2008).
10.48	Convertible Promissory Note dated September 25, 2008 issued in favor of James Davis (incorporated by reference to Exhibit 10.7 to Quarterly Report on Form 10-Q filed October 23, 2008).
10.49	Amendment of License Agreement by and between ProUroCare Medical Inc. and Artann Laboratories, Inc. dated December 19, 2008 (incorporated by reference to Exhibit 10.46 to Amendment No. 4 to Registration Statement on Form S-1 filed December 22, 2008).
10.50	Amendment to Development and Commercialization Agreement by and between ProUroCare Medical Inc. and Artann Laboratories, Inc. dated December 19, 2008 (incorporated by reference to Exhibit 10.46 to Amendment No. 4 to Registration Statement on Form S-1 filed December 22, 2008).
10.51	Promissory Note dated March 19, 2009 issued in favor of Crown Bank (filed herewith).
10.52	Financing Agreement by and between ProUroCare Medical Inc. and James Davis dated March 19, 2009 (filed herewith).
10.53	Form of Loan Guarantor Compensation Letter Agreement dated March 19, 2009 (filed herewith).
10.54	Letter agreement by and between ProUroCare Medical Inc. and the Phillips W. Smith Family Trust dated March 19, 2009 (filed herewith).
10.55	Amendment #2 to \$600,000 Promissory Note dated October 15, 2007 between ProUroCare Medical, Inc. and the Phillips W. Smith Family Trust, dated March 19, 2009 (filed herewith).
10.56	Convertible Promissory Note dated March 19, 2009 issued in favor of James Davis (filed herewith).
21.1	List of Subsidiaries of ProUroCare Medical Inc. (incorporated by reference to Exhibit 21.1 to Registration Statement on Form SB-2 filed August 3, 2004).
23.1	Consent of Virchow, Krause & Company, LLP (filed herewith).
24.1	Power of Attorney (included on signature page hereof).
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).

* Management contract or compensatory plan.

Note: In order that share data agree with the underlying documents, no share data in this list of Exhibits have been restated to reflect the Company's one-for-ten effect of the February, 2008 reverse stock split.

SIGNATURES

Pursuant to the requirements of Section 13 and 15 (d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ProUroCare Medical, Inc.

By: /s/ Richard C. Carlson
Richard C. Carlson
Chief Executive Officer
Date: March 26, 2009

Pursuant to the requirements of the Securities Act of 1934, this Annual Report has been signed as of March 26, 2009, by the following persons in the capacities indicated.

<u>Name</u>	<u>Title</u>
<u>/s/ Richard C. Carlson</u> Richard C. Carlson	Chief Executive Officer (Principal Executive Officer)
<u>/s/ Richard Thon</u> Richard Thon	Chief Financial Officer (Principal Financial and Accounting Officer)
<u>/s/ David Koenig</u> David Koenig	Director
<u>/s/ Robert Rudelius</u> Robert Rudelius	Director
<u>/s/ Scott e. Smith</u> Scott E. Smith	Director