MOFFITT TOTAL CANCER CARE™

Comprehensive Plan Leads
The Way To Personalized Treatment
3 | 2009 Year-In-Review

6 | Moffitt Total Cancer Care™ Project

14 | Robotic-Assisted Surgical Procedures

16 | Financial Highlights

18 | Leadership Listing

20 | Miles For Moffitt

ON THE COVER
Hongwei Wang, M.D., views lymphoma cells.

AT RIGHT, Itai Gwede, R.N. (left), and Kathy Gossett, R.N., review a patient chart.
I am pleased to introduce Moffitt’s 2009 annual report. Once again, this past fiscal year Moffitt achieved significant progress in cutting-edge research, translation of scientific findings to the clinic through novel clinical trials, clinical growth and expansion, and ultimately patient benefits.

Of particular note is the further development of Moffitt Total Cancer Care™, the institution’s model for personalized cancer care, which is described in the pages that follow.

Just as Moffitt Total Cancer Care™ is designed to identify and meet the needs of patients and their families, Moffitt is focusing all its efforts in this direction, whether working toward scientific research, clinical breakthroughs, novel treatments, or new and improved technology and equipment, as well as eliminating health disparities, enhancing patient well-being, and reaching out to the community. In all we do at Moffitt, our aim is to bring the benefits of scientific findings and the best treatments and support services to our patients and their families. We hope you enjoy reading the information in this annual report, which underscores Moffitt’s ongoing commitment to provide state-of-the-art individualized patient care.

Perhaps even more exhilarating than the past year’s achievements is the Cancer Center’s vision for the future. In these uncertain times Moffitt is facing multiple challenges head-on while aggressively working toward its mission — to contribute to the prevention and cure of cancer.

Robert Rothman
CHAIRMAN
research institutes, including TGen, Scripps Florida, the Burnham Institute for Medical Research and the Institute for Human & Machine Cognition.

- Moffitt’s Office of Technology Management and Licensing (OTML), the intellectual property protection and licensing arm of the Cancer Center, has steadily improved its commercialization efforts since its inception in 2003. During the 2009 fiscal year, OTML filed 55 patent applications, executed 11 license agreements and assisted in the formation of two startups.

- Moffitt’s research initiatives continue to mature, and at the close of fiscal year 2009, Moffitt was awarded $70,233,144 in grant funding, $54,756,382 of which came from peer-reviewed sources.

- Moffitt is committed to eliminating health disparities in Florida and beyond. The University of South Florida and Moffitt were awarded a highly competitive, $6-million federal grant to create what has been named the Center for Equal Health: Community Partnerships in Research, Education and Training. The five-year program grant from the National Institutes of Health will focus on research, education and training, and community outreach activities to reduce cancer-related health disparities among minority and underserved communities in Florida.

- The new Center for Equal Health will be among 50 nationwide, and one of three in Florida. Richard Roetzheim, M.D., M.S.P.H., professor and director of research for the USF Department of Family Medicine, and B. Lee Green, Ph.D., vice president of Moffitt Diversity, are co-principal investigators of the USF/Moffitt Center for Equal Health that will draw on faculty from Moffitt and USF.

- Additionally, Dr. Green was selected by State Surgeon General Ana M. Viamonte Ros to serve as a member of the Racial and Ethnic Health Disparities Advisory Committee. Members of this committee have a major role in developing innovative strategies for eliminating health disparities in Florida’s racial and ethnic populations. Moffitt Diversity works to direct and monitor Moffitt programs intended to advance the organization’s commitment to diversity and inclusion.


- The cover of Molecular Cell Proteomics featured a paper describing a model for the development of personalized cancer care, authored by a team of Moffitt scientists led by John Koomen, Ph.D.

- Hugo Fernandez, M.D., was the lead author of a study published in the New England Journal of Medicine that described a new standard of care for young adults with acute myeloid leukemia.

- Moffitt scientists were involved in an international study that showed a genetic link to increased risk of ovarian cancer. Published in Nature Genetics, the research described the location of a region of DNA that, when altered, can increase the risk of ovarian cancer. Because ovarian cancer has few signs and symptoms, the finding was important.

- Again this past year, Working Mother magazine named Moffitt one of the 2009 Working Mother 100 Best Companies, and Moffitt was chosen as one of Florida’s best companies to work for, as noted in Florida Trend magazine.

- For the 11th year in a row Moffitt appeared on U.S. News & World Report’s list of America’s Best Hospitals for cancer, ranking number 16.

- Moffitt President/Chief Executive Officer & Center Director William S. Dalton, Ph.D., M.D., was appointed vice president/president-elect of the Association of American Cancer Institutes (AACI). Dr. Dalton will assume the AACI presidency in 2011.

- With a focus on cancer prevention, the Tampa Bay Rays and Moffitt conducted the second annual Spring Swing – Moffitt’s Sun Safety Tour®, in which 695 people were screened for early signs of skin cancer. The program also promoted sun safety and skin cancer awareness during a six-stop tour of Major League Baseball spring training venues throughout Florida, at which approximately 44,000 more people were reached with the
message of sun safety. The screenings found an overall total increase of 10 percent more suspected cancerous lesions and suspected precancerous lesions or moles compared with the 2008 tour. Findings included 119 suspected cancerous lesions, including three suspected melanomas, as well as 292 suspicious moles or other precancerous lesions.

- Known for scientific innovation and the latest in clinical care, Moffitt also has taken its means of communication to the next level. In 2009 Moffitt’s Patient Portal was established, allowing patients to schedule their appointments online.
- The Cancer Center also launched InsideMoffitt.com, a new Web portal focused on patients, families and the general public. This new Web site was designed to complement and link to the information found on Moffitt’s corporate Web site, MOFFITT.org. With the launch of InsideMoffitt.com and a focus on an interactive patient experience, patients and the community can now view cancer patient testimonials, listen to physician podcasts and obtain information about Moffitt Total Cancer Care.

ARRA Grants Help Fund Cancer Center Research

The Cancer Center submitted 110 proposals for grants funded from the National Institutes of Health under the American Recovery and Reinvestment Act (ARRA) of 2009, and 26 projects have been awarded grant year-to-date for a total of $83,918 million. Moffitt Cancer Center Recovery Act grants include:

- $498,000 to Claudio Anasetti, M.D., to evaluate the effectiveness of a new compound to control life-threatening complications associated with bone marrow transplants.
- $109,696 to Scott Antonia, M.D., Ph.D., to develop and manufacture vaccines custom-designed to the genetic makeup of individual lung cancer patients to trigger immune responses that attack the tumor and/or increase the efficacy of other treatment agents being used.
- $256,642 to Gerdol Bepler, M.D., Ph.D., to support a Specialized Center of Research Excellence in lung cancer at Moffitt that currently includes five major clinical research studies aimed at improving survival rates for lung cancer patients through the development of genetically based treatment and detection methods.
- $2,087,500 to Sri Kumar Chellappan, Ph.D., to examine the role of the human gene IDI in the progression of non-small-cell lung cancer.
- $686,377 to PK. Epling-Burnette, Pharm.D., Ph.D., and Javier Pinilla-ibarz, M.D., Ph.D., to understand the molecular mechanism of a compound that has been shown to be successful in promoting lifesaving responses in certain blood-related cancers (myelodysplastic syndromes) and to determine if this therapy can be adapted to create immunotherapies for other types of cancer.
- $241,764 to Julie Ojeu, Ph.D., to train postdoctoral students for careers in immunological research, with a focus on the translation of scientific discoveries into new treatments to help patients fight cancer.
- $833,260 to Kathleen Egan, Ph.D., for an ongoing study to explain the excessive occurrence of lethal “glioma” brain tumors in the southeastern United States. Cancer cases and healthy volunteers from five sites in the southeastern United States are being studied to shed light on the possible link to diet, genes, and other risk factors.
- $459,000 to David Evans, Ph.D., to examine the role that specific genes play in attention deficits resulting from nicotine withdrawal. This research will inform the development of genetically personalized tobacco cessation programs.
- $334,525 to Leigh Anne Faul, Ph.D., to evaluate survivorship care planning in colorectal cancer.
- $2,005,467 to David Fenstermacher, Ph.D., to establish a health information system that synthesizes the data collected in Moffitt’s nationwide genetic profiling program with information collected through various other public health systems. This platform will be an invaluable, one-of-a-kind resource for comparing patient outcomes to develop personalized medicine.
- $508,515 to Dimitry Gabrilovich, M.D., Ph.D., to find out why many promising new immunological treatments fail to deliver tangible benefits to most patients. Tumor microenvironment may prevent tumor cells from being recognized by immune cells. Dr. Gabrilovich will study the mechanism of this process and test different therapeutic approaches to correct the situation.
- $1,809,000 to Robert Gatenby, M.D., to use advanced imaging methods and mathematical models to establish the role of the physical microenvironment in tumor development and growth and examine perturbations in critical parameters that can prevent tumor formation and reduce, halt, or even reverse progression of established cancers.
- $225,089 to Clement Gwedde, Ph.D., M.P.H., R.N., to develop a decision aid (educational DVD) to help men with a positive family history of prostate cancer make informed decisions about testing, with the ultimate goal of reducing the burden of prostate cancer.
- $404,030 to John Koomen, Ph.D., to use mass spectrometry, similar to the methods used for drug testing in athletes, to detect and assess multiple myeloma using blood and urine collected from patients.
- $663,994 to Cathy Meade, Ph.D., for supplemental funding to assist the Tampa Bay Community Cancer Network. TBCCN’s goal is to address critical access, prevention and control issues that impact medically underserved, low-literacy and low-income populations in selected areas of Hillsborough, Pinellas and Pasco counties.
- $65,068 to Alan Nyitray, Ph.D., to determine the prevalence and risk factors for human papillomavirus (HPV) in heterosexual men. Because HPV is the primary cause of anal cancer, this information will help formulate effective prevention strategies.
- $633,411 to W.J. Pledger, Ph.D., for a joint project with the Ponce School of Medicine in Puerto Rico to discover key molecules that can be targeted for new treatments and prevention methods for colorectal cancer.
- $334,000 to Thomas Sellers, Ph.D., M.P.H., to explore how inherited genetic variations might influence the risk of epithelial ovarian cancer.
- $568,700 to Edward Seto, Ph.D., to investigate the interaction of histone deacetylases (a type of enzyme) with certain proteins in the development and progression of cancer.
- $1,206,947 to Daniel Sullivan, M.D., Scott Antonia, M.D., Ph.D., and Hatem Soliman, M.D., to perform a phase II trial of 1methyl-D-tryptophan combined with a p53 dendritic cell vaccine in breast cancer. The Center’s cyclotron will also be used to generate (11C)-alpha methyl tryptophan for novel imaging during the phase II part of the trial.
- $783,190 to Javier F. Torres-Roca, M.D., to validate a model that uses genetic characteristics to predict response to radiation therapy.

In addition, $1.5 million in Recovery Act funds was allocated by Florida to provide general operating support to Moffitt’s cancer research programs.
The Moffitt Total Cancer Care™ project—merely an ambitious goal at the beginning of this 21st century—has established Moffitt as a national leader in the quest toward personalized cancer care through individual, evidence-based treatment decisions.

The comprehensive project is designed to improve the standard and scope of cancer care by combining information technology, science and clinical treatment to meet all the needs of a cancer patient. While personalized cancer care means getting the right drug, to the right patient, at the right time, its success depends on several key elements of the Moffitt Total Cancer Care™ program.

"Total Cancer Care combines screening, diagnosis, treatment and survivorship programs with life-long patient follow-up," says William S. Dalton, Ph.D., M.D., Moffitt's CEO and originator of Moffitt's Total Cancer Care™ approach. Patients agree to join this national research study in an effort to develop personalized cancer treatments, and patients will receive personalized survivorship plans and their health information. The study, involving 19 sites across the United States, collects tumor and clinical data from consented patients across Florida and nine other states. "One of the key goals of Total Cancer Care is the discovery of genetic biomarkers that we can use to predict those at high-risk for cancer and to provide better detection and predictors of response to therapy, all on an individual basis."

Every Moffitt patient is given the opportunity to enroll in the Total Cancer Care™ study, although at this time, tumors are being...
collected only for breast, prostate, colorectal, pancreas, brain, and lung cancers. Information about the patient’s medical history and tissue samples from surgeries and biopsies and molecular profiling data becomes part of the permanent and confidential record. These records comply with National Cancer Institute policies, including the safeguarding of patient-protected health care information.

Through the Total Cancer Care™ study, all participating patient tumors – like those of Beverly Norris – are genetically profiled and stored at the biorepository, located at M2Gen, Moffitt’s wholly owned subsidiary. (See accompanying stories on Norris, page 6, and M2Gen, page 9.)

As this annual report was going to press, Moffitt had enrolled 50,670 patients in the

TOTAL CANCER CARE™ – AN OVERVIEW

Moffitt Cancer Center is at the heart of a multifaceted, creative method to discover, translate and deliver personalized cancer care. The goal of this evidence-based approach to cancer care is to provide the “right treatment for the right patient.” Close collaboration among key participants with similar overlapping aims is essential to providing this visionary care – and it is well underway. Read on for a description of key concepts and players.

Moffitt Cancer Center | As a National Cancer Institute Comprehensive Cancer Center, Moffitt is one of the world’s most sophisticated cancer centers of excellence that employs fellowship-trained physicians and medical researchers who are among the best in their respective fields. Moffitt’s mission remains “to contribute to the prevention and cure of cancer.” One factor that distinguishes Moffitt from other institutions is the Cancer Center’s commitment to Total Cancer Care™.

Total Cancer Care™ | Total Cancer Care™ is Moffitt’s comprehensive approach to cancer care – designed to enable researchers and caregivers to identify and meet all the needs of a patient and his or her family during the patient’s lifetime and for future generations. The approach addresses cancer as a public health issue and takes a holistic approach by encompassing all aspects of the disease, including preventive measures such as the study of genetic predispositions, the impact of health lifestyles and integrative medicine.

Total Cancer Care™ Study | Moffitt’s national research protocol is open at Moffitt and at participating Total Cancer Care™ Consortium sites that have contracted to participate in the Total Cancer Care™ Study throughout Florida and in other states. (See accompanying story, page 11, for information on the Consortium.)

The protocol is a partnership among patients, doctors and researchers working to advance cancer care by maintaining a repository of human tissue specimens and clinical data. In addition to clinical information, patients donate excess tumor samples and body fluids not needed for their care.

Data are stored and may be analyzed by researchers for biological or clinical elements that may advance the care and treatment of cancer. Physicians would be able to contact patients if new information is discovered that could help in their care, including possible clinical studies. The tissue is stored at Moffitt or at Moffitt’s subsidiary, M2Gen. M2Gen assists in the collection and processing of Total Cancer Care™ Consortium Site data. (See accompanying story, page 9, for more information on M2Gen.)

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“Total Cancer Care provides the ‘data backbone’ for expanding our research into comparative effectiveness by integrating clinical and research data to identify the most effective and efficacious treatments,” says David Fenstermacher, Ph.D.

Federal CER Program And Moffitt Initiative Converge

Thanks in large part to the scope, nature and progress of the Moffitt Total Cancer Care study, the Cancer Center was awarded a new federal grant on patient-centered outcomes research called Comparative Effectiveness Research (CER). This project will expand and refine the role of information technology in the development of personalized medicine.

Through the 2009 American Recovery and Reinvestment Act (ARRA), the federal government has provided $1.1 billion nationally for comparative effectiveness research. The goal is to make health care more effective by basing treatment decisions on assessed outcomes and solid data drawn from the careful analysis of patient “subpopulations” with specific molecular markers. The Moffitt Total Cancer Care concept not only shares those goals and evaluative methods, but also provides a structure for achieving them.

Many of the research and analysis elements outlined in the ARRA CER initiative are in development with plans to expand and implement Moffitt’s Total Cancer Care project and further develop the tumor tissue biorepository.

“Total Cancer Care provides the ‘data backbone’ for expanding our research into comparative effectiveness by integrating clinical and research data to identify the most effective and efficacious treatments,” says David Fenstermacher, executive director of Biomedical Informatics at Moffitt.

Dr. Fenstermacher received a CER Grand Opportunities grant for the expansion of data management resources associated with the ever-growing biorepository and database of tumor tissue samples. (See 2009 Year-in-Review, page 5, for a list of ARRA projects awarded to Moffitt investigators.)

For Thomas A. Sellers, Ph.D., M.P.H., director of the Moffitt Research Institute, precision medicine (what some scientists are calling personalized medicine) means the selection of cancer therapy is based on the genetics of the patient and the tumor. This approach requires that the appropriate molecular tests are used to arrive at the correct diagnosis and to determine the treatment option most effective for each patient. “Getting it right requires data rather than intuition. It requires figuring out exactly which treatment is going to be most effective,” he says.

Coupling Total Cancer Care™ With CER Is “A Natural”

“It took us about a nanosecond to realize that CER was an important opportunity, critical to our mission of providing personalized medicine, and absolutely relevant to Total Cancer Care,” says Dr. Sellers. “Dr. Fenstermacher’s CER grant will help build an informational infrastructure that will improve our ability to look at and assess treatments, to see what works best by helping us evaluate the application of precision medicine.”

According to Dr. Sellers, CER will expand data management resources and help develop new ways of integrating patient data and tumor genetic profiles to identify the “Achilles heel” of a tumor and inform the appropriate therapy. Eventually, all Moffitt Total Cancer Care Consortium members will participate in a regional CER, says Dr. Sellers, as the ability to translate discoveries from scientists at Moffitt and around the world to more precise therapy requires a large population for effective validation.

Goal: Improving Lives Through Science

CER data analysis also will help support a new collaborative effort between Moffitt and the Institute for Human and Machine Cognition (IHMC), a nonprofit, Pensacola-based research institute of the Florida University System. Dr. Dalton serves on the Florida IHMC Board of Directors.

This effort involves applying science to change the future of how patients will access...
M2Gen, a wholly owned subsidiary of the H. Lee Moffitt Cancer Center & Research Institute, is now actively supporting the operation of Moffitt’s Total Cancer Care™ research initiative. M2Gen’s activities also include a research collaboration formed in December 2006 by Moffitt and the pharmaceutical company Merck & Co., Inc. A new facility that houses M2Gen opened in spring of 2009 and is located on North McKinley Drive (slightly more than a mile from the Moffitt main campus). Funding incentives for M2Gen came from many sources, including Hillsborough County, the state of Florida and the city of Tampa.

The M2Gen venture is dedicated to using molecular technology to identify biological markers unique to each patient-donated tumor, then matching the donor patients — all of whom are enrolled in the national Total Cancer Care™ Study — to select clinical trials.

“Our intent is to have consenting patients prescreened and genotyped so that information may be stored in the world’s largest cancer-centric database,” says M2Gen Chief Operating Officer Rick Garrison, B.S., M.B.A. “Mining of the database will allow us to identify patients and match them with a clinical trial.”

A driving idea behind M2Gen is to shorten the drug development cycle on behalf of the pharmaceutical and biotechnology industry so that patients can get new targeted drugs faster, explains Garrison, who leads a staff of 90 in Tampa and a total of 145 staff nationwide, counting those who work at Total Cancer Care™ Consortium sites.

The ability to select patients and match them to a clinical trial much faster than what is current industry standard will be what Garrison and others call “a game changer.”

The M2Gen operation assists in collecting and processing Total Cancer Care™ Consortium Site data and carrying out certain monitoring responsibilities. This involves receiving, analyzing and storing in its biorepository various tissue, tumor, blood and other samples from patients enrolled in the Total Cancer Care™ Study conducted at Moffitt and at Consortium sites.

According to Shane Huntsman, manager of Biorepository Operations for M2Gen, the second quarter of 2010 should see the arrival of four large freezers (18 feet wide, 12 feet deep and 10 feet high) that will keep biosamples at a crisp -80°C, or -112°F, in the approximately 2,500-square foot storage area — about the size of a few back-to-back tennis courts. The combined length of the four-unit bank will be about 80 feet.

“We will be able to store up to two-and-a-half million different-sized vials of samples,” says Huntsman.

As this annual report was in production, James D. Utterback, M.S., was named chief executive officer of M2Gen. Prior to joining M2Gen, Utterback was the founder and chairman of RxcelPartners, LLC, a corporate consultant firm to CliniRx, and a global ventures adviser.

What are some of Utterback’s expectations for M2Gen in 2010? “We will be enrolling new patients, enhancing our relationship with Merck, investigating additional commercial and research activities and expanding the Consortium internationally,” says Utterback.
identifying subpopulations of patients who would benefit most from enrolling in those trials. Ultimately, he sees the opportunity to tailor basic science research questions through the Moffitt Total Cancer Care™ database.

"Without Total Cancer Care, we would not have received the CER grant," says Dr. Craig. "Having the large database afforded by the Total Cancer Care study serving to identify subpopulations, followed by analysis through CER, we will be better able to evaluate and compare outcomes of alternative treatments. With more data, accessed through the Total Cancer Care tissue bank, patients can be recruited for clinical trials faster because we will be better able to identify distinctive subpopulations. Clinical trials will not need to last as long.

"Using genetic markers to design clinical trials is the wave of the future, but it's the wave at Moffitt today," says Dr. Craig. "There will come a day when all clinical trials will be conducted with smaller, genetically targeted populations."

**Genetic Profiling: An Essential Ingredient For Personalized Care**

Clinical trials that focus on prevention, treatment and quality of care are an essential aspect of the Moffitt Total Cancer Care™ approach to the development of personalized medicine. These clinical trials use genomic technologies — that is, technologies that pertain to assessing genetic information — to detect disease-related biomarkers. The identification of such biomarkers depends on data from patient-donated tissues that are profiled, analyzed and warehoused in the M2Gen biorepository. Because Moffitt’s clinical trials are an essential aspect of the quest for personalized medicine, both CER and Total Cancer Care™ depend on data derived from clinical trials to answer specific questions about the effectiveness of specific treatments for patients with specific genetic signatures.

"Clinical studies at Moffitt and throughout the Total Cancer Care Consortium increasingly are focused on analyzing patient molecular signatures to help predict an individual patient’s response to a specific type of cancer therapy," says Robert Wenham, M.D., principal investigator for the Total Cancer Care™ study at Moffitt. He adds that these efforts directly tie in with the CER initiatives to make better treatment decisions.

"CER provides a way to observe associations and generate ideas about how to provide better outcomes," says Dr. Wenham. "CER also provides a prospective way to compare our treatments. Doing this allows us to become more confident that we are doing what is best for the patient."

Various types of exciting studies involving Moffitt Total Cancer Care™ concepts and resources are being conducted at the Cancer Center. These studies, which focus on novel prevention and personalized treatment strategies, include:

• **Potential Risk Factors For Skin Cancer**

Moffitt epidemiologist Dana Rollison, Ph.D., is conducting two pilot projects studying...
TOTAL CANCER CARE™ CONSORTIUM MEMBERS SHARE VISION:
TO IMPROVE LIVES OF PATIENTS

As part of the Total Cancer Care™ study, Moffitt is partnering with institutions throughout Florida and across the nation to collect a global body of knowledge about cancer. Plans to further expand the Consortium sites in the United States and internationally are underway. Participating Total Cancer Care™ Consortium members are collecting tissue (both tumor and healthy), along with other key information, from thousands of patients to characterize the unique nature of each person’s tumor. As new drugs are discovered that act on specific genetic pathways, researchers can search the database to identify patients — based on their genetics and tumor type — who are most likely to respond to a specific drug’s anticancer properties. The Consortium sites, listed below, share in Moffitt’s vision and commitment to advancing scientific knowledge that leads to better treatments for cancer.

FLORIDA
Baptist Health South Florida, Miami
Boca Raton Community Hospital, Boca Raton
Watson Clinic Center for Research, Lakeland
Martin Memorial Medical Center, Stuart
Morton Plant Mease Health Care, Clearwater
Moffitt Cancer Center, Tampa (Coordinating Site)
Sarasota Memorial Health Care, Sarasota
University of Florida-Shands Hospital, Gainesville
St. Joseph’s Hospital, Tampa
Tallahassee Memorial HealthCare, Tallahassee

UNITED STATES
Carolinas Medical Center, Charlotte, NC
Greenville Hospital System, Greenville, SC
Hartford Hospital, Hartford, CT
Marquette General Health System, Marquette, MI
Our Lady of the Lake Regional Medical Center, Baton Rouge, LA
Southeast Nebraska Cancer Center, Lincoln, NE
St. Joseph’s Candler Health System, Savannah, GA
St. Vincent Hospital and Health Care Center, Indianapolis, IN
University of Louisville, Louisville, KY

potential risk factors for skin cancer that rely on Moffitt Total Cancer Care™ resources.
The first study, “Pilot case-control study of telomere length in melanoma,” seeks to evaluate the association between telomere length in peripheral blood leukocytes and melanoma. Should telomere length be associated with melanoma, then novel risk assessment strategies could be developed to identify those individuals at highest risk for disease. Her second study, “Merkel cell polyomavirus (MCV) and Merkel cell carcinoma,” will investigate the

CONTINUED ON NEXT PAGE
association between a newly discovered virus, MCV, and Merkel cell carcinoma, a rare neuroendocrine skin cancer. Should MCV be shown to be a cause of Merkel cell carcinoma, then novel prevention and therapeutic strategies could be developed.

**Predicting Response To Chemotherapy**

Johnathan Lancaster, M.D., Ph.D., is leading a study titled “Molecular profiling to predict response to chemotherapy.” It is a phase II National Cancer Institute-supported trial. “Ovarian cancer is the most lethal of the gynecologic cancers,” says Dr. Lancaster. “It kills more women than any other type of gynecologic cancer. Patients do well initially until they become resistant to chemotherapy; then they fail rapidly.” For years the challenge with ovarian cancer treatment has been that treatment is empiric. Clinicians try drug after drug until they find one that works. Response rates, however, are poor, with only one in five or so patients with resistant disease responding to any given treatment. Basic science and clinical researchers at Moffitt are studying the biology of ovarian cancer to determine what drives this resistance. Several clinical trials, developed under Moffitt’s push for more personalized cancer treatment, are showing signs of promise.

**Combination Therapy For Metastatic Colorectal Cancer**

Jonathan Strosberg, M.D., is initiating a project using information and tissue samples from the Total Cancer Care™ project in a trial with a novel biologically targeted drug, anti-IGF1R, in combination with standard chemotherapy in patients with metastatic colorectal cancer.

**Applying SPORE Grant Research To Personalized Medicine**

As reported in last year’s annual report, the National Cancer Institute awarded a SPORE (Specialized Programs of Research Excellence) grant in lung cancer to Moffitt’s Thoracic Oncology Program. Moffitt physician and researcher Eric B. Haura, M.D., leads the SPORE grant. Lung cancer SPORE research directly ties in with Moffitt’s Total Cancer Care™ approach to personalized medicine. It involves basing the selection of treatment on molecular and genetic characteristics of tumors and using either gene therapy or immunomodulatory drugs to enhance the ability of the immune system to recognize and destroy cancer cells.

These kinds of studies make good use of the Total Cancer Care™ biorepository and information technology resources to more effectively design and personalize treatment. In all these studies, the personalized medicine approach takes into account variations in each patient’s DNA, as well as variations in each patient’s tumor tissue. Additional new trials using Total Cancer Care™ information or tissue to inform clinical treatment are in development.
CER Aims At Improving Health Care Outcomes

Data gleaned from CER will be analyzed by Moffitt researchers, and the information will be placed on an evidence pyramid.

This involves raising the standard of care for all patients by integrating new technologies in an evidenced-based approach to maximize patient benefit.

When the term “evidence-based medicine” was coined in the 1990s, it formalized the hierarchy of evidence of what had come to be called the evidence pyramid. Randomized, controlled clinical trials provide investigators with data that can be put near the top of the pyramid. In vitro (test tube) research sits at the bottom of the pyramid. Data from CER will help decipher what works and what does not.

Knowledge of what works clinically and what doesn’t must be evidence-based, yet evidenced-based medicine does not replace the human factor, the physician’s judgment as he or she cares for the patient. The data help inform the physician so that he or she can make better decisions.

The implementation of CER will further enhance the global Moffitt Total Cancer Care project in identifying the best treatment for individual patients by integrating new technologies into the standard of care in an evidence-based fashion,” says Dr. Dalton. He stresses that the well-being of each cancer patient during his or her life journey is paramount. “Patients remain at the center of the growing Total Cancer Care collaborative network of researchers, health care providers and administrators who, together, are working to realize the vision of discovering, translating and delivering personalized cancer care.”

PROGRAM HELPS MEET NEEDS OF SURVIVORS

Moffitt is helping cancer survivors improve their quality of life after treatment through a special clinic that is part of the Cancer Center’s Survivorship Program. This new program is part of Moffitt’s Total Cancer Care™ approach – an important element in finding new and improved cures for cancer.

The Survivorship Clinic accepts patients who have completed their initial cancer treatment and have a favorable prognosis. Patients are selected and referred by their Moffitt medical and surgical oncologists.

“We recognize that patients may have complex needs following successful treatment,” says Richard Gross, M.D., medical director of the Survivorship Program. “We provide a multidisciplinary approach, monitoring for long-term and late effects from treatment and possible recurrences. We try to refocus patients on wellness, including prevention, screening and lifestyle modifications they can control to improve their health.”

Participating survivors now can access their patient records and personalized survivorship care plans via a patient portal.

Jane Edwards, 85, of Bradenton, Florida, first diagnosed and treated at Moffitt in 1996, is a long-time cancer survivor taking part in the Survivorship Program.

“Everyone always makes me feel comfortable and confident,” she says. “It’s a very special place. That’s why I have been coming back all these years.”

Jane Edwards

L-R: Kathy Daily, R.N., Dawn Kettner, P.A.-C., and Sharon Phelps. A multiple myeloma survivor, Phelps is participating in a clinical trial at Moffitt.
The addition of a second da Vinci® Surgical System is allowing Moffitt surgeons to perform even more complex and delicate procedures through very small incisions with unmatched precision. At the end of fiscal year 2009, 371 robotic-assisted surgical procedures had been performed at the Cancer Center.

“Our extensive experience with laparoscopy and the addition of robotic technology provides patients with state-of-the-art minimally invasive surgery,” says Julio Pow-Sang, M.D., director of the Moffitt Robotics Program, and department chair, Genitourinary Oncology at Moffitt.

**Surgical Applications Expand**

Currently Moffitt surgeons perform robotic surgery on patients with prostate and other urologic cancers, uterine and other gynecologic cancers and lung (thoracic) cancers, as well as certain endocrine tumors.

**Lung Cancer**

The first robotic lung surgery in Tampa Bay recently was performed at Moffitt (see story, page 15). Lung surgeries are complex operations because of the large vessels leading to and from the lungs and heart. Unlike the traditional open-chest method, the da Vinci® Surgical System promises minimal trauma to the patient and better surgical results, according to Moffitt thoracic surgeon Eric Sommers, M.D.

**Endocrine Tumors**

W. Bradford Carter, M.D., leader of Moffitt’s Endocrine Tumor Program, is performing robotic-assisted adrenal surgery. In October 2009 he performed a robotic-assisted adrenalectomy for pheochromocytoma, a rare tumor.

Moffitt has plans to expand its surgery services to include robotic-assisted surgery for the removal of thyroid tumors in 2010.

Dr. Pow-Sang also plans to develop educational programs to train the future generations of surgeons in robotic procedures.

**Urologic Surgery**

Typically referred to as robotic surgery for prostate cancer or robotic prostatectomy, this procedure is quickly becoming a popular treatment for removal of the prostate following early diagnosis of prostate cancer. With da Vinci® robotic-assisted prostatectomy, the likelihood of a complete recovery from prostate cancer without long-term side effects is, for most patients, better than it has ever been, notes Dr. Pow-Sang.

Moffitt urologic surgeons Wade Jeffers Sexton, M.D., and Philippe E. Spiess, M.D., are performing robotic-assisted surgery for patients with kidney cancer, and Drs. Pow-Sang, Sexton and Spiess are using this technology to perform surgery for patients with bladder cancer. Additionally, Dr. Pow-Sang has experience using robotic-assisted surgery to perform retroperitoneal lymph node dissection to remove abdominal lymph nodes in treating testicular cancer.
GOLFER RETURNS TO LINKS AFTER ROBOTIC-ASSISTED LUNG SURGERY

“Moffitt saved my life,” says Ray Berkelbach, who underwent da Vinci® robotic-assisted lung surgery for stage I lung cancer – the first such procedure performed in Tampa Bay. The Punta Gorda resident has had much to celebrate recently – his 50th high school reunion in 2008 and a lifesaving surgery in 2009. Berkelbach says that shortly following surgery he was outside walking three times a day. And to his delight, within six weeks of surgery he was back on the golf course. “It was amazing,” he says, of his surgery experience and rapid recovery, because he soon was able to perform all the activities associated with the game, including swinging and carrying his golf clubs.

“It was a good experience at the Center,” says Berkelbach. “I was treated very nicely. They did all the right things.” He says he wasn’t scared at all going in and that his thoracic surgeon, Eric Sommers, M.D., and Joe Garrett, A.R.N.P., “were great!”

Gynecologic Surgery

For gynecologic oncology patients who are candidates for robotic surgery, the system presents numerous advantages. With the precision, 3-D vision and dexterity of robotic technology, Moffitt gynecologic oncologists can offer the benefits of minimally invasive surgery to a greater number of patients. The robotic platform also allows the surgeon to perform more complex laparoscopic procedures with a greater margin of safety and efficiency, according to Sachin Apte, M.D., member of the Gynecologic Oncology Program, who performs these procedures together with William Roberts, M.D.

Lung surgeries are complex operations because of the large vessels leading to and from the lungs and heart. Unlike the traditional open-chest method, the da Vinci® Surgical System promises minimal trauma to the patient and better surgical results...

Greater Speed, Precision and Safety

Many surgical procedures performed today using standard laparoscopic techniques can be performed with greater speed, precision and safety using the da Vinci® Surgical System. Every surgical maneuver is performed with direct input from the surgeon. The system translates the surgeon’s hand, wrist and finger movements into precise, real-time movements of special instruments during the surgical procedure.

“Conventional open and laparoscopic surgery remains an important component of cancer treatment here at Moffitt,” says Dr. Pow-Sang. “Not all patients are optimal candidates for surgery, and Moffitt’s physicians help to weigh the risks and benefits to help patients select the best cancer treatment for their individual situation.”

If you or someone you know would like to learn more about this new treatment option, please call Cancer Answers at 1-888-MOFFITT.
### CONSOLIDATED BALANCE SHEET

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2009</th>
<th>June 30, 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASSETS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current Assets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash &amp; Cash Equivalents</td>
<td>$3,653,538</td>
<td>$8,050,115</td>
</tr>
<tr>
<td>Current Portion of Assets Limited as to Use</td>
<td>$14,372,780</td>
<td>$17,706,212</td>
</tr>
<tr>
<td>Current Portion of Pledges Receivable</td>
<td>$11,083,706</td>
<td>$10,912,755</td>
</tr>
<tr>
<td>A/R Less Allowance for Uncollectibles</td>
<td>$63,214,085</td>
<td>$72,089,591</td>
</tr>
<tr>
<td>Other Current Assets</td>
<td>$30,902,028</td>
<td>$26,571,306</td>
</tr>
<tr>
<td><strong>Total Current Assets</strong></td>
<td>$123,226,137</td>
<td>$135,329,979</td>
</tr>
<tr>
<td>Assets Limited as to Use, Net of Current Portion</td>
<td>$159,864,335</td>
<td>$210,375,498</td>
</tr>
<tr>
<td>Pledges Receivable, Net of Current Portion</td>
<td>$2,675,129</td>
<td>$6,406,464</td>
</tr>
<tr>
<td>Property, Plant &amp; Equipment</td>
<td>$353,713,338</td>
<td>$275,003,846</td>
</tr>
<tr>
<td>Construction in Progress</td>
<td>$5,432,287</td>
<td>$52,695,252</td>
</tr>
<tr>
<td>Other Assets</td>
<td>$2,383,238</td>
<td>$2,558,765</td>
</tr>
<tr>
<td><strong>Total Assets</strong></td>
<td>$647,294,464</td>
<td>$682,369,804</td>
</tr>
</tbody>
</table>

|                     |                |                |
| **LIABILITIES AND NET ASSETS** |                |                |
| Current Liabilities  | 96,618,127     | $119,376,078   |
| Other Liabilities    | 3,340,657      | 3,363,635      |
| Long-Term Debt, Net of Current Portion | 195,296,999   | 205,192,441    |
| **Net Assets**       | 352,038,681    | 354,437,650    |
| **Total Liabilities and Net Assets** | $647,294,464 | $682,369,804  |

#### Patient Care

<table>
<thead>
<tr>
<th></th>
<th>FY 09</th>
<th>FY 08</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admissions</td>
<td>7,742</td>
<td>7,482</td>
</tr>
<tr>
<td>Outpatient Visits</td>
<td>289,502</td>
<td>272,687</td>
</tr>
<tr>
<td>Patient Days</td>
<td>51,916</td>
<td>47,388</td>
</tr>
<tr>
<td>Average Length of Stay</td>
<td>6.6 days</td>
<td>6.3 days</td>
</tr>
</tbody>
</table>

#### 2009 Payer Mix

- 23% Medicare
- 52% HMO/PPO
- 8% Medicaid
- 2% Medicaid Managed Care
- Other 7%
- Medicare Managed Care 6%
- Commercial <1%
- Private Pay 2%
### CONSOLIDATED STATEMENT OF REVENUE AND EXPENSES

#### REVENUE

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2009</th>
<th>June 30, 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Patient Service Revenues</td>
<td>$484,528,611</td>
<td>$406,311,045</td>
</tr>
<tr>
<td>Other Revenues</td>
<td>77,111,308</td>
<td>73,370,620</td>
</tr>
<tr>
<td>Net Assets Released from Restrictions and Used for Operating Expenses</td>
<td>38,257,243</td>
<td>30,005,916</td>
</tr>
<tr>
<td>Total Unrestricted Revenue and Other Support</td>
<td>$599,897,162</td>
<td>$509,687,581</td>
</tr>
</tbody>
</table>

#### EXPENSES

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2009</th>
<th>June 30, 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Expenses</td>
<td>$570,863,859</td>
<td>$488,804,976</td>
</tr>
<tr>
<td>Depreciation and Amortization</td>
<td>37,217,051</td>
<td>34,499,509</td>
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<tr>
<td>Interest</td>
<td>6,770,696</td>
<td>4,897,066</td>
</tr>
<tr>
<td>Provision for Bad Debts</td>
<td>5,299,524</td>
<td>6,861,028</td>
</tr>
<tr>
<td>Total Expenses</td>
<td>$620,151,130</td>
<td>$535,062,579</td>
</tr>
</tbody>
</table>

(Loss) from Operations $(20,253,968) $(25,374,998)

Non-operating (Losses) Gains, Net (1,218,772) 4,659,495

(Deficiency) of Revenues and Gains over Expenses and Losses $(21,472,740) $(20,715,503)

### 10 Most Frequent Cancer Sites: 2008*

- Breast 12.39%
- Skin** 12.70%
- Other Sites 32.49%
- 9.37% Bronchus and Lung
- 7.11% Prostate
- 5.09% Colorectal
- 5.00% Non-Hodgkin’s Lymphoma
- 3.94% Leukemia
- 3.01% Bladder
- 3.00% Kidney
- 3.00% Pancreas
- 2.90% Other Hematopoietic and Reticuloendothelial Systems

### Moffitt Patient Origin FY 2009

- Pasco County 12%
- Hillsborough County 38%
- Others Florida 24%
- Non-Florida 2%
- Pinellas County 10%
- Polk County 5%
- Hernando County 3%
- Manatee County 3%
- Sarasota County 3%

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* Includes analytic and non-analytic cases for accession year 2008
** Excludes basal cell and squamous cell carcinoma
Source: Cancer Registry

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2009 Annual Report | Moffitt Cancer Center
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Member-at-Large
Five years ago, a group of passionate individuals had a little idea that struck a big chord. Their plan: Give the community a meaningful and affordable way to help find a cure for cancer. Give them a venue to express their passion that involves health and fitness. Give them a message of hope that an end to a dreadful disease is possible… and they will come. And they did.

Each year, on a Saturday in May, they arrive by the thousands to be part of Miles for Moffitt, which is five races in one — 5K, Five-Mile, One-Mile, Kids Fun Run and Ultra Endurance event — held at the USF Sun Dome.

They are runners, walkers, cancer survivors, families, friends, coworkers, physicians, researchers, nurses and volunteers — all with one cause in mind. They want to support a loved one who has experienced cancer and raise money for cancer research.

In four years, the race has earned $355,000 for Moffitt’s cancer research programs.

Joining Florida Bank as major sponsors are the Tampa Bay Rays as Presenting Sponsor, Gerdau Ameristeel as Survivor Celebration Sponsor and Greenberg Traurig as the Ultra Endurance Race Sponsor.

New to the family of sponsors are the St. Petersburg Times and 10 Connects WTSP who are graciously providing media support along with WFUS-FM US103.5 and WMTX-FM Mix 100.7.

The generosity of all the sponsors helps cover expenses so that 100 percent of race entry fees and individual donations goes directly to support research programs at Moffitt.

“Presenting a check to young cancer investigators every year is the proudest moment for the race board of directors,” said Mrs. Dalton, wife of Moffitt CEO William S. Dalton, Ph.D., M.D., who, together with Race Sponsor Chair Priscilla Mack, wife of Senator Connie Mack, chair emeritus, Moffitt Board of Directors, presents the Milestone Award check at Moffitt’s annual Scientific Retreat conference.

E-Newsletter Signup Moffitt’s bimonthly e-newsletter, Moffitt MOMENTUM, covers a range of cancer prevention and treatment topics, along with the ForkWise™ nutrition tips and healthy recipes column. To subscribe, visit InsideMoffitt.com, enter your e-mail address in the E-Newsletter Sign-Up Section, and click “Submit.” Or you can send us your thoughts at moffitt.momentum@moffitt.org.