


A young girl with braids is laughing joyfully while a doctor in a white coat uses a stethoscope on her chest. The doctor is leaning over her, and the girl has her mouth wide open in a hearty laugh. The scene is set in a clinical or hospital environment.

The Institute
for Pediatric
Innovation

2007

ANNUAL REPORT



IPI stimulates public, private, nonprofit, and for-profit collaboration to develop products to improve pediatric care.

Our Vision

With a Consortium of national leaders in pediatric care, we are identifying those areas where new products are most needed to **improve quality of care**.

We are qualifying the needs identified by the Consortium and designing products to meet these needs with the help of a unique resource network.

IPI will **offer product opportunities for commercial adoption** by companies that seek to extend the fruits of medical innovation to our society's youngest beneficiaries.

From the CEO

To our many friends, supporters, and stakeholders,

We started the year with an organizational concept for realizing our mission; a hard-working group of volunteers; several interested potential sponsors; and service delivery models for pediatric and industry stakeholders. The challenge was to translate all this potential into deals, action plans, works in progress, and the resources to support our work.

IPI closed 2007 with three world-class pediatric institutions as financial sponsors and program collaborators; two corporate sponsors; an eight-member board that includes national figures in pediatric care; three full-time staff members; our own offices at Cambridge Innovation Center in Kendall Square; a small portfolio of neonatal care product opportunities under intensive analysis; and action plans for evaluating needs for pediatric medical device technology. The latter includes tools for cardiac care and pharmacy technology to produce liquid oral formulations.

In addition, IPI has initiated a major program to reformulate off-patent drugs that require new dosage and delivery forms for pediatrics. Further, IPI has attracted Stephen Spielberg, MD, PhD, a national leader in pediatric drug development, to execute this project with us. We closed the year with cash and contractual commitments already in hand to underwrite the bulk of a robust program in 2008.

This annual report includes some of the details about how we launched this exciting social venture. It is the work of many hands. Staff members Ross Trimby, chief operating officer, and Caron D'Ambruso, RN, vice president for product innovation, will describe the highlights of our pediatric hospital consortium program and our corporate sponsored project in neonatal care. Dr. Stephen Spielberg, board member and now principal investigator for the IPI Pediatric Pharmaceutical Reformulation Program, will outline the scope of this effort.

I would like to especially thank the following people who have shared the IPI vision and helped significantly in bringing it into reality: Jonathan Fleming and Ellen Baron (Oxford Bioscience Partners); Anthony Atala (Wake Forest Baptist Medical Center); Jonathan Rosen and Jerry Schaufeld (founding Board members); Lesa Mitchell (Ewing Marion Kauffman Foundation); Cathy Bush (Children's Medical Ventures); John Barr (AGA Medical Corporation); our friends, collaborators, sponsors and Board members from our three Consortium hospitals: Children's Mercy Hospitals and Clinics, Lucile Packard Children's Hospital at Stanford, and University Hospitals Rainbow Babies and Children's Hospital; and friends, family and colleagues who have assisted as Children's Angels.

Along with our strategic partners and supporters, I look forward with tremendous excitement to the work and challenges that lie ahead, and to the progress I know we will make together to improve care for our smallest patients.

Donald Lombardi
President and Chief Executive Officer



"The Institute for Pediatric Innovation (IPI) has completed an extraordinary year, marked by exciting growth of staff, fiscal support, important partnerships, and enthusiasm for our mission. We are pleased to provide this 2007 annual report to the many people who are interested in IPI and its mission of improving pediatric care through product innovation."

"If one problem is solved as a result of our needs survey backed by the strength of the Consortium, then we have achieved a significant milestone in the care of infants and children."

Caron D'Ambruso, RN
*Vice President,
Product Innovation*



AN EXCITING START

The tasks of hiring staff, securing funding, and finding and organizing office space were critical steps that laid a strong foundation for IPI's "real" work during 2007. This work included the creation of the IPI Pediatric Hospital Consortium, which today includes three world-class pediatric hospitals:

- Lucile Packard Children's Hospital at Stanford;
- Children's Mercy Hospitals and Clinics in Kansas City, MO; and
- University Hospitals Rainbow Babies and Children's Hospital in Cleveland, OH.

Along with the Consortium hospitals, our work centered around three main areas:

- NICU product opportunity analysis;
- Resource inventories; and
- Pediatric pharmaceutical reformulation program.

NICU PRODUCT OPPORTUNITY ANALYSIS

The neonatal intensive care unit (NICU) is a clinical area often overlooked by device manufacturing corporations. Many products in the NICU today are adult products that, while FDA-approved, are not optimized for infants.

In an effort to address this unmet market need and to develop NICU-specific products, IPI worked with its Pediatric Hospital Consortium to analyze the current state of NICU equipment and identify needs. We interviewed clinical staff in each NICU to understand their unmet needs and challenges in caring for their patients. Consortium member hospitals opened their doors for this research, subject to HIPAA standards and hospital protocols. The hospitals permitted IPI to spend two to three days in their NICUs to ask about equipment challenges in this setting.

The needs identified by each of the Consortium hospitals overlapped in many areas. The largest areas of concern involved respiratory care, comfort and security of the infant, and the use of adhesives on infants' delicate skin. In addition to these common themes, IPI also uncovered new and valuable information from each of the hospitals due to the diversity of staff and the varied NICU environments and procedures at these institutions.

IPI next conducted a quantitative on-line survey of 100 neonatology physicians and NICU nurses from hospitals throughout the nation. The survey verified the results of the qualitative research, quantified the relative importance of needs identified by the consortium, and helped us determine the most widely perceived needs in the NICU.

Using this information, IPI conducted a product imagination workshop in December 2007 with one of our sponsors, Children's Medical Ventures, along with IPI executives, a nurse clinician from one of the Consortium hospitals, and Product Genesis, an engineering strategy and design group based in greater Boston. The next phase will be to select two product opportunities for detailed analyses and commercialization.

RESOURCE INVENTORIES

In order to build a sound, long-term basis for collaboration, IPI worked with each Consortium hospital to identify its key assets relevant to our shared mission. To obtain baseline information, IPI conducted a two-day resource inventory in each Consortium hospital. The objectives were to characterize the size and activity volume of the hospitals; identify key clinical and research staff members at each institution who could contribute to the innovation process; begin to identify needs that could potentially be addressed by new products; categorize current organizational structures, processes, and resources that could contribute to the innovation mission; and understand patient care infrastructure for quality improvement, safety, and professional development at each institution.

IPI provided detailed reports of the resource inventories, including primary sources of innovation, innovation support resources, and institutional services. Staff at each institution indicated that medication reformulation was a serious issue. We also found a common need for automated liquid drug reformulation systems. These systems could improve the ability to accurately and efficiently dispense individualized liquid oral doses.

PEDIATRIC PHARMACEUTICAL REFORMULATION PROGRAM

While much progress has been made to provide pediatricians information on the safe and effective use of medicines in children, many medicines are not available in a dosage or delivery form that is optimized for use by children and their families. Extemporaneous preparations of medicines may simply not be available, and those that are, often are not validated for quality. The gap in availability of safe, stable, validated, and palatable formulations defines the need for a robust portfolio of new, differentiated, value-added formulations of existing medicines.

IPI's Pediatric Pharmaceutical Reformulation Program focuses on existing medicines that already have FDA approval for use in children, but that require reformulation to enhance their safe, effective, and compliant use. We have consulted with the FDA, the National Institute of Child Health and Human Development (NICHD), United States Pharmacopeia (USP), the World Health Organization (WHO) and other public and private organizations to define needs and to develop new medicinal products for children.

Members of the Pediatric Hospital Consortium have provided detailed data on the compounds they reformulate. Our advisors and other collaborators have agreed to participate at critical stages of defining product needs and specifications, and in evaluating products as they are developed. IPI will work with our colleagues at all levels to help develop initial formulations, and to work with commercial entities who can convert concepts into products for pediatric use that are manufactured and marketed according to Good Manufacturing Practice (GMP) standards.

Children's Mercy Hospital and Clinics in Kansas City, one of our hospital partners, has provided initial funding for the program. The hospital's leadership in pediatric care and in pediatric therapeutic research promises to be the basis for a successful and rewarding collaboration.

"The enthusiasm with which clinical and administrative staff members at our Consortium hospitals are working with IPI is amazing."

Ross Trimby
Chief Operating Officer



"I've joined IPI because I believe the timing is right, the technology is available, and the partnerships are in place to drive real advances that can benefit children."

Stephen Spielberg,
MD, PhD
Principal Investigator



FISCAL YEAR 2007 WAS A YEAR OF SOLID FINANCIAL GROWTH FOR IPI

IPI began the year with one employee, Donald Lombardi, Founder and CEO, working out of contributed office space in the offices of Oxford Bioscience Partners. IPI had been awarded a \$96,600 grant from the Ewing Marion Kauffman Foundation along with two individual contributions in FY 2006 totaling \$20,000. IPI started 2007 with \$27,443 cash on hand and net assets of \$26,740. Total recognized revenue in FY 2006 was \$54,049.

Financial Summary

FISCAL AND ORGANIZATIONAL HIGHLIGHTS FROM 2007 INCLUDE:

- Won a twelve-month \$250,000 development contract from Children's Medical Ventures to investigate and analyze product opportunities in the neonatal intensive care clinical unit of its member institutions.
- Contracted with three pediatric hospitals with the support of \$100,000 each to become founding IPI Pediatric Hospital Consortium members. Each hospital has subsequently extended its commitment for an additional year.
- Received an unrestricted grant in the amount of \$100,000 from AGA Medical Corporation, a private medical device company specializing in cardiac closure devices for pediatric patients.
- Received a \$300,000 grant to support a new drug reformulation project from Children's Mercy Hospitals and Clinics.
- Finished FY 2007 with net assets of \$423,785 including cash of \$359,048.
- Earned ordinary income of \$505,552, a 935% increase over the previous year, and 96% of budget.
- Recorded a \$92,832 net surplus for the year.
- Engaged the audit firm of Linda M. Smith, CPA, to conduct an audit covering 2007.
- Finished the year with:
 - three full-time employees;
 - a company-supported employee health care plan;
 - a company-provided 401K plan;
 - a 350-square foot furnished office in the Cambridge Innovation Center;
 - an expanded, eight-member board of directors; and
 - 63% of targeted FY 2008 ordinary income accounted for in signed contracts or prepaid deposits.

Donald P. Lombardi
President and Chief Executive Officer

Stephen Spielberg, MD, PhD
Principal Investigator

Ross Trimby
Chief Operating Officer

Caron D'Ambruso, RN
Vice President for Product Innovation

Leadership

BOARD OF DIRECTORS

Ellen Baron, PhD
Partner
Oxford Bioscience Partners

Philip A. Cola
Vice President for Research and Technology
University Hospitals Case Medical Center

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Lucile Packard Children's Hospital at Stanford

Charles Homer, MD, MPH
Chief Executive Officer
National Initiative for Children's Healthcare Quality

Donald P. Lombardi
President and Chief Executive Officer
Institute for Pediatric Innovation

Randall L. O'Donnell, PhD
President and Chief Executive Officer
Children's Mercy Hospitals and Clinics

Stephen Spielberg, MD, PhD
Principal Investigator
Institute for Pediatric Innovation

Ross Trimby
Chief Operating Officer
Institute for Pediatric Innovation

ACCOUNTING ADVISOR

Linda Smith
CPA
Linda M. Smith, CPA, P.C.

LEGAL ADVISOR

Karin A. Gregory, Esq.
Partner
Furman Gregory Hahn pllc

"IPI is at the nexus of great university research and industry/venture partnerships with the goal of developing innovations that will change the face of children's health care.

IPI brings forth this opportunity by collaborating with the best children's research institutions in the country. In less than a year, IPI has proven itself to be an example of **venture philanthropy at its finest.**"

Lesa Mitchell
*Vice President for Advancing Innovation
Ewing Marion Kauffman Foundation*