



Bronchoscopy Unit Consolidation and Expansion Project

Level III Business Plan

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Submitted May 27, 2009

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EXECUTIVE SUMMARY

This plan outlines the resources needed to support the continued growth of the bronchoscopy program in the Respiratory Institute. Expansion and improvement of this clinical program is a critical element of the Institute's strategic agenda and is essential for its continued financial success and academic prestige. The clinical applications for bronchoscopy are expanding each year and the service shows great promise for treating and attracting many new patients. By combining an unparalleled commitment to basic and clinical research and immediately applying new discoveries to clinical practice, the bronchoscopy service will improve its clinical volumes and revenues and position itself at the forefront of one of the most promising areas of pulmonary medicine.

A summary of the critical elements of this plan is detailed below:

Program Description and Rationale

- Bronchoscopy is a “destination” service with over 60% of patients originating outside Northeast Ohio. Strengthening the service will solidify our reputation as a leading airway center and positively impact our US News ranking (currently # 5).
- This is not a proposal for a new line of business – historic and projected volume trends and profitability are the strongest rationale for this plan.
- Failure to create capacity in bronchoscopy will stunt the growth in other areas like lung transplant, radiation therapy and lung cancer.
- This project is consistent with and supportive of Cleveland Clinic's strategic priorities.
- With aggressive physician recruitment by competitors and no addition of space for bronchoscopy in the last 20 years, we are at risk of losing key physicians and crippling our pulmonary service line.

Market Analysis and Needs Assessment

- The current delivery of bronchoscopy services is inefficient, unfriendly to patients and restricts capacity for future growth and innovation.
- Volume has more than doubled in the last 6 years and new procedures are creating potentially explosive new demand.
- The increase in underlying disease prevalence - even in a shrinking NE Ohio population - is a rational justification for expansion.
- We are building on existing strength relative to local, regional and national competitors.

Implementation Plan

- Many other departments will be positively impacted by implementation of this plan – primarily by creating capacity for their own program growth or improving their efficiency. Those services whose resources demands may be impacted have been consulted. Anesthesia labor expense and revenue analysis is outlined in the Appendix to this plan.
- There will be no change to the program management or staffing model. Incremental staffing needs are variable and volume-driven – not based on operational implications of this plan *per se*.

- We have delineated a plan to accommodate interim growth and have envisioned a way to create additional capacity should demand exceed our forecast.

Financial Analysis

- The total capital outlay required is \$2.38 million (\$3.8 construction cost minus \$1.2 received philanthropy)
- Approximately \$2 million was budgeted in the backfill plan leaving \$352,448 in unbudgeted, unfunded incremental capital needed.

<i>Net Present Value (5 years)</i>	<i>\$1.96 million</i>
<i>Return on Investment (5 years)</i>	<i>159%</i>
<i>Internal Rate of Return (5 years)</i>	<i>30.1%</i>
<i>Payback Period (in years)</i>	<i>3.4</i>

PROGRAM DESCRIPTION AND RATIONALE

Proposed Service/Program

The proposed bronchoscopy suite will be located on F26 in existing vacant space (prep/recovery and administrative areas) and in procedure room space to be vacated by the EP lab. The project allows not only for the consolidation of services which are currently geographically distributed across 7 locations, but it also creates additional capacity for growth.

Over the last 6 years, the volume for bronchoscopy service has increased 95% putting a serious strain on resources. Demand has been driven by several factors including:

- Growth in other services that create the need for bronchoscopy (e.g. each lung transplant patient will have 6 surveillance bronchoscopies in first year post transplant)
- Growth in pulmonary patient volume
- Advances in bronchoscopy which create “new market” – treatments or procedures that were not formerly available (see page 10 for examples)
- Increasing complexity of both diagnostic and therapeutic procedures resulting in longer procedure time, deeper sedation and the need for new room configuration
- Increase in MICU service

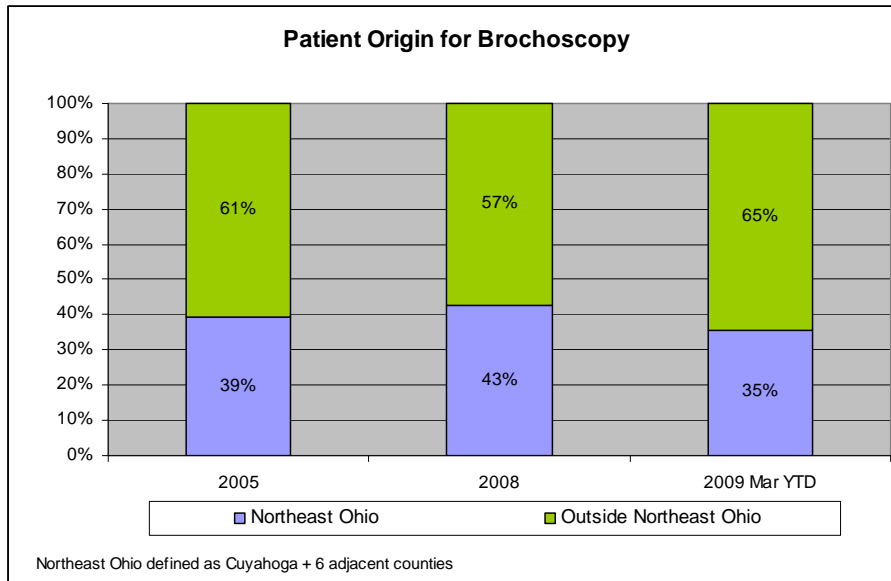
To accommodate the growing demand for services, the bronchoscopy service has negotiated with other clinical services to have access to their unused procedure room space. Although effective in allowing growth in the short term, this solution is not stable or sustainable.

The co-location and expansion of the bronchoscopy program will achieve the following:

- Positively impact the patient experience
- Increase inpatient throughput
- Facilitate shared practice models for complex airway management - Center for Major Airway Diseases (Thoracic surgery, ENT, Anesthesia, Pulmonary Medicine)
- Improve efficiency and productivity
- Create capacity for continued growth in profitable bronchoscopy procedures
- Create capacity for growth in critical services that require support from the bronchoscopy service
- Allow for the delivery and continued advancement of more complex, state-of-the-art, break-through procedures
- Attract clinical research funds
- Attract philanthropic contributions
- Positively impact the reputation of the Institute
- Facilitate the recruitment and retention of top clinicians and trainees

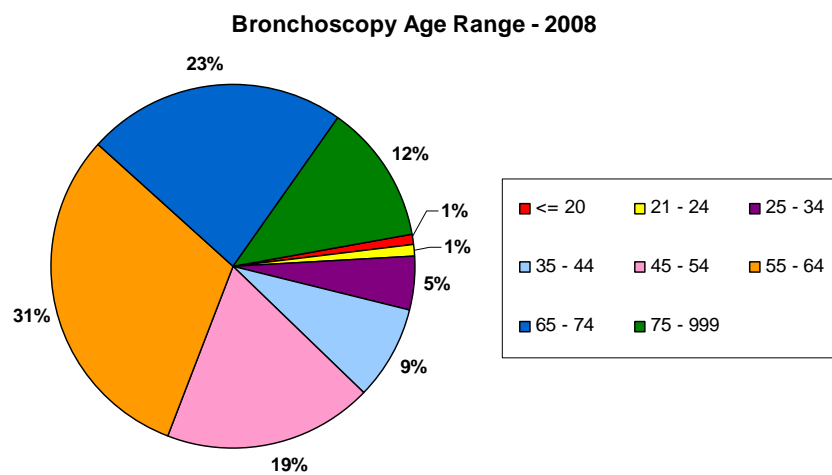
Population to be served

Interventional Pulmonary Medicine has evolved into an entirely new specialty practice built around the bronchoscopy spectrum of procedures. New techniques, equipment, professional staff and extending new indications have resulted in massive demand of increasingly complicated procedures. Bronchoscopy is no longer a “down-stream” procedure driven exclusively from referrals from other practices, but is now a destination referral program for therapeutic procedures.



In 2008, well over half of bronchoscopy patients came from outside our immediate service area. This demonstrates the nature of this program as a regional and national referral center. With the enhancements to the program proposed in this plan, it is expected that out-of-market referrals will increase.

Below is the age distribution of bronchoscopy patients at Cleveland Clinic. As earlier interventions have become possible, the age distribution of patients has shifted downward slightly over the past 5-10 years.



Strategic Relevance

This project supports Cleveland Clinic Health System goals in the following ways:

CCHS Goal	Relevance
Patients first	<ul style="list-style-type: none"> • Providing state-of-the-art diagnostic and treatment in a convenient, patient-friendly facility. • Easy access from the first floor of the Glickman Building with patient drop-off on E 96th Street possible
Safety, Quality and Operations	<ul style="list-style-type: none"> • Improved efficiency in staffing and • Improved access to services and availability of same day service and consults • On-site pathology resulting in shorter procedure time and elimination of the need for iterative procedures on the same patient • Streamlined operations using equipment that is most appropriate • Physicians and support staff co-located to facilitate communication and safety • Improved hospital throughput since inpatients will no longer have to wait for OR time (currently one day per week) to receive advanced procedures
Smart Growth	<ul style="list-style-type: none"> • Generates a positive margin as a stand-alone • Allows for continued growth in Respiratory and other clinical programs (e.g. Bariatric Surgery, Digestive Disease, Head and Neck, etc)
Research and Innovation	<ul style="list-style-type: none"> • There is no procedure performed anywhere else in the world that is not commonly done here. This attracts research funds and vendor support • Capacity allows CCF to lead multi-center trials of new treatments • Enrollment of more clinical trial patients <ul style="list-style-type: none"> ✓ Fiducial implants ✓ Dye Marking ✓ Cryotherapy ✓ Thermoplasty ✓ Lung Volume Reduction ✓ Systematic Mediastinal Staging
Excellence in Education	<ul style="list-style-type: none"> • the new suite will strengthen our CAST program by providing a comprehensive training experience for enrolled physicians • Olympus America (vendor) would like to make CCF the first Center of Excellence in Pulmonary Medicine / Bronchoscopy – making Cleveland Clinic a destination training site for bronchologists around the world

Great Place to Work and Grow	<ul style="list-style-type: none"> • Physician retention and recruitment – the current situation is a staff dissatisfier • Improved communication enhances teamwork and shared knowledge
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SWOT Analysis

Strengths – *Factors that can advantageously position the service in the market. These include features that are beneficial and/or unique to this program or service.*

- Longstanding reputation for innovation and clinical leadership
- Dedicated and stable physician and nursing leadership
- Strong volume from internal “feeder” programs (transplant, cancer, MICU, pulmonary sub-specialties)
- The program already enjoys “destination” status – attracting patients from outside the primary service area and mitigating the risk of continued economic decline in NE Ohio.

Weaknesses – *Those characteristics that detract from the service line’s success. The identified weaknesses may be a result of not having the proposed product or service.*

- Capacity constraints due to equipment limitations and inefficiency of geographic dispersion
- Lack of state-of-the-art equipment in all procedure locations
- Based on anecdotal feedback, we feel that we are already losing business and patients are choosing to go elsewhere due to access problems (may be asked to quantify this leakage which would be difficult)

Opportunities – *Those activities or occurrences in the external environment that may have a positive impact on the proposed project.*

- More than 30% of the required capital has already been secured through philanthropy with the potential for additional funds
- Incidence of diseases and conditions that currently require bronchoscopy is increasing
- New clinical applications for bronchoscopy are emerging rapidly driving year-over-year growth – even in a stagnant market
- Opportunities for new incremental volume and revenue in space vacated through this consolidation
- Addition of new or acquired pulmonology practices in the regional satellites will increase referrals

Threats – *Those activities or occurrences in the external environment that may hamper the success of the proposed project.*

- ☒ The new cancer hospital at University Hospitals (which will contain new bronchoscopy labs) may draw away loyal referring physicians, patients and staff – especially from a weakened bronchoscopy program at Cleveland Clinic.
- ☒ Uncertainty of reimbursement trends over the next decade
- ☒ Project is contingent on the relocation of EP services thus complicating the project's approval process and threatening its timely implementation.

MARKET ANALYSIS AND NEEDS ASSESSMENT

CCHS System Current State

Main Campus

There can be little doubt that the current delivery of bronchoscopy services is inefficient and operationally sub-optimal. Today at Cleveland Clinic, bronchoscopy is provided in seven different locations – not one of which has the capability to provide the full range of services. As a result schedules must be managed to match the anticipated procedure type to the location. In many cases, clinical slots are blocked to account for procedure uncertainty.

Below is a summary of the current state at Cleveland Clinic main campus:

Location	Percent of total volume*	Days Available	Limitations / Issues
A90 (Pulmonary)	42.1%	five days / week	<ul style="list-style-type: none"> cannot support therapeutic bronchoscopy Outpatients compete with inpatients Safety concerns of A-90
A30 (Digestive)	10.8%	one day / week	<ul style="list-style-type: none"> under pressure to vacate limited/inconsistent recovery space no advanced diagnostic/therapeutic options
G62 (MICU)	2.3%	one day / week	<ul style="list-style-type: none"> has no recovery space as MICU expansion is complete this will become fluoroscopy suite no advanced diagnostic/therapeutic options
M62 (Bariatric)	16.2%	four days / week	<ul style="list-style-type: none"> under pressure to vacate for Bariatric Surgery expansion most inconvenient for patients and staff due to unit restrictions no advanced diagnostic/therapeutic options
bedside	19.4%	ad hoc	<ul style="list-style-type: none"> this will not be impacted by this project
OR	8.9%	one day / week	<ul style="list-style-type: none"> dramatic volume growth (260% since 2004) – space constrained

			<ul style="list-style-type: none"> • limited to one day block time • only capable for 4-5 cases/week • not properly equipped or staffed for advanced diagnostic bronchoscopy
Brachytherapy	0.4%	ad hoc	<ul style="list-style-type: none"> • this will not be impacted by this project

* based on first quarter 2009 volumes

We also perform bronchoscopy in the Thoracic ORs with thoracic surgery and occasionally with ENT and pediatric ENT. We also on rare occasion do bronchoscopies in the pediatric OR/ICUs. These will not be affected directly, but if we can coordinate peds anesthesia we would prefer to do these in our new area.

Despite the inherent problems with this configuration of services, the bronchoscopy program has maintained a productivity rate above 100% for over a year. However, physician and employee burn-out is beginning to negatively impact morale and employee engagement.

Health System

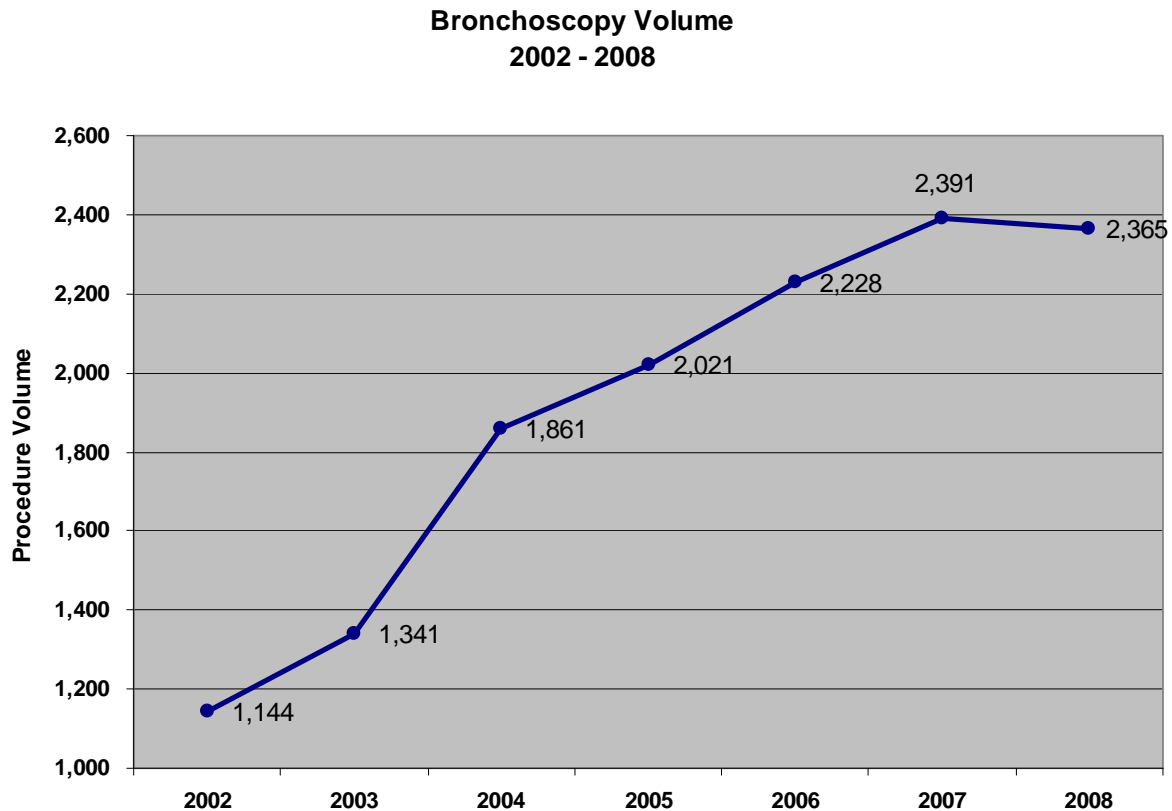
Our current project is designed to meet the cutting edge needs and help define the forefront on the advanced diagnostic and therapeutic bronchoscopy service line as well as serve the routine bronchoscopy needs of the larger immediate health care system. This new space is purely designed to meet the needs of bronchoscopy for our main campus institution and provide referral service for our advanced techniques.

As a point of reference, currently routine diagnostic bronchoscopy includes lung lavage for cultures, simple endobronchial biopsies, transbronchial biopsies and brush biopsies. Fewer than 30% of pulmonologists perform transbronchial needle aspirations across the country.

The standard of care for needle biopsies is evolving toward endobronchial ultrasound and this particular technique is still very uncommonly practiced outside of major referral areas such as ours. This is increasing the number of procedures overall- not diverting them from other centers. Electromagnetic Navigational Bronchoscopy is also fulfilling the unmet need by performing a safer minimally invasive bronchoscopic procedure rather than a surgical biopsy or watchful waiting. In the last year the FDA has approved 3 new adjuncts to this technology in the therapeutic realm for pleural dye marking, fiducial implantation for radiosurgery and brachytherapy radiation catheter placement. These have the potential not only to expand our current referral patterns for thoracic surgery and radiation therapy but also serve the regional practices that also require these techniques. This points to the impact of advanced bronchoscopy in growing other specialty practices within our institution.

Recent Volume Trends

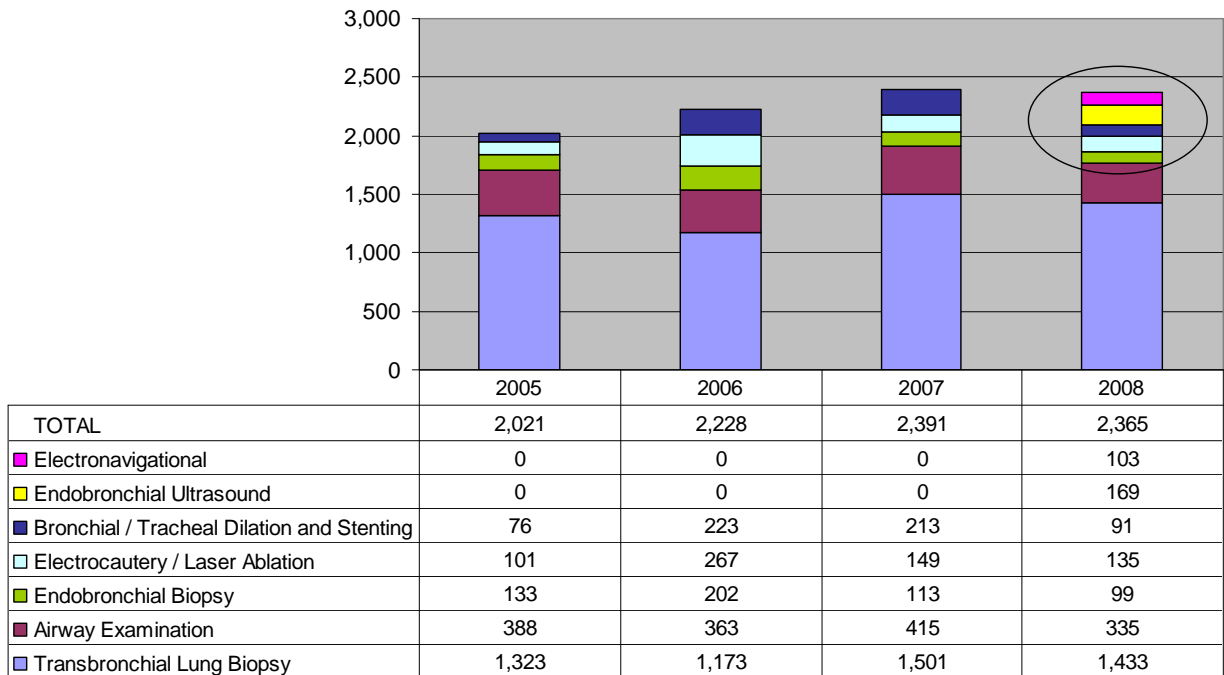
The dramatic growth in volume between 2002 and 2007 is demonstrated here. It is important to note the impact of capacity constraints coupled with increasing case lengths and complexity on the volume between 2007 and 2008.



The chart below demonstrates the increasing complexity of procedures performed over the last several years. Electromagnetic navigation bronchoscopy (superDimension) and Endobronchial Ultrasound (EBUS) procedures take nearly twice as long as traditional procedures and can only be performed in suites specifically designed to perform these complex services.

So while volume from 2008-2009 appears to be flat, the acuity, complexity and case length of these new techniques distorts the growth trend. Only in 2008 when we began to a capacity constraint did we start tracking volume on these more complex cases since it required a change in the bronch slot allocation.

Bronchoscopy Volume by Procedure Type



Market Potential - Population Projections

As referenced on page 4, only 35% of bronchoscopy patients reside in Northeast Ohio making population-based projections of limited value. Nonetheless, a population-based forecast was completed through 2013.

With a 5.4% population decline in Cuyahoga County and 2.2% growth in the surrounding 6-counties, the net 7-county decline is -1.3%. However, offsetting the population decline is an increase in incidence and utilization. The outpatient 7-county estimate for CPT and ICD 9 codes are trending upward at 4.6% and 1.8% respectively. The increase in disease prevalence - even in a shrinking population - is a rational justification for expansion.

The details of the forecast are shown below (source: Thompson):

7-County Market Outpatient Estimate / Forecast by CPT

CPT-4	Procedure	TOTAL		
		2008	2013	%
31622	Dx bronchoscope/wash	739	767	3.8%
31623	Dx bronchoscope/brush	658	696	5.7%
31624	Dx bronchoscope/lavage	645	672	4.3%
31625	Bronchoscopy w/biopsy(s)	411	431	4.8%
31628	Bronchoscopy/lung bx, each	714	746	4.4%
TOTALS		3,167	3,311	4.6%

NOTES: Total is understated as no data was available for codes 31626 and 31629 through 31656. Also, not included is the emerging technology of bronchial thermoplasty.

7-County Market Outpatient Estimate / Forecast by Related Diagnosis

ICD-9	Diagnosis	TOTAL		
		2008	2013	%
162	Malignant Neoplasm Trachea, Bronchus & Lung	49,869	52,832	5.9%
197	2nd Malignant Neoplasm Resp & Digestive Sys	6,860	7,109	3.6%
490	Bronchitis NOS	83,729	82,904	-1.0%
491	Chronic Bronchitis	22,593	23,840	5.5%
492	Emphysema	5,571	5,947	6.7%
493	Asthma	136,327	134,551	-1.3%
494	Bronchiectasis	2,087	2,209	5.8%
496	Chronic Airway Obstruction NEC	83,821	88,400	5.5%
TOTALS		390,859	397,792	1.8%

Market Potential - Other Factors

It is difficult to make specific forecasting statements about an evolving specialty. It is long recognized that Bronchoscopy can be used to diagnose, treat or palliate almost any lung disease. The newer techniques that we have described are making this more relevant.

There are two sources of growth for the bronchoscopy service: 1) as a tool to other specialty programs; and 2) as an increasingly vital tool in the management of pulmonary disease.

The easiest example of the former is the Lung Transplant program. Each lung transplant patient requires a minimum of 6 bronchoscopies within the first year. Based on this year's numbers alone we have exceeded all of last years expected procedures for this program. Should this program continue on its current path, an additional 100 patients will be transplanted resulting in at least 600 new bronchoscopies within the next year alone.

Another example of this supportive relationship with another specialty is in Radiation Oncology where the Bronchoscopy service has been asked to place fiducial markers on every patient they expect to treat and expect the current number to be about 100 additional procedures a year.

In the field of Pulmonary Medicine, new procedures are emerging for the treatment of patients with emphysema. It is estimated that there are approximately 10 million patients with emphysema that may benefit from these procedures as their diseases inexorably progress.

For example, we expect to see FDA approval for Bronchial Thermoplasty in the next 12 months. We already have a waiting list of over 60 patients for bronchial thermoplasty which requires 3 bronchoscopies (i.e. 180 procedures).

Two devices are also approaching the conclusion of their clinical trial periods – bronchial bypass and bronchial valve. It is difficult to estimate the numbers of procedures that would be associated with the approval of these devices, but evaluation of these patients often leads to surgical lung volume reduction evaluations as well as lung transplant evaluations.

From a geographic perspective, the target market has been widening over the last 5 years (see page 4). This trend is expected to continue as the Clinic further distinguishes itself as a national referral center and as the clinical programs that channel patients to the bronchoscopy program experience ongoing growth and success (e.g. MICU, transplant, other hospital consultative services areas)

From a demographic perspective, the patient population served by this program will remain largely unchanged as the incidence of disease is predictable and stable. However, emerging techniques and new clinical applications will create “new market” for both diagnostic and therapeutic procedures. Some examples of therapeutic techniques under investigation are:

- Bronchial Thermoplasty - granted expedited review for FDA approval for the treatment of asthma. When approved, each patient will require three separate procedures to complete one treatment. Cleveland Clinic was the second highest enrolling site in the US for this trial and is well positioned to adopt this new technology ahead of competitors. (see excerpt from the 2009 ATS conference below)



ATS 2009: Bronchial Thermoplasty Improves Quality of Life, Reduces Asthma Exacerbations

Kristina Rebelo

May 26, 2009 (San Diego, California) — One-year results from the pivotal AIR2 Trial, which evaluated the safety and effectiveness of bronchial thermoplasty delivered by the Alair System, an investigational novel therapeutic nondrug procedure, found that it can significantly improve quality of life and reduce asthma exacerbations and respiratory-related emergency-department visits in adults with severe asthma, according to clinical-trial results released here at ATS 2009: the American Thoracic Society International Conference.

- Bronchial bypass for emphysema
- Intrabronchial valves for emphysema
- ENB-electromagnetic navigation bronchoscopy for diagnosis/placement of fiducial markers/placement of brachytherapy catheters

Finally, techniques that are currently not performed or are performed on a limited basis at Cleveland Clinic due to the logistical challenges of the current configuration will now be possible.

- EBUS- endobronchial ultrasound for mediastinal staging
- Pleural Dye Marking
- Fiducial implantation/Brachy Catheter placement
- Complete EBUS/EUS mediastinal staging

Physician Community Dynamics

As international experts in the published literature we have a referral base of patients from all over the world specifically coming for our expertise in electromagnetic navigational bronchoscopy. We are recognized as one of the few centers that have specific expertise in all aspects of disease treated or diagnosed via bronchoscopy. As a result, we have patients who come from all over the country for advanced diagnostic and therapeutic techniques.

In this region, we partner with local experts to manage the more complicated aspects of their airway disease patients.

Competitive Analysis

Cleveland Clinic has the only Interventional Pulmonary program in the region. There are no other physicians in our system outside of main campus performing any of the advanced diagnostic or any of the therapeutic procedures.

Regional competitor highlights

- **University Hospitals:** The new cancer facility will include a new bronchoscopy lab which may attract leading clinicians. It is anticipated that a significant and sustained marketing push for the entire cancer program will roll out in the next 12-18 months. They also intend to offer bronchoscopy service at the new Ahuja Medical Center. The hospital is also attempting to build a lung transplant program. The new bronchoscopy suites and services may help them recruit an interventional pulmonologist.
- **MetroHealth:** No program exists and often patients are sent here for complex airway disease.
- **Henry Ford:** Dr. Simmoff is a nationally recognized leader in interventional pulmonology. He has new bronchoscopy space, block time in the OR several days per week and has been trying to recruit a new interventionalist. He has been the leader on writing a position statement about the bronchoscopy suite of the future sponsored by the ACCP (the current version of the document is being reviewed by Dr. Mehta for publication)
- **Ohio State:** Dr. Islam is an interventional pulmonologist performing the full range of procedures at OSU. He does not have all the surgical support that we have so he has sent patients here on occasion. They for not have electromagnetic navigation yet.

National Competitor Highlights

- **National Jewish Health** (Denver) - US News and World Report #1 in Respiratory Disease. They hired Dr. Ali Musani an Interventional Pulmonologist from U.Penn (one of Dr. Machuzak's former mentors). They advertise a Nodule Clinic built around the technology we pioneered in the US and tout the only Interventional Pulmonologist in the Rocky Mountain Region. They have a working relationship with the other medical centers around the Denver area and provide the advanced bronchoscopy services of the other regional hospitals. The Bronchoscopy unit exists as part of the core of the diagnostic pulmonary unit among the pulmonary function labs. There are 4 fully functional suites with available general anesthesia with a CRNA available for all procedures including major intervention.
- **Mayo Clinic** - US News and World Report #2 in Respiratory Disease. They have a 6 person bronchoscopy service is rotated upon by several expert bronchoscopists. The

general pulmonologists do not perform their own bronchoscopies at Mayo Clinic. Their bronchoscopy service functions from the operating room where they have a dedicated room where the pulmonary service has no direct oversight into the preoperative and postoperative recovery of these patients as this is done by the operating room teams. The OR/bronchoscopy suite has full functional capacity for advanced diagnostic and therapeutic procedures with the assistance of an anesthesiologist in the room. The pulmonologist performing the service do not have a specific role in the patient's care other than the procedure itself.

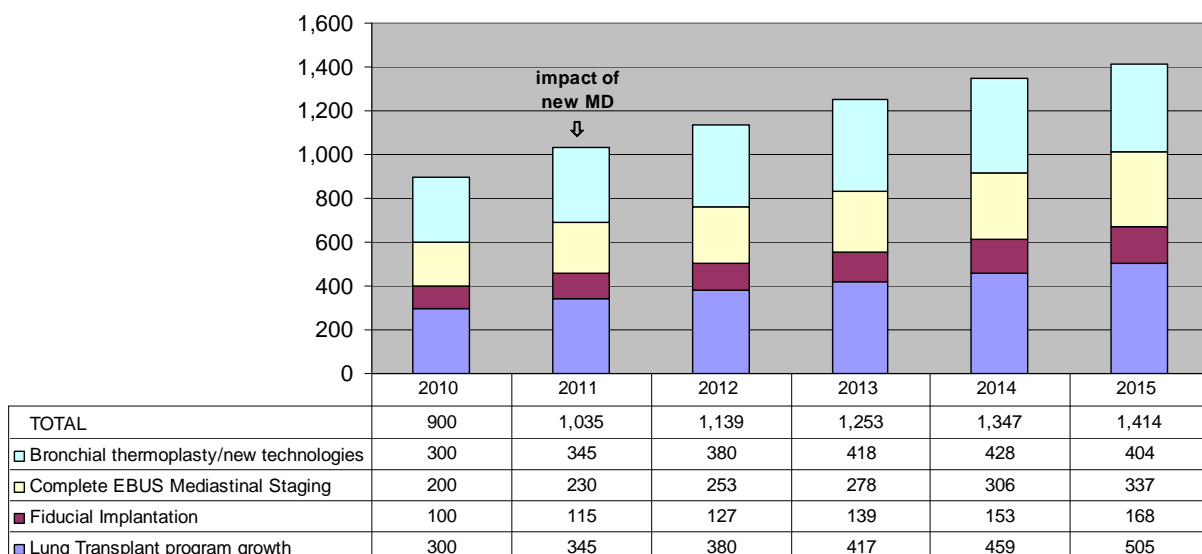
- **Johns Hopkins Hospital** - US News and World Report #3 in Respiratory Disease. They have a pair of interventional bronchoscopists. One of whom performance most of the advanced therapeutic procedures and an interventional pulmonary fellowship program separate from the general pulmonary fellowship program. Dr. Feller-Kopman performed the full range of advanced diagnostic and therapeutic bronchoscopy, upper GI endoscopy and medical pleuroscopy.
- **Massachusetts General Hospital** - US News and World Report #4 in Respiratory Disease. This hospital has been actively recruiting and interventional pulmonologists for the last two years. They do not have a well known interventional pulmonary program and compete directly with one of the most famous bronchoscopists in the United States (Dr. Armin Ernst at Beth Israel/Deaconess hospital).

Volume Projections

The incremental volume projections for the bronchoscopy program are detailed below.

The 2010 incremental projection is based on the expected follow up volume from the 2009 lung transplant boom (300 cases) increased in subsequent years based on continued transplant volume and the exponential downstream volume impact in post-transplant years . The fiducial implantation and complete EBUS mediastinal staging are existing techniques with quantifiable unmet demand due to capacity constraints. Bronchial thermoplasty and other new technologies are most difficult to project and have been forecasted conservatively here.

Incremental Volume Projection Summary



IMPLEMENTATION PLAN

Organization and Management

This project does not involve any change in organization and management. Virtually every staff member in the pulmonary section of the department will perform bronchoscopy procedures.

The leadership for this program includes:

Physician leadership

- Tom Gildea, MD Section Head of Bronchology
- Mike Machuzak, MD

Nursing leadership

- Jodi Krizmanich, RN

Volume and Productivity

The productivity rate for the bronchoscopy team has consistently exceeded 100% in spite of inefficiencies in the current configuration.

Staffing

The current staffing model and the FTE count will not change. Incremental staffing will be added as volume increases. Based on our volume projections (referenced later in this document), it is expected that the program will need one additional Physician Assistant and one PSR to accommodate this growth.

In addition, it is expected that the clinical volume and the increase in research activity will necessitate the need for an additional physician to be fully involved in the bronchoscopy service by 2011 (recruitment to begin in 2010). This estimate is based on the activity thresholds used to justify prior staff recruitments and will ultimately be subject to review by the Office of Professional Staff Affairs.

A separate analysis was done for anesthesiology staffing needs (see **Appendix A**).

Impact to Other Departments and/or Entities

Consolidation and expansion of the bronchoscopy service impacts many other departments. Most directly, of course, is Electrophysiology, which is currently occupying the proposed space in F26. Members of the Heart and Vascular Institute have been involved in this planning process and are presenting a concurrent plan for relocation of their Electrophysiology lab to create the space needed for the bronchoscopy unit.

Other internal clinical stakeholders whose operations will be impacted are Anesthesiology and Cytopathology. Both of these services have been consulted in the development of this plan.

For Anesthesia, this change presents an opportunity for new billable procedures in a satellite which is close to existing operating room locations. Anesthesia equipment is built into the equipment expense for this project. In discussion with the Institute Administrator for

Anesthesiology, it is likely that they will need incremental labor which will be largely offset by incremental professional revenue. The financial summary for the anesthesiology staffing plan is included in **Appendix A**.

For Pathology, increasing use of on-site cytopathology has been shown to be cost effective and time efficient and augments patient safety to minimize excessive procedures. Our location is very close to other high volume areas (endocrine/M24) thus increasing cytopathology efficiency.

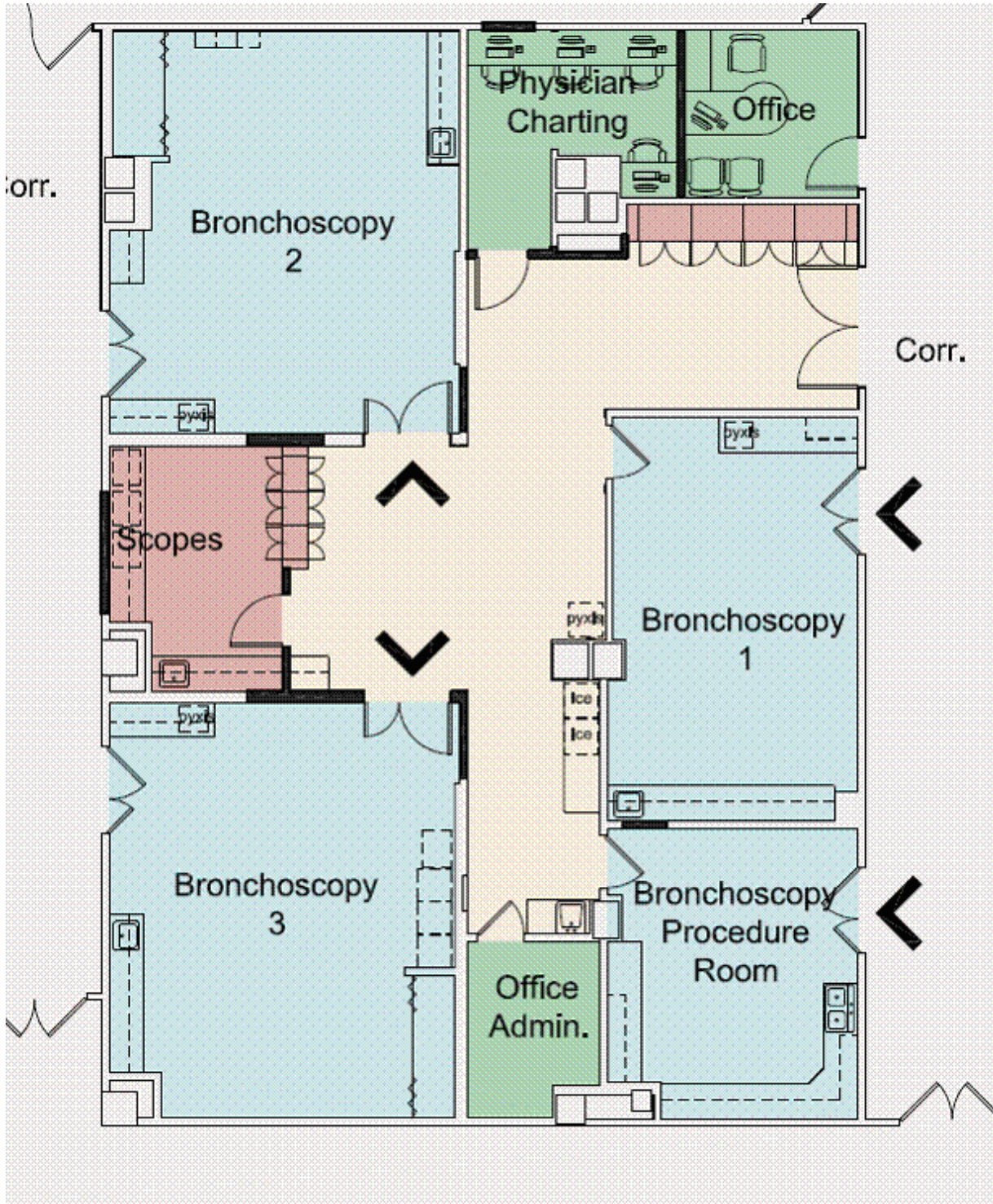
As has been discussed elsewhere in this plan, other departments and programs will be positively impacted through the creation of capacity and/or enhanced utilization of their services:

- Lung Transplant - bronchoscopy is a support service for this program as a pre-operative and post operative management tool.
- Radiation Oncology- fiducial implantation to be performed on all patients
- Oncology - growth in oncology begins with a diagnosis; new advanced techniques increase exposure to Cleveland Clinic through the Bronchoscopy program.
- Thoracic Surgery - The entry point for major airway surgery (IE- trancheobronchoplasty, airway reconstruction, lung volume reduction surgery, cancer resection) generally flows through the bronchoscopy program.
- Rheumatology- the Vasculitis section is World Renowned for Wegener's Granulomatosis which has a common airway complication that is managed by the bronchoscopy service. Several new lines of therapy require bronchoscopy (EG mycobacterial/fungal infection) prior to starting advanced immunotherapy.
- ENT- both pediatric and adult ENT practices work in conjunction with Thoracic Surgery and the Bronchoscopy section for the comprehensive management of subglottic stenosis.
- Cardiac Surgery and CT anesthesia- Approximately 10% of all patients with endotracheal tubes develop airway complications that are routinely managed by the bronchoscopy service.
- Current "tenants" (Digestive, Bariatric, MICU, OR, Pulmonary procedure room) – creates a backfill growth opportunity
- Education Institute / Center for Advanced Skills Training (CAST) program - Respiratory is the second only to Bariatrics in requests from outside physicians. New initiative for medical simulators is particularly useful for bronchoscopic skills (similar to other minimally invasive procedures).

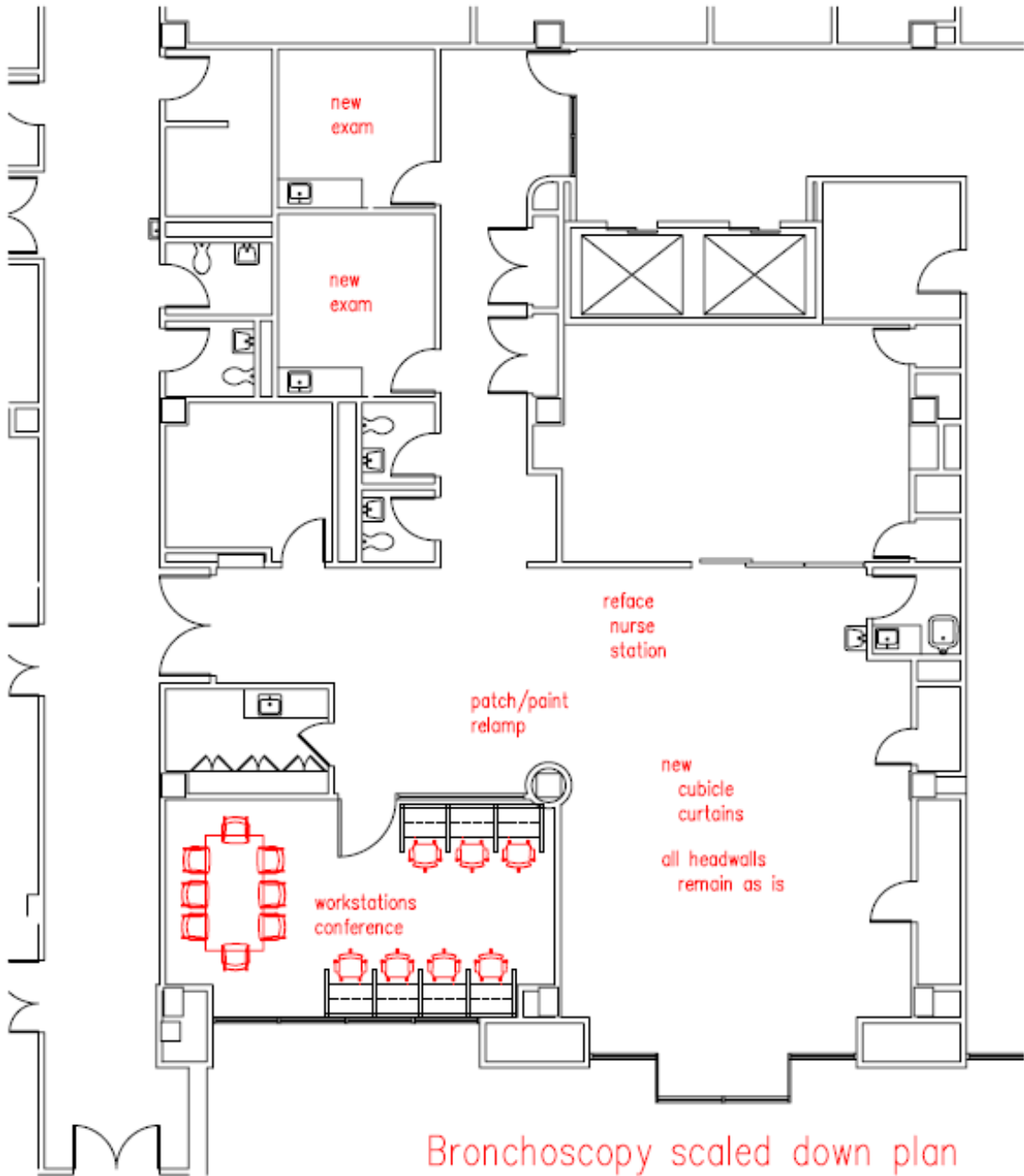
Location and Facilities

The existing location summary is outlined previously in this document (page 8). The proposed location and facility configuration is pictured below:

Bronchoscopy Suite Procedure Area



Bronchoscopy Suite - Prep and Recovery Area



Bronchoscopy scaled down plan
3,000 s.f.

Some features of the new bronchoscopy suite to note are:

- Exam rooms are included in the suite, but they are slightly separated from the prep and recovery area (routine outpatients will not be exposed to patients pre-and post-procedure). This allows patients to receive an exam prior to procedure and post-procedure which creates continuity for both patients and staff.
- There is a patient-friendly “front door” to the unit with a staffed dedicated sub-waiting area.
- Efficient and cost-effective retrofit of existing space.
- Group practice model is facilitated through shared administrative space
- The procedure suites are all equipped to perform the full range of procedures which allows clinical flexibility if necessary.
- Physicians can cover multiple procedures in rapid succession or simultaneously
- Suite is near other resources (such as MICU, pathology, OR, anesthesia)

Capacity – short-term and long-term flexibility

Short-term coverage

With the sudden explosion in lung transplant volume in 2009, the bronchoscopy service finds itself struggling to accommodate demand in the first 4 months of the year. The expected open date for the new facility of January 1, 2010 creates the need for a short-term plan to create additional capacity.

With an immediate release of equipment capital (fluoroscopy and endobronchial ultrasound) and the hiring of an RN FTE approved in Q1 2008, additional capacity can be created in G6. While this exacerbates inefficiency, it may be necessary to keep up with the growing needs. We should also expect increases in overtime pay.

Long-term upward potential

Based on the volume trend of the last 7 years and the potentially explosive impact of new technologies currently in clinical trials, we felt it necessary to also envision opportunities for growth beyond those projected in this plan.

There is a procedure room in the suite that can be converted into a small bronchoscopy room. In addition, the bronch suite in A90 – which is intended to revert to a pulmonary procedure room – can be reclaimed for bronchoscopy (particularly post-transplant patients seen on A10).

Space Utilization

There will continue to be variability in the utilization due to the increasing complexity of the procedures being performed. The projected utilization rate in the new suite is based on a projected annual volume of 2,812 procedures. The table below presents the projected utilization rate for the Bronchoscopy Suite procedure area and the Bronchoscopy Suite prep and recovery area.

Procedure Area	
Projected volume	2,812
Procedure time (hrs)	2.0
Room time requirement (hrs)	5,624
Number of procedure rooms	3
Annual available hours per room	2,295
Total annual available procedure room hours	6,885
Projected utilization rate	82%

Prep and Recovery Area	
Projected volume	2,812
Prep and recovery time (hrs)	2.5
Bed time requirement (hrs)	7,030
Number of available beds	6
Annual available hours per bed	2,295
Total annual available bed hours	13,770
Projected utilization rate	51%

Equipment Requirements

The equipment list below was provided by the equipment vendors and reviewed by the clinical team for accuracy. It is important to note that much of this equipment included embedded IT capability which minimizes the need for significant additional IT investment. In addition to the detail below, the IT cost included in the construction estimate was \$87,500 and was reviewed by ITD for accuracy.

Bronchoscopy Suite Equipment	Price Per Unit	Units Requested	Total Cost	Procedure Rooms	Prep / Recovery
Bryan Corporation Rigid Bronchoscope	\$ 37,330.00	1	\$ 37,330.00	\$ 37,330.00	
Commed Beamer	\$ 45,110.95	3	\$ 135,332.85	\$ 135,332.85	
Abatement Technologies Hepa Filter	\$ 4,918.00	3	\$ 14,754.00	\$ 14,754.00	
Olympus rigid camera head	\$ 7,167.18	1	\$ 7,167.18	\$ 7,167.18	
Steris Monitor Towers (quote for 3)	\$ 161,955.00	1	\$ 161,955.00	\$ 161,955.00	
Steris Ceiling Equipment	\$ 392,113.00	1	\$ 392,113.00	\$ 392,113.00	
Olympus Stack w/scopes	\$ 96,779.16	2	\$ 193,558.32	\$ 193,558.32	
Olympus EBUS stacks w/scopes	\$ 140,826.00	2	\$ 281,652.00	\$ 281,652.00	
SuperDimension System	\$ 137,800.00	1	\$ 137,800.00	\$ 137,800.00	
ERBE cryotherapy	\$ 16,789.00	3	\$ 50,367.00	\$ 50,367.00	
Transmotion Medical Fluoro Procedure/Rec. tables	\$ 7,930.00	9	\$ 71,370.00		\$ 71,370.00
Sonosite	\$ 52,064.00	1	\$ 52,064.00	\$ 52,064.00	
Datascope- 8 Recovery monitors- 3 proce. Rm monitors	\$ 5,057.43	12	\$ 60,689.16		\$ 60,689.16
GE OEC mobile c- arm- fluoroscopy	\$ 137,760.00	3	\$ 413,280.00	\$ 413,280.00	
Steris Machines	\$ 23,510.50	3	\$ 70,531.50	\$ 70,531.50	
Totals			\$ 2,079,964.01	\$ 1,947,904.85	\$ 132,059.16

Bronchoscopy Suite Equipment	Price Per Unit	Units Requested	Total Cost	Procedure Rooms	Prep / Recovery
Full anesthesia system	\$ 95,400.00	2	\$ 190,800.00	\$ 190,800.00	
Portable anesthesia system	\$ 75,000.00	1	\$ 75,000.00	\$ 75,000.00	
Recovery systems	\$ 15,000.00	4	\$ 60,000.00		\$ 60,000.00
Totals			\$ 325,800.00	\$ 265,800.00	\$ 60,000.00

\$ 2,405,764.01 \$ 2,213,704.85 \$ 192,059.16

Marketing Plan

To date, the bronchoscopy program has not been promoted directly to either patients or referring physicians due to capacity constraints. Nonetheless, volume has increased almost exponentially and pulmonary physicians from across the country (including those at competitor hospitals) are referring patients to Cleveland Clinic due to its unparalleled scope of services.

Based on the relative weakness of our regional and national competitors, it is very reasonable to believe that any promotional campaign will be successful in driving direct referrals to the program. The primary target audience for this program must continue to be physicians – patients are rarely in a position to self-refer for bronchoscopy. Physician audiences with a higher likelihood to refer to us are: other pulmonologists, oncologist, general practitioners and family medicine physicians.

However, supporting the direct-to-consumer marketing efforts of the asthma, lung transplant and cancer programs will also yield volume for the bronchoscopy program.

A summary marketing tactical overview is included below:

Target Audience	Tactics
Referring physicians and potential trainees	Direct mail communication to Pulmonologists nationally, messages include: <ul style="list-style-type: none"> – Olympus Bronchoscopy Center of Excellence – Unparalleled range of service (technology, complexity of case mix) – Access commitment
	Feature article: <ul style="list-style-type: none"> • Respiratory Exchange: National publication to pulmonologists and critical care specialists • Cleveland Clinic Rounds: regional (6-state) publication to primary care/internal medicine physicians • Cancer Consult: National publication to Oncologist
	ACCP/ATS/ASTRO/STS/MPMD special sessions
	Hosting World Congress of Bronchology (2012)
	Plan an annual Airway (Bronchoscopy) summit
Potential patients	Support marketing efforts for “feeder” services (cancer, lung transplant, critical care transport)
	Media / PR awareness effort
	Announcement of new suite on website
	Airway disease community health talk

FINANCIAL ANALYSIS

This project will allow for incremental expansion of the current bronchoscopy business line which is now almost at capacity within current facilities. The start date for this project is January 2010. A financial summary for this project is shown below:

Bronchoscopy Unit Consolidation & Expansion Project - Incremental Impact over Current Operations

	<u>2009</u>	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2014</u>	<u>2015</u>
Capital Investment	\$ 3,583,631	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Net Revenue	\$ -	\$ 1,650,481	\$ 1,954,857	\$ 2,215,734	\$ 2,510,592	\$ 2,766,885	\$ 2,992,636
Expenses (excl depr)	\$ -	\$ 789,511	\$ 922,387	\$ 1,040,928	\$ 1,175,859	\$ 1,301,809	\$ 1,414,474
EBITDA	\$ -	\$ 860,970	\$ 1,032,470	\$ 1,174,805	\$ 1,334,733	\$ 1,465,076	\$ 1,578,162
Depreciation	\$ -	\$ 214,290	\$ 428,580	\$ 428,580	\$ 428,580	\$ 428,580	\$ 416,145
Operating Income	\$ -	\$ 646,680	\$ 603,890	\$ 746,225	\$ 906,153	\$ 1,036,496	\$ 1,162,017
Philanthropy	\$ -	\$ 1,200,000	\$ -	\$ -	\$ -	\$ -	\$ -
Cash Flow from Operations	\$ (3,583,631)	\$ 2,060,970	\$ 1,032,470	\$ 1,174,805	\$ 1,334,733	\$ 1,465,076	\$ 1,578,162
Cum. Cash Flow	\$ (3,583,631)	\$ (1,522,661)	\$ (490,191)	\$ 684,614	\$ 2,019,347	\$ 3,484,423	\$ 5,062,585
FTES:							
Staff	-	1.0	1.1	1.2	1.3	1.4	1.5
Non-Staff	-	2.0	2.2	2.4	2.6	2.8	2.9
	-	3.0	3.3	3.6	3.9	4.2	4.4
Procedures	-	900	1,035	1,139	1,253	1,347	1,414

The \$3.58 million capital requirement consists of \$2.41 million for bronchoscopy equipment, \$0.18 million for furniture, \$0.75 million for construction and \$0.24 million for project design, ITD and other.

The Brundige Bronchoscopy Fund has been established for the purpose of supporting development of bronchoscopy suites, including purchasing state-of-the-art technology in order to benefit patient care. This fund currently has a balance of \$1.2 million. These philanthropic funds are included in this project's financial analysis.

Financial results of this proposed project are as follows: Payback Period = 3.4 years, Internal Rate of Return (5 years) = 30.1%, Return on Investment (5 years) = 159% and Net Present Value (5 years) = \$1.96 million.

The project requires three FTEs starting in 2010 - one physician, one physician assistant and one patient service representative. As procedure volume rises over the following years, the FTE requirement also rises from the initial 3.0 in 2010 to 4.4 in 2015. An additional summary of Anesthesia staffing requirements is included in **Appendix A**.

The detailed financial analysis is included in the StrataCap proposal entitled – “RSI – Bronch Suites”.

OTHER CONSIDERATIONS

Exit Strategy and Associated Costs

If technology changes eliminate the need for bronchoscopy services or the program collapses for any other reason, the proposed suites can be converted to fully-functional, minimally-invasive operating rooms with minimal investment.

Alternatives

Since this project does not involve the creation of a new clinical program, but rather the improvement and expansion of an existing service, the alternative would be to remain in the current state. However, this plan has clearly articulated the lost opportunity and risks associated with that alternative.

Risks

The volume projections upon which this proposal is based have been thoroughly vetted with clinical leadership of the program. Under certain scenarios, the projections are overly conservative. However, should the lung transplant program collapse or shrink dramatically in subsequent years, the volumes forecasted here will not be met. Similarly, the failure of the FDA to approve new techniques anticipated in the next 12 months would also negatively impact volume. Neither of these scenarios seem likely based on what is known today, however, they represent risks to the project's success.

APPENDIX A – ANESTHESIOLOGY STAFFING FINANCIAL SUMMARY

Bronchoscopy Unit Consolidation and Expansion Project						
Assumes: 2 days per week with 1 Staff and 2 CRNAs in 2 Rooms						
<i>ASA Code:</i>	00520 Anesthesia for closed chest procedures: (including bronchoscopy) not otherwise specified Could include additional procedures based on need					
Base units:	6					
Avg time units:	6					
Revenue per case:		<u>Professional</u>	<u>Technical</u>	<u>Total</u>		
Gross: \$		1,236	\$ 1,328	\$ 2,564		
Net: \$		433	\$ 465	\$ 897		
<i>Cases per Day per Room</i>	1					
Expense per day:		<u>1 Staff</u>	<u>1 CRNA</u>	<u>Other Operating Expense</u>	<u>Total</u>	
		1,472	623	511	2,606	
Projected % Contribution Margin:						
Depreciation (Anesthesia Equipment)	~\$392,000					
Other Indirects						
Projected 5 year Pro Forma						
		2010	2011	2012	2013	2014
		<u>2 days 2 rooms</u>	<u>3 days 2 rooms</u>	<u>4 days 2 rooms</u>	<u>5 days 2 rooms</u>	<u>5 days 2 rooms</u>
Gross Revenue		1,599,936	2,399,904	3,199,872	3,999,840	3,999,840
Net Revenue		559,978	839,966	1,119,955	1,399,944	1,399,944
Cases per Day per Room		3	3	3	3	3
Direct Expenses Salary and other operatir		388,960	583,440	777,920	972,400	972,400
Contribution Margin		171,018	256,526	342,035	427,544	427,544
Equipment Depreciation		78,400	78,400	78,400	78,400	78,400
Other Indirect Expenses						