

Reason for report:

INITIATION

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## VERACYTE, INC.

### Unique Market Opportunity, Growth Trajectory; Initiate at Outperform

• **Bottom Line:** We initiate coverage of VCYT with an Outperform rating and \$17 price target. We believe several upcoming catalysts should drive outperformance of VCYT's stock over the next 12 months, including: (1) continued physician adoption of its Afirma test to help resolve indeterminate thyroid nodules, (2) additional guideline endorsement and reimbursement coverage for Afirma, (3) launch of the Afirma malignant test (2Q:14), and (4) presentation of lung data in 2014. Our \$17 price target represents 50% upside to yesterday's close.

• **Novel test offering targets an underserved market.** The opportunity to improve thyroid cancer diagnosis is an underserved but growing market. We believe that VCYT's Afirma Thyroid Fine Needle Aspirate (FNA) analysis is the only molecular cytology solution commercially available that identifies which thyroid nodules deemed indeterminate by traditional cytology are truly benign, thus enabling physicians and patients to confidently forgo unnecessary thyroid surgery.

• **Clinical validity and utility demonstrated in multiple peer-review studies.** Multiple peer-reviewed studies support the clinical validity and utility of the Afirma Gene Expression Classifier (GEC).

• **Third-party payers have been supportive.** VCYT has garnered positive coverage decisions for the Afirma GEC at an impressive pace. The company has received positive coverage decisions covering north of 100M lives.

• **Inclusion in clinical practice guidelines.** Molecular tests such as VCYT's Afirma GEC are currently included in National Comprehensive Cancer Network (NCCN) guidelines for thyroid nodule evaluation, and we expect additional guideline endorsements could occur in 2014.

• **Strong test adoption to date.** Since it commercially launched Afirma in January 2011, VCYT has processed more than 60,000 FNAs and performed approximately 12,000 GECs to resolve indeterminate cytology results.

• **Product pipeline presents additional growth opportunities.** VCYT has a number of R&D projects which offer upside beyond the initial indeterminate thyroid classification indication of the Afirma GEC.

• **Risks include uncertainty over the growth trajectory, lack of leverage in the GENZ agreement, the pace and amount of reimbursement coverage, and regulatory uncertainty.**

Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2012A	\$1.5	\$2.5	\$3.2	\$4.5	\$11.6	(\$6.53)	(\$7.11)	(\$7.59)	(\$7.44)	(\$28.68)	NM
2013E	\$4.4A	\$5.1A	\$5.6A	\$6.2	\$21.3	(\$8.48)A	(\$7.99)A	(\$6.59)A	(\$0.45)	(\$6.19)	NM
2014E	--	--	--	--	\$39.6	--	--	--	--	(\$1.28)	NM
2015E	--	--	--	--	\$73.4	--	--	--	--	(\$0.98)	NM

Source: Company Information and Leerink Swann LLC Research  
Revenues in \$ millions.  
IPO: 10/30/13



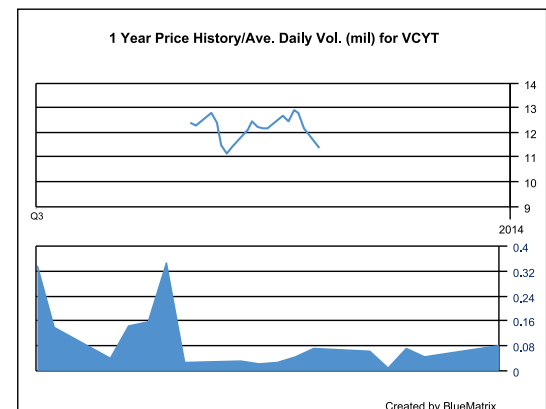
LEERINK SWANN

HEALTHCARE EQUITY RESEARCH

#### Key Stats:

(NASDAQ:VCYT)

<b>S&amp;P 600 Health Care Index:</b>	<b>1,273.91</b>
<b>Price:</b>	<b>\$11.36</b>
Price Target:	\$17.00
Methodology:	~6.5x EV/Sept-15 TTM revs
52 Week High:	\$14.12
52 Week Low:	\$10.88
Shares Outstanding (mil):	21.0
Market Capitalization (mil):	\$238.6
Book Value/Share:	\$2.70
Cash Per Share:	\$3.27
Dividend (ann):	\$0.00
Dividend Yield:	0.0%



Please refer to Pages 21 - 23 for Analyst Certification and important disclosures. Price charts and disclosures specific to covered companies and statements of valuation and risk are available at <https://leerink2.bluematrix.com/bluematrix/Disclosure2> or by contacting Leerink Swann LLC Publishing Department, One Federal Street, 37th Floor, Boston, MA 02110.



## INVESTMENT THESIS

We are initiating coverage of San Francisco, California-based Veracyte (VCYT) with an Outperform rating and a \$17 price target. VCYT markets a proprietary 142 gene expression test that identifies which thyroid nodules deemed indeterminate by traditional cytology are truly benign, thus enabling physicians and patients to confidently forgo unnecessary thyroid surgery. Additionally, the company has multiple products in development which can improve diagnosis for a range of conditions using a cytology sample. We believe adoption of VCYT's gene expression test for thyroid nodules should increase, and that forthcoming data on its pipeline offer additional catalysts. Thus, we rate VCYT's stock Outperform.

## INVESTMENT POSITIVES

Underserved Market Opportunity, Payer Support, Strong Adoption

**Novel test offering targets an underserved market.** The opportunity to improve thyroid cancer diagnosis is an underserved but growing market. The incidence of thyroid cancer has grown nearly three-fold since 1975 and is the fastest growing cancer in the United States according to the American Cancer Society. We believe that VCYT's Afirma Thyroid Fine Needle Aspirate (FNA) analysis is the only commercially available molecular cytology solution that identifies which thyroid nodules deemed indeterminate by traditional cytology are truly benign, thus enabling physicians and patients to confidently forgo unnecessary thyroid surgery.

**Clinical validity and utility demonstrated in multiple peer-review studies.** Multiple peer-reviewed studies support the clinical validity and utility of the Afirma Gene Expression Classifier (GEC). A pivotal study published in the *New England Journal of Medicine* (NEJM) in August 2012 showed that the risk of malignancy associated with a benign score on the GEC was ~5% (i.e., ~95% negative predictive value), comparable to the risk of malignancy with a benign FNA cytology. Studies have also demonstrated the clinical utility and cost-effectiveness of Afirma, showing that the test led to a reduction in the rate of unnecessary surgeries while generating significant cost savings. We believe the body of published evidence suggests that Afirma has a unique ability to change the way physicians diagnose thyroid cancer.

**Third-party payers have been supportive.** VCYT has garnered positive coverage decisions for the Afirma GEC at an impressive pace. In January 2012, the Medicare administrative contractor (MAC) for California issued a positive coverage decision for the GEC, deeming that the test met criteria for analytical and clinical validity, and clinical utility as a reasonable and necessary Medicare benefit. This provided ~50M Medicare beneficiaries with access to Afirma. In 2013, VCYT gained positive coverage decisions from several commercial payers, including national plans such as UnitedHealth (MP) (36M lives; March 2013), Kaiser Permanente (9M lives; March 2013), Aetna (MP) (18M lives; June 2013) and Humana (OP) (5M lives; July 2013). We believe the test will continue to gain positive coverage decisions from payers.

**Inclusion in clinical practice guidelines.** We believe that the continued inclusion of the Afirma GEC into clinical practice guidelines will help build greater awareness of the test and drive further adoption by physicians and as a covered health plan benefit. The National Comprehensive



Cancer Network (NCCN) modified its guidelines for thyroid nodule evaluation in January 2013. If a thyroid nodule is deemed indeterminate by cytology, the NCCN advocates that providers consider use of molecular testing if testing predicts a risk of malignancy comparable to the risk of malignancy seen with a benign FNA cytology ( $\sim \leq 5\%$ ), language which indicates the Afirma GEC in all but name. We believe that VCYT's published evidence provides a basis for the American Association of Clinical Endocrinologists (AACE) and the American Thyroid Association (ATA) to also include GEC in their treatment guidelines, and expect guideline committees for both could issue updates in 2014.

**Strong test adoption to date.** Since the commercial launch of its Afirma test in January 2011, VCYT has processed more than 60,000 FNAs and performed approximately 12,000 GECs to resolve indeterminate cytology results. We believe the company counts as customers more than 20% of the  $\sim 3,500$  endocrinologists in the U.S. who specialize in thyroid disease and perform FNA biopsies. The company's FNA volumes continue to grow at a rapid clip, with 74% year-on-year growth in the September quarter. We expect strong test adoption in the U.S. will continue, and we believe VCYT's nascent efforts internationally could begin to bear fruit in 2014.

**Product pipeline presents additional growth opportunities.** VCYT has a number of R&D projects which offer upside beyond the initial indeterminate thyroid classification indication of the Afirma GEC. VCYT is developing the Afirma Malignant GEC test to identify rare forms of thyroid cancer or metastases to the thyroid; this test is intended to better inform surgical strategy. In addition to thyroid cancer, the company is targeting other complex diseases in which cytology samples play a critical role in clinical decision making. VCYT is in late biomarker discovery for a test informative in interstitial lung disease (ILD), a group of lung diseases affecting the tissue and space around the microscopic air sacs of the lungs; these diseases are difficult to diagnose prior to surgery. Among the test's clinical objectives is to improve the accuracy of diagnosis of idiopathic pulmonary fibrosis (IPF), one of the more progressive, often fatal, ILDs, and to provide critical information to inform treatment strategy. We expect VCYT will launch its Malignant GEC test in 2Q:14 and its ILD/IPF test in 2016.

## INVESTMENT RISKS

Trajectory of Revenue Ramp Is the Greatest Uncertainty

**Pace and sustainability of revenue ramp an unknown.** With any diagnostic test targeting a new market, the trajectory of the revenue ramp and its ultimate ceiling are uncertainties in the early days. We can support a wide range of market sizes for Afirma's GEC, anywhere from  $\sim \$350\text{M}$  to  $\$800\text{M}+$  in annual opportunity, though we believe reality resides in the top half of this range using reasonable assumptions. The uncertainty over the ceiling reflects disparate sources of FNA market data, the size of the target audience, and the impact the Afirma GEC could have on clinical practice. The high end assumes  $\sim 100,000$  indeterminate FNAs annually in the U.S. are candidates for the GEC. The low end assumes fewer indeterminate FNAs to allow for different data sources as well as several clinical uncertainties which will resolve over time. Sources of clinical uncertainty include: (1) the proportion of indeterminate biopsies that will be re-biopsied rather than sent to VCYT; (2) the impact of the GEC on physician economics; some proportion of FNA samples come from surgeons, who might prefer surgery on indeterminate FNAs; additionally,



we've received inconsistent feedback from endocrinologists, including a MEDACorp physician, on whether the GEC requires more or less time per patient appointment, which impacts economics; and (3) physicians' loyalty to their current cytology lab (VCYT requires physicians send it the FNA sample for both traditional cytology as well as reflex to the GEC on indeterminate, save in the case of academic medical centers). Additionally, the dispersion of FNA volume among the ~3,500 endocrinologists is an unknown. As such, there is uncertainty around how much low hanging fruit (i.e., endocrinologists who perform a large number of FNA biopsies) remains un-penetrated by VCYT already. All of this said, we believe our forecasts for Afirma growth are realistic and achievable, perhaps even conservative when measured against the penetration of VCYT's closest comparator in the gene expression signature market, GDHX's (OP) Oncotype Dx for invasive breast cancer.

**Genzyme agreement a positive for adoption and tech validation but dilutes leverage in the model.** In January 2012 VCYT entered a co-marketing agreement with Genzyme, a subsidiary of Sanofi (MP), whereby it granted Genzyme the co-exclusive right to market Afirma in the U.S. and in 40 countries. Leveraging the complementary commercial infrastructure of Genzyme, which markets the drug Thyrogen to endocrinologists in over 42 countries worldwide, enables VCYT to accelerate the sales of Afirma compared to what it could accomplish on its own. However, VCYT does pay Genzyme 40% of cash collected for this privilege, a rate which drops to 32% in March 2014 and thereafter. This rate represents a lot of missing dollars from VCYT's P&L in forward years, and dilutes leverage in the model. While this agreement expires in 2027, either party may terminate the agreement at any time without cause and with six months' prior notice.

**Diagnostic testing reimbursement is undergoing reform.** Reimbursement for both routine and esoteric diagnostic testing is undergoing comprehensive reform, and reimbursement for many molecular tests was recently reduced by Medicare. Several clinical labs have noted challenges getting payment for molecular testing in 2013. In addition, CMS has proposed to reduce reimbursement for anatomic pathology codes by 26% on average under the 2014 physician fee schedule (PFS), which would include a cut to the cytopathology code VCYT uses to process FNA samples. Fortunately, VCYT already has a contract with Medicare for its GEC test and positive coverage decisions with several national payers. Additionally, we believe VCYT is positioned on the correct side of any emphasis to reduce healthcare costs. Broad deployment of VCYT's Afirma test should save payers ~\$2,600 per patient by reducing the number of unnecessary thyroid surgeries. While a cut to the cytopathology code might be forthcoming, we note that cytology services for Medicare patients comprise <10% of our VCYT revenue forecast, and we have already incorporated a cut in our modeling, eliminating incremental downside.

**FDA has become more vocal on regulating LDTs.** The FDA has stated on several occasions its intent to more tightly regulate laboratory developed tests (LDTs). Rumblings of enhanced regulatory efforts have continued since at least 2006. More recently (June 2013), the commissioner of the FDA spent nearly a third of her address at the American Society of Clinical Oncology (ASCO) annual meeting highlighting the potential risks of LDTs and the FDA's efforts to make sure that the accuracy and clinical validity of high-risk tests are established before they come to market. Most recently, the FDA issued a warning letter to 23andme, a high profile consumer genomics company. VCYT's Afirma GEC test is an LDT. While we believe enhanced regulatory oversight at some point in the future is a real possibility, we do not envision this



oversight as something that happens in the near future or impairs VCYT's market opportunity. Two key opinion leaders who presented at the Association for Molecular Pathology (AMP) analyst meeting reaffirmed our view by expressing their skepticism that the FDA's LDT guidance document will see the light of day anytime soon.

## COMPANY PROFILE

### High Growth, Commercial Stage Company With Novel Cancer Diagnostic

Veracyte (VCYT) is a commercial-stage company that employs pioneering molecular cytology technology to target diseases that often require invasive procedures for an accurate diagnosis. The company's first solution (Afirma Thyroid FNA Analysis) includes a novel molecular cytology assay based on a 142-gene signature (Gene Expression Classifier; GEC) that targets the thyroid market. The test is designed to improve the accuracy of diagnosis at an earlier stage of patient care by deriving clinically actionable genomic information from cytology samples collected in an outpatient setting. Since VCYT commercially launched Afirma in January 2011, the company has processed over 65k fine-needle aspiration (FNA) samples for evaluation using Afirma and more than 12k GECs to resolve indeterminate cytopathology results. The clinical validity, utility, and cost effectiveness of the GEC have been published in several peer-review journals.

As of October 1, 2013, VCYT had 107 employees, including 25 in laboratory operations, 20 in R&D and clinical development, 15 in sales and marketing, and 47 in general and administrative functions (billing and client services, information technology and quality and regulatory affairs). The company operates from two locations including its headquarters in San Francisco, California where it leases 24k square feet of office and laboratory space; and in Austin, Texas where it leases 10.4k square feet of office and laboratory space.

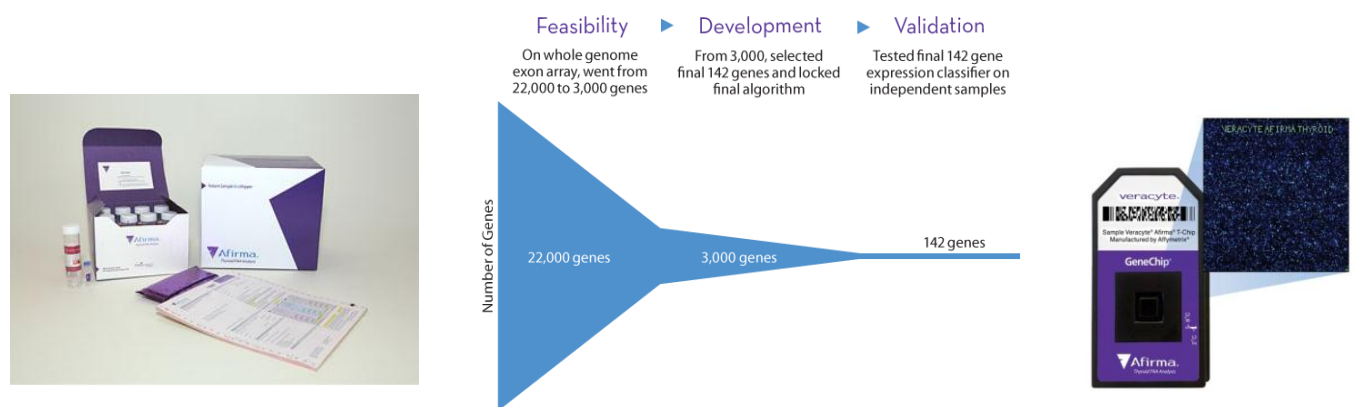


## SERVICE OVERVIEW

### Novel Molecular Cytology Offering Targeting Thyroid Market

In December 2010, researchers published findings from a multisite, prospective study that ultimately led to the development of a molecular test that would provide an alternative to more invasive procedures, such as surgery, for diagnosing thyroid cancer. Rather than developing a molecular test by assaying known cancer biomarkers, e.g., BRAF, KRAS, the researchers approached the scientific question by starting with the entire human genome. Beginning with 22,000 genes, the researchers used mRNA expression analysis to measure more than 247,000 transcripts and eventually identified 142 genes whose signature indicated benign expression, including genes known and previously unassociated with thyroid cancer pathways (process illustrated in following table). This gene signature and proprietary algorithms represent the technology driving VCYT's Gene Expression Classifier (GEC), a molecular diagnostic assay that distinguishes between benign and malignant thyroid nodules using fine-needle aspiration (FNA) samples. The GEC is part of VCYT's Afirma Thyroid FNA Analysis (Afirma) solution, and is employed only when cytopathology analysis of FNA samples reveals an indeterminate clinical conclusion.

### Afirma Thyroid FNA Analysis



Source: Veracyte

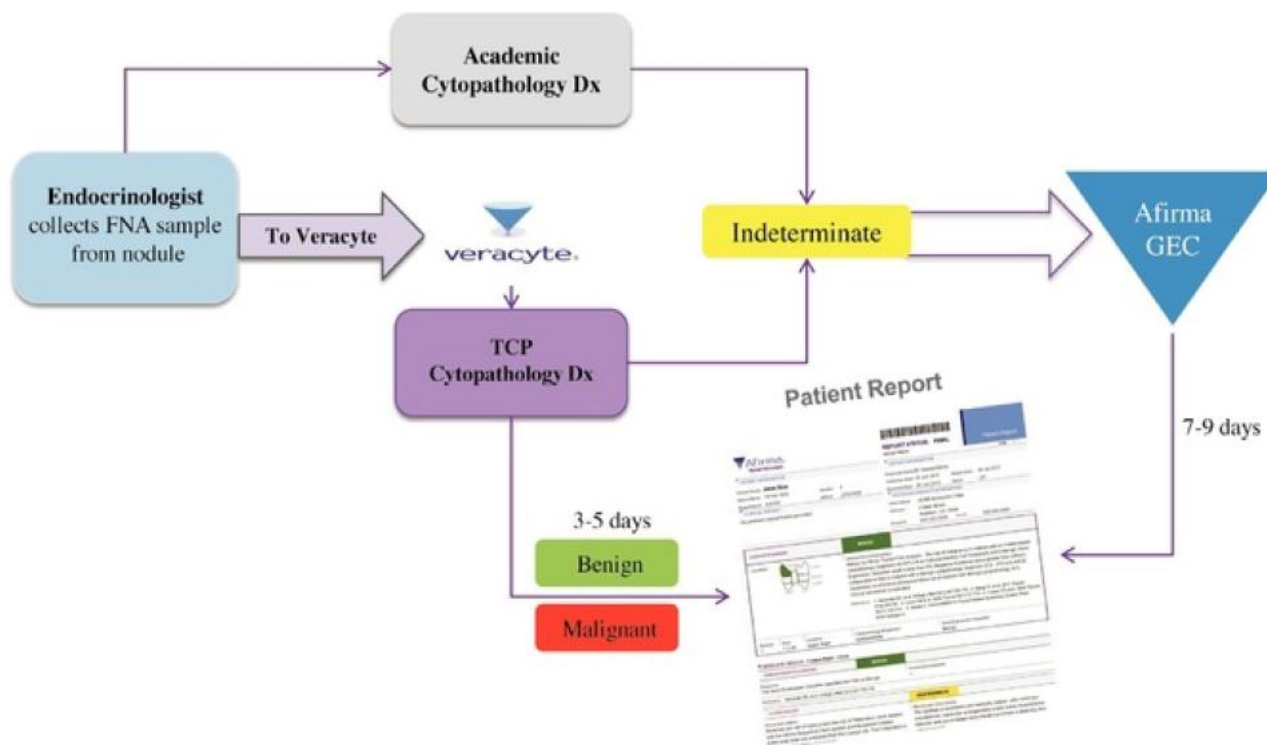
The ordering physician for Afirma is typically a community-based endocrinologist, radiologist, or head and neck specialist. When the physician observes a suspicious thyroid nodule on a patient, the practitioner will most often perform an FNA biopsy as a first-line diagnostic, and send this sample to an academic medical center (AMC), locally practicing pathologist, or reference lab. VCYT's technology now offers physicians a unique alternative that is consistent with practitioners' day-to-day workflow. VCYT's solution couples access to thyroid-only cytopathologists (TCP: Thyroid Cytology Partners) and an alternative to thyroid surgery if the sample is indeterminate. TCP will typically determine whether an FNA sample is benign or malignant in 3 – 5 days, and provide a report to the ordering physician. If the cytopathology is indeterminate, TCP will reflex the FNA sample to Afirma GEC for molecular classification at VCYT's lab in San Francisco. The GEC





will generate a result in 7 – 9 days and also reports the findings to the ordering physician. We depict the aforementioned workflow for Afirma Thyroid FNA Analysis in the following schematic:

#### Afirma Thyroid FNA Analysis Workflow



Source: Veracyte

The output of this process is an Afirma Thyroid FNA Analysis report, an example of which follows.



## Afirma Thyroid FNA Analysis Sample Report



REPORT STATUS: FINAL

Sample Report

Patient Report

PAGE 1 of 1

## PATIENT INFORMATION

Patient Name: Jane Doe

Date of Birth: 14 Feb 1955

Gender: F

Regulation #: AA1001

MRN #: JD123456

## CLINICAL HISTORY

No pertinent clinical history provided.

## REPORT INFORMATION

Physician Name: Dr. Donald Demo

Collection Date: 25 Jun 2012

Report Date: 09 Jul 2012

Received Date: 26 Jun 2012

Site #: 101

## PHYSICIAN CONTACT INFORMATION

Clinic Name: ACME Endocrine Clinic

Address: 1 Main Street

Anytown, CA 12345

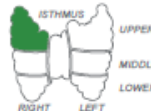
Phone #: 555.555.5000

Fax #: 555.555.5001

## DIAGNOSTIC SUMMARY

BENIGN

Location:



Clinical Recommendation:

Benign by Afirma Thyroid FNA Analysis. The risk of malignancy in nodules with an Indeterminate cytopathology diagnosis (AUS/FLUS or Follicular/Hürthle Cell Neoplasm) and a Benign Gene Expression Classifier result is less than 8% (Negative Predictive Value greater than 94%)(1), comparable to that in nodules with a Benign cytopathology diagnosis (2,3). ATA and AACE Guidelines recommend ultrasound follow-up of nodules with Benign cytopathology (4,5). Clinical correlation is indicated.

References: 1. Alexander EK, et al. *N Engl J Med* 2012;367:705-715., 2. Wang CC et al. 2011 *Thyroid* 21(3):243-251., 3. Lewis CM et al. 2009 *Thyroid* 19(7):717-723., 4. Cooper DS et al. 2009 *Thyroid*, 19(11) 1167-214., 5. Gharib H, AACE/AME/ETA Thyroid Nodule Guidelines, *Endocr Pract.* 2010;16(Suppl 1).

Nodule: 1

Size: 1.2 cm

Location: Upper Right

Cytopathology Diagnosis: Indeterminate

Gene Expression Classifier: Benign

## ▼ DETAILS BY NODULE : 1 (Upper Right - 1.2cm)

## GENE EXPRESSION CLASSIFIER

BENIGN

Diagnosis:

The Gene Expression Classifier identifies the FNA as Benign.

Technical Comments:

—

Reference: Alexander EK, et al. *N Engl J Med* 2012;367:705-715.

## CYTOPATHOLOGY

INDETERMINATE

Gross Description:

Received one vial of CytoLyt and one vial of FNAprotect, each labeled with the Afirma Requisition Form number and the patient's initials. A thin-prep slide was prepared from the CytoLyt vial. The FNAprotect is held for possible molecular analysis.

Microscopic Description:

The cytologic preparations are markedly cellular, with numerous microfollicles, trabecular arrangements and/or some macrofollicles; follicular cells are enlarged and crowded and there is relatively little colloid present.

Comments:

These features are best categorized as Follicular Neoplasm (Bethesda Thyroid Classification, 2009).

E-SIGNED ON 09 JUL 2012 09:00 AM BY:

Rob Monroe MD, PhD

Veracyte, Inc. CLIA # 05D2014120

CYTOPATHOLOGY E-SIGNED ON 29 JUN 2012 09:00 AM BY:

John Sample, MD

Thyroid Cytopathology Partners CLIA # 45D1075258

Veracyte performs the Gene Expression Classifier (GEC) as part of the Afirma Thyroid FNA Analysis for thyroid nodule fine-needle aspirates (FNA). The GEC's performance characteristics were determined by Veracyte based on a prospective independent validation study (Alexander EK et al. *NEJM* 2012; 367:705-715). Nodules with indeterminate cytopathology (Atypia of Undetermined Significance (AUS) / Follicular Lesion of Undetermined Significance (FLUS) or (suspicious for Follicular/Hürthle Cell Neoplasm) showed a negative predictive value (NPV) of greater than 94%, clinical sensitivity of 88% and clinical specificity of 51%. Nodules with Suspicious for Malignancy cytopathology showed a NPV of 85%, clinical sensitivity of 94% and clinical specificity of 52%. Analytical sensitivity studies of the GEC demonstrated the ability to detect as low as 20% malignant cells in a background of benign cells (data on file).

The Veracyte laboratory is regulated by the Centers for Medicare & Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical laboratory testing. The Afirma Thyroid FNA Analysis is used for clinical purposes.

veracyte.

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Anagh Vora, MD

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VCYT has a pathology services agreement with TCP, a specialized, thyroid-only pathology practice. TCP has exclusive access to diagnose the FNA samples sent to VCYT, offering consistent cytopathology analysis and potential quality and services utilization benefits. For example, approximately 14% – 17% of thyroid FNAs from TCP have been classified as indeterminate and have been reflexed to the GEC. This rate is at the low end of the 15% – 30% range cited in the 2009 American Thyroid Association Guidelines, suggesting TCP's specialized focus on thyroid cytopathology offers results more consistent with academic settings. Furthermore, studies have shown more consistent diagnostic concordance rates among specialists versus local pathologists (Wang et al, 2011).

Not only does VCYT's relationship with TCP offer benefits associated with specialization to providers, but it also confers advantages on VCYT. Converting ordering physicians to the entire Afirma workflow creates a stickiness with physicians that is analogous to an installed base in traditional lab-based diagnostics. Physicians are less likely to switch test providers when they are receiving more than one service from VCYT. This stickiness enables VCYT reps to spend more time closing new business versus maintaining existing business, since maintenance interaction can be maintained via phone by lab personnel.

During the development of the GEC, the molecular classification using FNA samples exhibited greater sensitivity and specificity than thyroid surgical tissue for samples with indeterminate cytopathology; for all samples, including benign and malignant, the molecular classification showed equal sensitivity with greater specificity compared to tissue samples (Chudova et al, 2010). This 2010 study was the inaugural demonstration that less invasive cell-based methods than surgery could identify thyroid nodules as benign or malignant. A pivotal study published in the *New England Journal of Medicine* (NEJM) in August 2012 showed that the risk of malignancy associated with a benign score on the GEC was ~5% (i.e., ~95% negative predictive value), comparable to the risk of malignancy with a benign FNA cytology. The authors concluded that a benign GEC result has similar predictive value of malignancy as cytologically benign indicators on an FNA (Alexander et al, 2012). The results from this study further validate the GEC as an alternative method to diagnose thyroid cancer.

#### Afirma Avails Several Benefits Compared to Traditional Methods

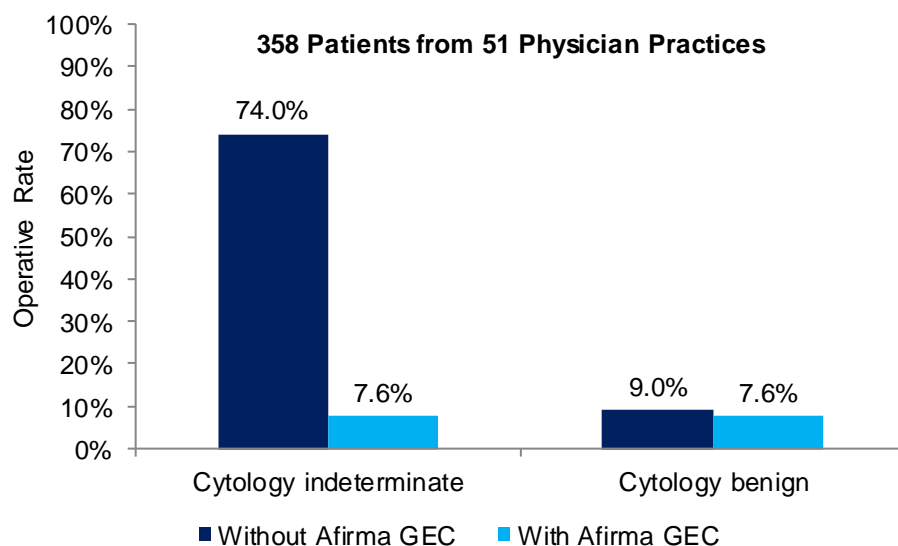
We believe VCYT's technology offers a unique and compelling solution to improve the diagnosis of thyroid cancer. The Afirma Thyroid FNA Analysis addresses a complex, clinical question in a cost-effective manner that could benefit several stakeholders including: patients, payers, and physicians. Our comparison of Afirma to traditional methods of diagnosing indeterminate thyroid samples (thyroid surgery) follows:

**Reduces unnecessary surgeries:** Pathologists who assess thyroid nodules microscopically fail to conclude whether samples are benign or malignant at a rate of 15% – 30%, depending on the experience of the pathologist. In such cases, the physician typically recommends the patient for surgery to remove the thyroid nodule to mitigate the risk of thyroid cancer. However, 66% – 80% of these nodules surgically removed are found to be benign postoperatively, indicating a significant rate of unnecessary surgery. Across 358 patients from 51 physician practices, Afirma GEC reduced the surgery rate for cytology indeterminate nodules by almost 90% versus clinical decision making



without Afirma GEC. The surgery rate for cytology indeterminate samples with Afirma GEC (7.6%) was also lower than nodules that tested cytology benign (9.0%).

#### Comparison of Surgery Rate With and Without Afirma GEC



Source: Duick et al. *Thyroid* (2012), Wang et al. (2011).

**Cost-effective versus traditional methods:** At a list price of \$4,275 for the GEC, VCYT's alternative to thyroid surgery has potential to reduce healthcare costs for government and private payers. The average cost of a diagnostic surgery for a thyroid nodule is \$12,000 – \$15,000 depending on where it occurs geographically and at which facility. Researchers from Johns Hopkins School of Medicine found that the use of GEC could reduce surgeries for patients with indeterminate thyroid nodules by ~75%, and yield a direct cost savings of \$1,453 per patient on average (Li et al., 2011). This estimate was based on an estimated 14% rate of surgery on a GEC benign nodule, which is almost double the 7.6% rate subsequently reported in the Duick paper (noted previously). Based on the rate of surgery on GEC benign nodules reported in the Duick paper, the cost savings per test jumps to approximately \$2,600.

**Mitigates co-morbidities:** Our secondary research suggests that Afirma could avert complications that occur when a patient undergoes thyroid surgery. Thyroid surgery is associated with complications at an incidence as high as approximately 2% to 10%, including: hypoparathyroidism (hypoPTH), temporary and permanent hypocalcemia, recurrent laryngeal nerve injury and voice change, dysphagia, airway compromise, and bleeding (Randolph, 2012; Sosa et al., 1998; Bergenfelz et al., 2008). We consider these co-morbidities and their associated costs to be non-trivial. For example, in the case of hypoPTH, the cost associated with annual treatment could be \$75,000, the estimated annual treatment cost of NPS Pharmaceuticals' (OP) Natpara, in Phase III clinicals. The rate of complications associated with thyroid surgery is material in part because half of thyroid surgeries are done by surgeons who perform  $\leq 5$ /year, though high volume surgeons have fewer complications (Saunders et al., 2003).



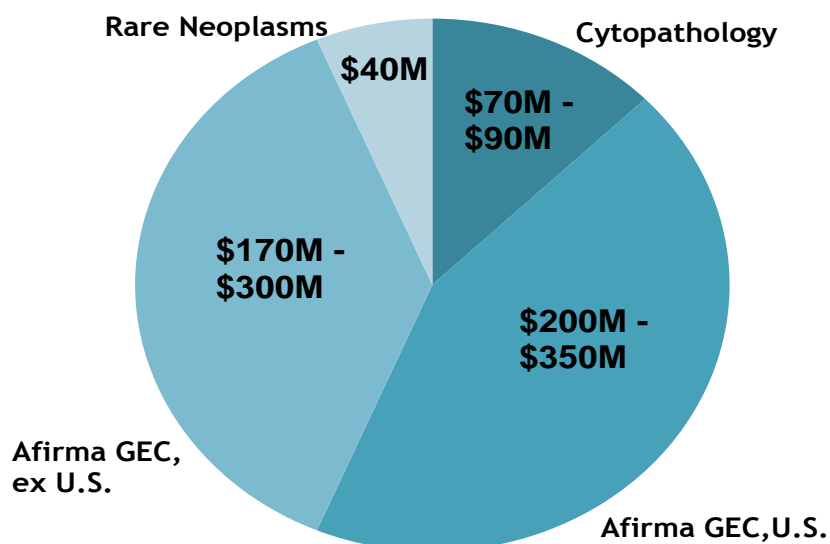
## GROWTH RUNWAY

Well Established Strategy to Deliver Growth for Several Years

VCYT identified a solution to a niche market that has yet to be contemplated by other companies with molecular diagnostic capabilities. Given the complexity of the biological question for which the company has identified a solution, the company could be on the verge of transforming the diagnosis of indeterminate thyroid samples.

We size the worldwide thyroid market opportunity at roughly \$500M – \$800M for VCYT and segment the opportunities here:

### Thyroid Cancer Diagnostic Global Market (\$M)



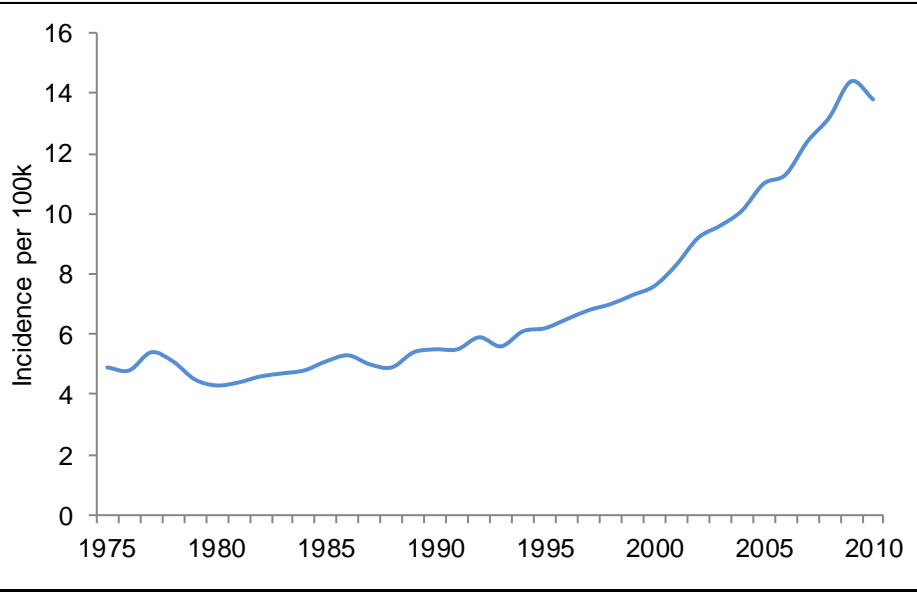
Source: Veracyte; Leerink Swann estimates

We see a pathway to growth via the company's novel technology as we discuss in the following section:

**Organic market expansion in thyroid:** Thyroid cancer is the fastest growing cancer in the United States according to the American Cancer Society, and screening of nodules suspicious for cancer is increasing the number of thyroid FNAs performed. The incidence of thyroid cancer has increased nearly three-fold from 1975 to 2010, for reasons researchers have yet to determine.



Thyroid Cancer Incidence per 100k, 1975 – 2010



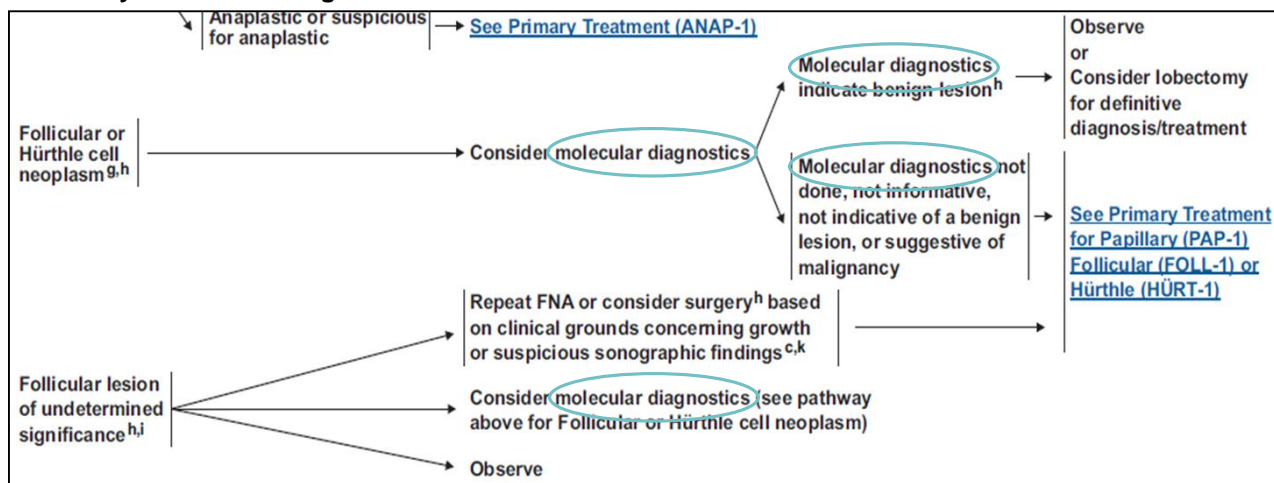
Source: SEER 9 registry



**Continued physician adoption:** Of the 5,800 board-certified endocrinologists (American Board of Internal Medicine), we estimate approximately 3,500 endocrinologists specialize in thyroid disease. We believe VCYT counts more than 20% of this group as customers, suggesting nearly 80% of the U.S. physician market is un-captured thus far. Thus, VCYT has plenty of runway to drive further physician penetration.

**Inclusion in clinical practice guidelines:** We believe the inclusion of Afirma and molecular tests into clinical practice guidelines would help build greater awareness of the test and drive further adoption by physicians and as a covered health plan benefit. For example, the National Comprehensive Cancer Network (NCCN) modified its thyroid cancer guidelines to consider use of molecular diagnostics in certain treatment pathways. An excerpt from the guidelines suggests an alternative to thyroid surgery: “if molecular testing predicts a risk of malignancy comparable to the risk of malignancy seen with a benign FNA cytology ( $\sim 5\%$ ) consider observation.” A schematic of NCCN guidelines for the evaluation of thyroid nodules follows.

#### NCCN Thyroid Cancer Diagnostic Guidelines



Source: NCCN

We believe VCYT's published evidence provides a basis for the American Association of Clinical Endocrinologists (AACE) and the American Thyroid Association (ATA) to also include GEC in their treatment guidelines.

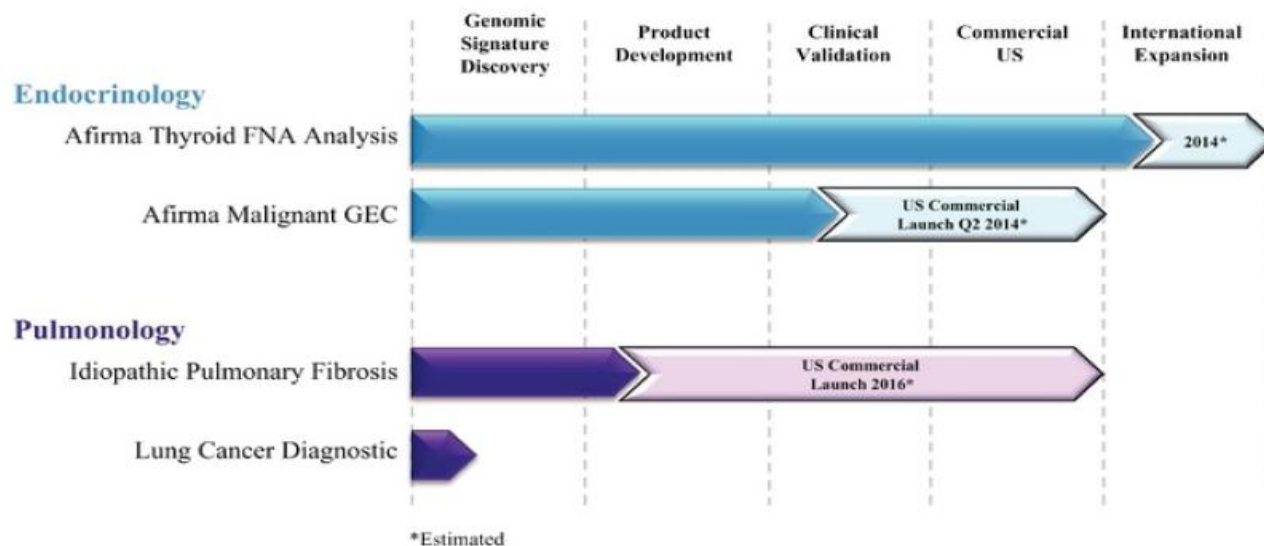
**International expansion:** VCYT entered a co-marketing agreement with Genzyme in January 2012 and is partnering with the company to commercialize Afirma internationally. Genzyme has a geographic footprint and already markets Thyrogen to endocrinologists in over 42 countries. Together, VCYT and Genzyme plan to selectively enter targeted international markets in 2014.

**Product pipeline:** VCYT has a number of projects in its R&D pipeline. In addition to thyroid cancer, the company is targeting other complex diseases in which cytology samples play a critical role in clinical decision making. VCYT is developing the Afirma Malignant GEC test to identify rare forms of thyroid cancer or metastases to the thyroid; this test is intended to better inform surgical strategy. The company is also in late biomarker discovery in interstitial lung disease (ILD), a group of lung diseases affecting the tissue and space around the microscopic air sacs of the lungs;



these diseases are difficult to diagnose prior to surgery. The clinical objective is to improve the accuracy of diagnosis of idiopathic pulmonary fibrosis (IPF), one of the more progressive, often fatal ILDs, and to provide critical information to inform treatment strategy. We elaborate on the company's pipeline here.

### Veracyte's Product Pipeline



Source: Veracyte

### Afirma Malignant GEC

- Several clinical manifestations that may present as a malignant thyroid nodule, such as a recurrent metastatic cancer from another organ or parathyroid conditions, would not be treated by removing the thyroid. Additionally, medullary thyroid cancer, a rare and aggressive form of thyroid cancer, requires a full central neck and lymph node surgery for treatment.
- VCYT is developing Afirma Malignant GEC test to inform the surgery strategy for rare neoplasms. The company plans to launch to product in 2Q:14.

### Idiopathic Pulmonary Fibrosis and Nodules Suspicious for Lung Cancer

- The ILD vertical is a large market opportunity (~200k patients) that VCYT's technology is suited to address. Lung diseases are difficult to diagnose without surgery.
- More than one-third of diagnostic bronchoscopies fail to yield an accurate or complete diagnosis, and invasive diagnostic biopsies cost ~\$25k per procedure.





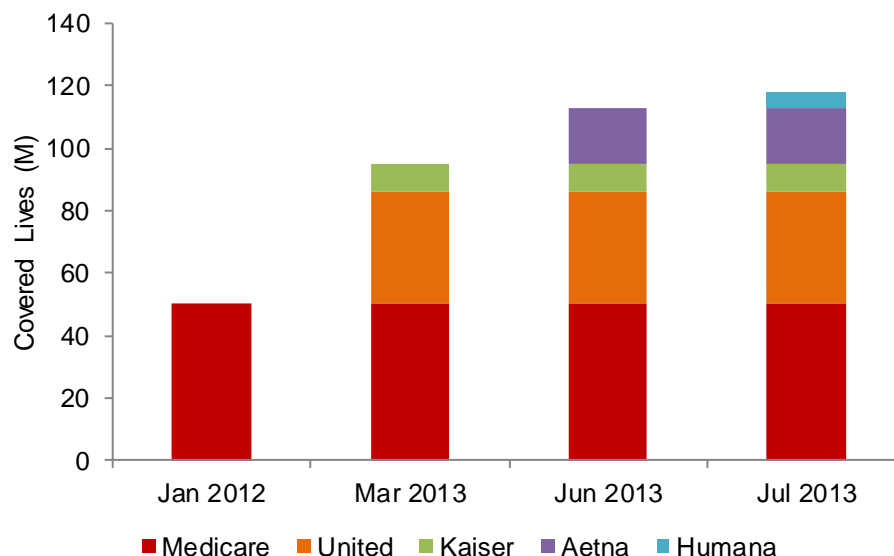
- VCYT is in late stage biomarker discovery for an IPF diagnostic test, with U.S. commercial launch targeted for 2016. The test could be adopted in clinical guidelines as a companion diagnostic or go/no-go decision for expensive biopsies.
- The availability of quality drugs to treat IPF could change the diagnostic calculus and expand the opportunity further. We believe, in a broader sense, the area of fibrosis and scarring is a fairly intense area of investigation with several drugs in the pipeline. For example, InterMune (ITMN, OP) is currently bringing Esbriet (pirfenidone), a drug for IPF, through Phase III clinicals in the U.S., and already markets the drug in the EU and Canada.

## REIMBURSEMENT LANDSCAPE

### Third-Party Payers Have Been Supportive

VCYT has garnered positive coverage decisions from payers at an impressive pace. In January 2012, the Medicare administrative contractor (MAC) for California published an independent technology assessment, and found that Afirma met criteria for analytical and clinical validity, and clinical utility as a reasonable and necessary Medicare benefit. This provided 50M Medicare beneficiaries with access to Afirma. In 2013, VCYT gained positive coverage decisions from several commercial payers, including national plans such as UnitedHealth (36M lives; March 2013), Kaiser Permanente (9M lives; March 2013), Aetna (18M lives; June 2013), and Humana (5M lives; July 2013). Afirma has positive coverage for more than 100M health plan members. VCYT accrues only Medicare revenue and recognizes all other payers on a cash basis. The company will begin accruing revenue for a given payer once it has sufficient collections history.

### Timeline of Afirma Positive Coverage Decisions by Payers, Jan 2012 to Jul 2013



Source: Veracyte, Leerink Swann



## COMPETITIVE LANDSCAPE

Direct Competition Is Thin; VCYT Largely Occupies Its Own Space

VCYT's principal competition for Afirma comes from traditional methods used by physicians to diagnose thyroid cancer. Practice guidelines in the United States have historically recommended that patients with indeterminate diagnoses from cytopathology results be considered for surgery to remove all or part of the thyroid to rule out cancer. Alternative testing methods to resolve indeterminate thyroid nodules are unsatisfactory, in our view: the performance of additional immunocytochemical testing with markers for thyroid cancer (HBME-1 and cytokeratin 19) is highly variable, while tests for mutations in known oncogenes offer insufficient sensitivity for malignancy and a poor negative predictive value.

## VALUATION

Trading at a Discount to High Growth Peers

VCYT's current stock price implies an enterprise value that is ~6.5x our 2014 revenue forecast. While this multiple is a premium to the median multiple for our broader life science tools and diagnostics coverage (~3.7x), it is a discount to the most appropriate comparable peer group based on business and growth (see following table).

### Emerging Growth Life Science Tools & Diagnostics Public Comps

Company	Ticker	Stock price	EV (M\$)	Revenue (M\$)			'14/ 15 Growth	Multiples	
				2013e	2014e	2015e		2014e	2015e
Cepheid	CPHD	\$44.02	\$2,902	\$390	\$447	\$521	17%	6.5x	5.6x
GenMark	GNMK	12.03	499	27	27	42	56%	18.3x	11.8x
Nanosphere	NSPH	2.11	159	10	22	37	72%	7.4x	4.3x
Fluidigm	FLDM	32.07	755	70	84	101	21%	9.0x	7.5x
Cellular Dynamics	ICEL	14.50	228	12	29	53	84%	7.9x	4.3x
PacBio	PACB	3.93	258	28	44	56	26%	5.8x	4.6x
Foundation Medicine	FMI	26.32	741	28	54	105	93%	13.7x	7.1x
Trovagene	TROV	5.39	102	0	4	11	164%	24.1x	9.1x
Exact Sciences	EXAS	11.81	838	4	27	85	220%	31.5x	9.9x
Nanostring	NSTG	12.17	178	31	54	81	50%	3.3x	2.2x
Genomic Health	GHDX	\$35.88	\$1,046	\$262	\$295	\$334	14%	3.6x	3.1x
MEDIAN (OVERALL)							56%	7.9x	5.6x

Source: Leerink Swann, FactSet (all estimates are FactSet consensus; prices are 11/22/2013 close)

With a forecast for continued commercial penetration, incremental news flow anticipated on coverage and guidelines, as well as new product news flow, we believe it reasonable to assume that VCYT can trade more closely to the high growth group and sustain its current premium multiple. Our \$17 price target corresponds to an enterprise value (using projected levels of debt and cash) that is ~6.5x our revenue estimate for the twelve months ended September 2015.



## RISKS TO VALUATION

The primary risks to our price target for VCYT include, but are not limited to: the trajectory of the Afirma GEC revenue ramp, ability to obtain positive coverage decisions and contract terms with third-party payers, competitive pressures from incumbent cytology labs, and ability to change traditional practice patterns among the physician community.

## MANAGEMENT

**Bonnie H. Anderson, President and CEO.** Bonnie H. Anderson is the President and Chief Executive Officer of VCYT. Prior to joining VCYT in February 2008, Anderson was an independent strategic consultant from April 2006 through January 2008 (including a consultant for VCYT). Anderson was a Vice President at Beckman Coulter, Inc., a manufacturer of biomedical testing instrument systems, tests and supplies, from September 2000 to March 2006, and held various positions in both Beckman as well as Coulter since 1989. In all, her career spans nearly 30 years in regulated diagnostics and life science markets. She graduated from Indiana University of Pennsylvania with a Bachelors of Science degree in Medical Technology.

**Shelly D. Guyer, CFO.** Shelly D. Guyer joined VCYT as Chief Financial Officer in April 2013, bringing over 25 years of experience in the finance and life science industries. Prior to VCYT, she served as CFO and Executive Vice President of Finance and Administration at iRhythm Technologies, a medical device and services company, where she was responsible for Finance, Accounting and administrative functions. Prior to that, she served on the management team and as Vice President of Business Development and Investor Relations at Nuvelo, a biotechnology company. Guyer began her business career at J.P. Morgan Securities and its predecessor companies, where for over 17 years she held various positions, including Principal and VP of Health Care Banking for the West Coast, leading financings for a variety of large and small cap life science companies; as a manager in the Investment Banking Division; and as VP with Hambrecht & Quist Venture Partners. She received an M.B.A. from the Walter A. Haas School of Business at the University of California, Berkeley, and a B.A. from Princeton University.

**Christopher M. Hall, Chief Commercial Officer.** Christopher Hall joined VCYT in 2010 as Chief Commercial Officer. Prior to VCYT, Hall most recently served as a Senior Vice President of Celera Corporation. Prior to this, Hall held several executive positions at Berkeley HeartLab, including Chief Clinical Operations Officer and Vice President, Marketing. Hall has also held management and sales positions with Asimba, Kenan Systems, and Symmetrix. He holds a Bachelor of Arts degree from DePauw University in Greencastle, Indiana and an M.B.A. from Harvard University.

**Giulia C. Kennedy, Ph.D., Chief Scientific Officer.** Giulia C. Kennedy joined the company in April 2008 and serves as Chief Scientific Officer. Prior to joining VCYT, Kennedy led the Genomics Collaborations and Genotyping Technology R&D groups at Affymetrix, Inc. Prior to joining Affymetrix, Kennedy was a scientific leader for the colon cancer and breast cancer gene discovery efforts at Chiron Corporation, resulting in the identification of oncology markers for therapeutic drug development. Kennedy was previously a scientist at Millennium Pharmaceuticals,



where she implemented genomic and genetic approaches to uncover diabetes susceptibility genes. She holds a Ph.D. degree in biochemistry, and completed postdoctoral training at the University of California at San Francisco in the Biochemistry Department and Hormone Research Institute. Kennedy has published more than 50 articles in peer-reviewed scientific journals and is a co-inventor on more than 20 patents.

**Richard B. Lanman, M.D., Chief Medical Officer.** Richard Lanman joined VCYT in 2008 as Chief Medical Officer. He previously served as Executive Vice President and Chief Medical Officer of diaDexus. Lanman previously served as Executive Vice President of Corporate Development and Chief Medical Officer at Atherotech, an advanced cardiodiagnostics testing laboratory, where he lead clinical studies and business development. Prior to Atherotech, Lanman was Founder and CEO of Adesso, an application service provider profiling quality and utilization for specialist physician networks. Earlier in his career, he was in physician practice management roles as Senior Vice President and Medical Director for San Jose Medical Group, and as a Chief of Quality at Kaiser Permanente.

**Veracyte (VYCT)**

Dan Leonard, 212-277-6116

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Income statement											dan.leonard@leerink.com		
Period Ended (\$ thousands)	2011	Mar-12	Jun-12	Sep-12	Dec-12	2012	Mar-13	Jun-13	Sep-13	Dec-13e	2013e	2014e	2015e
Revenues													
Testing service revenue	\$2,645	\$1,468	\$2,480	\$3,224	\$4,457	\$11,628	\$4,385	\$5,067	\$5,594	\$6,219	\$21,265	\$39,550	\$73,429
Other	0	0	0	0	0	0	0	0	0	0	0	0	0
Total revenues	2,645	1,468	2,480	3,224	4,457	11,628	4,385	5,067	5,594	6,219	21,265	39,550	73,429
Cost of service	2,925	1,254	1,746	1,984	2,600	7,584	2,773	3,231	3,132	3,420	12,557	20,961	32,309
Gross profit	(281)	214	734	1,240	1,857	4,044	1,611	1,836	2,462	2,798	8,708	18,588	41,120
SG&A	8,305	2,982	3,683	4,449	5,252	16,365	5,494	5,352	6,535	6,716	24,097	33,212	47,729
R&D	6,680	1,481	1,677	1,729	1,721	6,608	2,010	1,902	2,028	2,456	8,396	12,458	14,686
Operating income (loss)	(15,265)	(4,248)	(4,626)	(4,938)	(5,116)	(18,929)	(5,893)	(5,418)	(6,101)	(6,374)	(23,785)	(27,081)	(21,294)
Interest expense (income) and other, net	(820)	(0)	(0)	(0)	(279)	(280)	1,002	1,073	202	120	2,397	495	517
Pretax income	(14,445)	(4,248)	(4,625)	(4,938)	(4,837)	(18,649)	(6,895)	(6,491)	(6,303)	(6,494)	(26,182)	(27,577)	(21,812)
Taxes	0	0	0	0	0	0	0	0	0	0	0	0	0
Net income	(\$14,445)	(\$4,248)	(\$4,625)	(\$4,938)	(\$4,837)	(\$18,649)	(\$6,895)	(\$6,491)	(\$6,303)	(\$6,494)	(\$26,182)	(\$27,577)	(\$21,812)
Basic shares outstanding	580	650	650	650	650	650	813	813	956	14,342	4,231	21,535	22,335
Diluted shares outstanding	580	650	650	650	650	650	813	813	956	14,342	4,231	21,535	22,335
EPS diluted	(\$24.90)	(\$6.53)	(\$7.11)	(\$7.59)	(\$7.44)	(\$28.68)	(\$8.48)	(\$7.99)	(\$6.59)	(\$0.45)	(\$6.19)	(\$1.28)	(\$0.98)
EPS growth													
Testing service revenue growth						339.7%	198.8%	104.4%	73.5%	39.5%	82.9%	86.0%	85.7%
FNA volume	6,402	3,925	5,610	7,052	9,303	25,890	10,757	12,424	12,417	13,489	49,087	73,443	102,820
Gross margin	(10.6%)	14.6%	29.6%	38.4%	41.7%	34.8%	36.7%	36.2%	44.0%	45.0%	41.0%	47.0%	56.0%
SG&A % of revenue	314.0%	203.2%	148.5%	138.0%	117.8%	140.7%	125.3%	105.6%	116.8%	108.0%	113.3%	84.0%	65.0%
R&D % of revenue	252.6%	100.9%	67.6%	53.6%	38.6%	56.8%	45.8%	37.5%	36.3%	39.5%	39.5%	31.5%	20.0%
Operating margin	(577.2%)	(289.5%)	(186.6%)	(153.2%)	(114.8%)	(162.8%)	(134.4%)	(106.9%)	(109.1%)	(102.5%)	(111.9%)	(68.5%)	(29.0%)
Tax rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
D&A expense	\$611	\$172	\$177	\$177	\$181	\$706	\$197	\$231	\$289	\$233	\$950	\$1,186	\$2,203
EBITDA	(\$14,654)	(\$4,076)	(\$4,449)	(\$4,762)	(\$4,935)	(\$18,222)	(\$5,696)	(\$5,187)	(\$5,812)	(\$6,141)	(\$22,835)	(\$25,895)	(\$19,092)
Free cash flow													
Operating cash flow	(\$13,524)	\$6,007	(\$4,021)	(\$5,127)	(\$4,025)	(\$7,167)	(\$6,649)	(\$3,974)	(\$5,238)	(\$6,624)	(\$22,485)	(\$30,221)	(\$12,509)
CapX	(276)	(94)	(549)	(406)	(413)	(1,462)	(577)	(364)	(120)	(516)	(1,577)	(2,528)	(6,003)
Free cash flow	(\$13,800)	\$5,913	(\$4,570)	(\$5,534)	(\$4,438)	(\$8,629)	(\$7,226)	(\$4,338)	(\$5,358)	(\$7,141)	(\$24,063)	(\$32,750)	(\$18,512)

**Notes:**

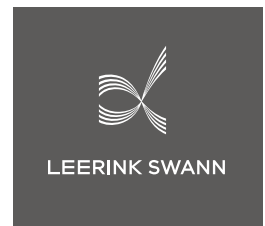
Source: Company reports and Leerink Swann estimates

**Veracyte (VCYT)****Balance sheet**

Period Ended (\$ thousands)	Mar-12	Jun-12	Sep-12	Dec-12	Mar-13	Jun-13	Sep-13	Dec-13e
<b>Assets</b>								
Cash, equivalents, ST investments, restricted cash	\$13,539	\$8,975	\$3,441	\$14,002	\$7,072	\$20,683	\$15,426	\$68,735
Accounts receivable	549	580	567	569	464	991	714	681
Inventory	295	726	767	1,050	737	770	1,392	937
Prepaid expenses and other current assets	<u>435</u>	<u>587</u>	<u>806</u>	<u>760</u>	<u>854</u>	<u>1,398</u>	<u>2,938</u>	<u>1,368</u>
Total current assets	14,818	10,869	5,582	16,381	9,127	23,841	20,470	71,722
Property and equipment, net	1,608	1,895	2,210	2,446	2,826	3,025	2,826	3,109
Restricted cash / LT investments	168	168	168	118	118	118	118	118
Other assets	<u>29</u>	<u>27</u>	<u>61</u>	<u>122</u>	<u>108</u>	<u>175</u>	<u>157</u>	<u>157</u>
Total assets	\$16,623	\$12,958	\$8,021	\$19,067	\$12,179	\$27,159	\$23,571	\$75,106
<b>Liabilities and shareholders' equity</b>								
Notes payable - current portion	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Accounts payable	884	1,217	1,434	1,888	1,651	1,906	5,604	1,949
Accruals	1,605	2,672	2,859	4,021	3,168	5,387	4,416	5,472
Other liabilities	<u>2,500</u>	<u>2,500</u>	<u>2,500</u>	<u>3,083</u>	<u>4,085</u>	<u>2,500</u>	<u>2,500</u>	<u>2,960</u>
Total current liabilities	4,989	6,390	6,793	8,992	8,903	9,793	12,520	10,382
Notes payable - long-term portion	0	0	0	0	0	4,826	4,863	4,863
Deferred revenues - long-term portion	0	0	0	0	0	0	0	0
Deferred Genzyme co-promotion fee	6,989	6,364	5,739	5,114	4,489	3,864	3,239	2,614
Other liabilities	<u>0</u>	<u>0</u>	<u>54</u>	<u>61</u>	<u>71</u>	<u>439</u>	<u>502</u>	<u>502</u>
Total liabilities	\$11,978	\$12,754	\$12,586	\$14,167	\$13,463	\$18,922	\$21,124	\$18,361
Convertible preferred stock	\$49,297	\$49,297	\$49,297	\$63,372	\$63,372	\$79,025	\$79,022	\$0
Shareholders' equity	(\$44,652)	(\$49,092)	(\$53,862)	(\$58,472)	(\$64,656)	(\$70,789)	(\$76,575)	\$56,745
Total liabilities and shareholders' equity	\$16,623	\$12,958	\$8,021	\$19,067	\$12,179	\$27,159	\$23,571	\$75,106

Source: Company reports and Leerink Swann estimates





## Disclosures Appendix

### Analyst Certification

I, Dan Leonard, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.



Distribution of Ratings/Investment Banking Services (IB) as of 09/30/13				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	111	64.90	27	24.00
HOLD [MP]	60	35.10	0	0.00
SELL [UP]	0	0.00	0	0.00

## Explanation of Ratings

**Outperform (Buy):** We expect this stock to outperform its benchmark over the next 12 months.

**Market Perform (Hold/Neutral):** We expect this stock to perform in line with its benchmark over the next 12 months.

**Underperform (Sell):** We expect this stock to underperform its benchmark over the next 12 months. The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.



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