AEGIS CAPITAL CORP

Molecular Diagnostics
Raghuram Selvaraju, Ph.D.
(646) 502-2464
rselvaraju@aegiscap.com

Yi Chen, Ph.D.
(646) 502-2463
ychen@aegiscap.com

Initiating Coverage

December 12, 2012

Key Metrics

TROV - NASDAQ	$4.61
Pricing Date	Dec 12 2012
Price Target	$12.00
52-Week Range	$6.66 - $1.86
Shares Outstanding (mm)	14.2
Market Capitalization ($mm)	$65.5
3-Mo Average Daily Volume	49,095
Institutional Ownership	3%
Debt/Total Capital	NM
ROE	NM
Book Value/Share	$0.35
Price/Book	13.2x
Dividend Yield	NM
LTM EBITDA Margin	NM

EPS ($) FY: December

	2011A	Prior 2012E	Curr. 2012E	Prior 2013E	Curr. 2013E
1Q-Mar	--	--	(0.11)A	--	(0.07)E
2Q-Jun	--	--	(0.28)A	--	(0.09)E
3Q-Sep	--	--	(0.05)A	--	(0.09)E
4Q-Dec	--	--	(0.07)E	--	(0.09)E
FY	--	--	(0.49)E	--	(0.34)E
P/E	NM		NM		NM

Company Description:

TrovaGene, Inc. (http://www.trovagene.com/), based in San Diego, CA, develops non-invasive molecular tests in cancer, infectious disease and prenatal diagnostics.

Trovagene, Inc.

Rating: Buy

TrovaGene: As Non-Invasive As It Gets

Investment Highlights:

- **Initiating Coverage.** We are initiating coverage of TrovaGene, Inc., an emerging molecular diagnostics company, with a Buy rating and a 15-month price target of $12.00 per share. In our view, this firm has the most non-invasive technology platform in the diagnostics arena. TrovaGene's proprietary platform involves the use of transrenal nucleic acids, which are pieces of genetic material present in urine samples, to conduct screening for a wide array of conditions and disorders. The company is currently focused on developing an array of molecular diagnostics in the domain of oncology, which could have broad applicability across a range of different types of malignancies. In addition, TrovaGene owns its own clinical laboratory to enable the screening of samples in-house, and has demonstrated its ability to conduct fetal gender determination and human papillomavirus screening as well.
- **Multiple Shots On Goal.** We believe that TrovaGene is substantially more risk-mitigated than many of its peers in the diagnostics sector, because it focuses on developing tests based on highly-validated disease markers and mutations known to be correlated with disease prognosis as well as responses to specific drugs. In addition, the company possesses multiple potential product initiatives, several of which have been validated in terms of accuracy in various clinical trials.
- **As Non-Invasive As Humanly Possible.** We note that the transrenal nucleic acid-based diagnostic approach essentially means that TrovaGene's tests are not invasive at all. Nothing is less invasive than using urine as an analyte, since urine is voided naturally by the body (often multiple times per day) and therefore constitutes a natural and ideal basis for non-invasive diagnostics.
- **Attractive Valuation.** We note that, despite having a broad array of tests in development and a proprietary CLIA laboratory that we believe could permit self-commercialization in the next year or two, TrovaGene currently trades at a market cap of roughly $60mm, a significant discount to our risk-adjusted Net Present Value (rNPV)-based total firm value estimate of $340mm, which factors in exercise of 3.3mm options and 6.8mm warrants currently outstanding.

The Disclosure section may be found on pages 30 - 31 of this report.

Investment Thesis

TrovaGene, Inc. is an emerging firm that holds broad rights to the use of transrenal nucleic acids as the basis for non-invasive molecular diagnostic tests. The firm focuses on the development and marketing of urine-based nucleic acid tests, which predominantly use transrenal DNA, or Tr-DNA, and transrenal RNA, or Tr-RNA. Transrenal nucleic acids refer to those DNA and RNA molecules that pass through the renal filtration system and end up in the urine. Since urine is naturally produced by the body and voided – generally several times a day – it represents the most non-invasive analyte that can possibly be used as the basis for molecular diagnostic tests. Other analytes, such as tissue, skin, and blood, are much more invasive to obtain than urine. Transrenal nucleic acids are derived from dying cells in the body. The intact DNA is fragmented in dying cells and released into the blood stream. These fragments have been shown to cross the kidney barrier (i.e. are transrenal) and can be detected in urine. In addition, there is evidence that some species of RNA or their fragments are stable enough to cross the renal barrier. These RNA can also be isolated from urine, detected and analyzed. TrovaGene's proprietary technology is applicable to all transrenal nucleic acids. Accordingly, therefore, we believe that the firm's technology platform is likely to have significant strategic importance to a wide range of diagnostics-focused companies, as well as pharmaceutical firms seeking to identify biomarkers that could predict responsiveness to specific drugs. TrovaGene has already demonstrated the effectiveness of its platform by generating sensitivity and specificity data proving the accuracy of diagnostic tests using its transrenal nucleic acid detection approach.

We are initiating coverage of TrovaGene (TROV) with a Buy rating and a 15-month price target of $12.00 per share, which assumes a total firm value of roughly $340 million and 28 million shares outstanding (fully-diluted) as of end-1Q 2014.

Investment Positives

The Most Non-Invasive Approach Available Targeting Massive Markets. We note that there is no analyte that is more non-invasive than urine. In addition to being easy to collect, urine provides the possibility of sampling over a theoretically unlimited time period, permitting real-time monitoring of disease. Such flexibility would be of particular importance in the assessment of cancer patients, especially those at risk of recurrence. The molecular diagnostics market is massive – various estimates place its global value at nearly $7 billion in 2011, with a compound annual growth rate (CAGR) estimated at 15% – 20%. Certain emerging markets, such as India and China, contain diagnostics sectors exhibiting even faster growth rates.

Significant Clinical Validation With Multiple Shots On Goal. TrovaGene possesses a forward-integrated structure, with in-house sample processing capability through its wholly-owned Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory. In addition, the firm has established a broad network of strategic partnerships, which could enable it to rapidly expand its reach into different indications. Unlike many other molecular diagnostics firms of its size, which have only a few tests, TrovaGene has demonstrated the validity of its technology platform through several clinical studies for a range of applications. These include the identification of specific disease markers in oncology, fetal sex determination, and infectious disease diagnosis.

Profitability Potential. In our view, the diagnostics arena is more attractive than the drug development arena in one sense – that of the amount of capital required for clinical validation and commercialization. We believe that TrovaGene could begin commercializing the first of its proprietary diagnostic tests in 2013 and that the firm could achieve sustainable profitability in late 2014 / early 2015.

Investment Risks

Clinical Development Risk. Although the business of developing diagnostics is considered somewhat less risky than endeavors to develop new drugs, it is nevertheless still uncertain. If TrovaGene cannot demonstrate the predictive value of its tests, we believe that these tests may never become commercially successful. The future ability of the company to launch additional tests based on its proprietary technology platform rests upon being able to demonstrate the clinical utility of these tests.

FDA Unpredictability. While currently there are hundreds of diagnostic tests that are available in the U.S. through the so-called CLIA pathway, which implies classification as a Laboratory-Developed Test (LDT), we note that regulations on LDTs could change at any time. If the FDA decides to regulate these tests in a stricter manner, TrovaGene's ability to market its LDTs could be impaired or restricted.

Competitive Landscape. A multitude of other diagnostic tests are currently available that are aimed at similar indications and market niches to those being targeted by TrovaGene's products. Several other companies are trying to develop nucleic acid-based diagnostics and therapeutics, including Alnylam Pharmaceuticals, Inc., Asuragen Inc., CombiMatrix Corp., EXACT Sciences, Exiqon A/S, GenMark Diagnostics, Life Technologies Corp., Isis Pharmaceuticals, Merck & Co., Inc., Santaris Pharma A/S, Regulus Therapeutics, Response Genetics and others. In addition, TrovaGene faces competition from companies in the life sciences tools arena that are attempting to enter the molecular diagnostics sector, such as Affymetrix, Fluidigm, Illumina, and others.

Intellectual Property Risk. The company relies on patents and trade secrets to protect its products from competitors. The healthcare industry is litigious, and lawsuits are considered to be a normal part of doing business. A court might not uphold TrovaGene's intellectual property rights, or it could find that TrovaGene infringed upon another party's property rights. In addition, competing diagnostics firms could potentially find loopholes in TrovaGene's intellectual property estate. One particularly central aspect of the TrovaGene IP portfolio is the patent estate covering rights to transrenal nucleic acids. The patents covering these claims expire between 2018 and 2027.

Reimbursement Risk. In recent years, reimbursement agencies have grown more wary of systematically reimbursing for marginal benefit at excessive cost. If Medicare spending growth continues to outpace GDP growth, and the government's ability to fund healthcare becomes impaired, changes could be made to reimbursement policy that would negatively affect the company's business, despite what we believe to be the compelling value proposition inherent in transrenal nucleic acid-based diagnostics.

Additional Risks. TrovaGene currently has about $10.5 million in cash and equivalents (*pro forma*). During the next 12 months, we do not expect the firm to generate any net income from the sales of its diagnostic tests, as we believe that the company could require up to 24 months in order to reach sustainable profitability. Although the current burn rate implies that TrovaGene should not need to raise additional capital for at least 12 months, if the burn rate were to increase substantially or the firm's most advanced diagnostic tests fails to achieve commercial traction, TrovaGene could be forced to raise additional capital. Sources of cash could include: licensing fees, warrant and option exercises, or issuance of more shares. TrovaGene may not be able to raise cash at all.

Industry Risks. Emerging healthcare stocks are inherently volatile and increasingly subject to development and regulatory risk. Meeting or missing commercialization milestones may result in a significant change in the perception of the company and its stock price. We do not expect volatility to subside near term. For additional risk considerations, please refer to the company's SEC filings.

Valuation

Comparables Analysis: Since TrovaGene is unprofitable, we use a discounted cash flow-based approach to value the shares. Based on a comparables analysis, we believe that the stock is worth $12 per share, given our estimate of a $275 million risk-adjusted net present value (rNPV) for the firm's technology platform and its various commercial applications. This assumes that the shares trade in line with the comp group average enterprise value of roughly $290 million and that the firm has 28 million shares outstanding (fully-diluted) in early 2014.

Table 1: Comparable Company Analysis

(Millions, Except Per-Share Data)

Development	Therapeutic Area	Company	Ticker	Rating	Closing price 12/11/2012	Shares (MM)	Market cap ($MM)	Cash ($MM)	Debt ($MM)	Enterprise value ($MM)
Marketed	Molecular Diagnostics / Life Science Tools	Affymetrix	AFFX	Not Rated	$3.34	71	236	32	192	396
Marketed	Molecular Diagnostics	EXACT Sciences	EXAS	Not Rated	$10.35	64	660	119	2	544
Marketed	Life Science Tools	Fluidigm Corp.	FLDM	Not Rated	$14.43	25	361	86	2	276
Marketed	Molecular Diagnostics	Genomic Health	GHDX	Not Rated	$27.85	31	856	126	0	730
Marketed	Molecular Diagnostics	GenMark Diagnostics	GNMK	Not Rated	$9.42	33	308	54	1	255
Marketed	Molecular Diagnostics	NeoGenomics	NEO	Not Rated	$3.00	45	134	2	0	132
Marketed	Molecular Diagnostics	Response Genetics	RGDX	Not Rated	$1.38	33	45	11	1	36
Marketed	Molecular Diagnostics	Rosetta Genomics	ROSG	Buy	$4.26	9	38	36	0	3
Marketed	Molecular Diagnostics	Sequenom	SQNM	Not Rated	$4.82	115	553	193	150	510
Marketed	Molecular Diagnostics	Vermillion	VRML	Not Rated	$1.36	15	21	16	7	11
		Average					**321**			**290**
									Discrepancy	
Current valuation	**Molecular Diagnostics**	**TrovaGene**	**TROV**	**Buy**	**$4.61**	**14**	**65**	**9**	**0**	**56**
					Derived 12-month compa-month comparable value					**Projected**
Target valuation (15-month)	**Molecular Diagnostics**	**TrovaGene**	**TROV**	**Buy**	**$12.00**	**28**	**350**	**60**	**0**	**290**

Source: First Call and Aegis Capital Corp. estimates

Free Cash Flow: We estimate that TrovaGene will not be cash flow-positive in 2012 and 2013, due to the time required to validate its tests and commercialize them using a proprietary sales force. We define free cash flow as operating cash flow minus capital expenditures and dividend payments. We utilize a discounted cash flow analysis supporting a risk-adjusted Net Present Value (rNPV) framework to derive our $12 price target; this is described further in the next section of this report.

Our detailed analysis has three components: our discounted cash flow model, including the rNPV assessment of the firm's most mature diagnostics; our assessment of the markets for these tests; and the near-term financial outlook for the firm. Our historical income statement and financial projections are presented at the back of this report.

Risk-Adjusted Net Present Value Analysis

We are projecting peak annual U.S. sales for the company's proposed suite of oncology-focused diagnostic tests of approximately $300 million in 2018, with gradual erosion occurring in the subsequent years leading up to the final projected patent expirations in the 2027 time frame. This estimate includes the following:

- Sales in pancreatic and colorectal cancer for the firm's K-ras mutation test
- Sales in melanoma, colorectal and ovarian cancer for the firm's B-raf mutation test
- Sales in breast, colorectal, bladder and ovarian cancer for the firm's PIK3CA test

We estimate that, at a peak market share of around 10% – 15% of all eligible patients, there would be approximately 640,000 tests being administered annually in the U.S. alone. This assumes that each patient screened using these tests winds up being screened at least twice a year, on average. In our view, given the platform's non-invasiveness, assuming two tests per year is relatively conservative. Our risk-adjusted base case NPV calculation yields a $200 million value, or roughly $7 per share for the oncology tests. We are also ascribing $75 million in value, or roughly $2.70 per share, to the firm's diagnostic approaches in fetal gender determination and infectious disease. At this time we do not assign additional value to TrovaGene's extensive IP portfolio in the transrenal nucleic acid domain. Therefore, we believe that there are multiple additional sources of potential upside to our projections, and consider our valuation approach conservative.

Table 2: Oncology Diagnostic Test Market Metrics

Oncology Tests - U.S. only	Base-case
Total patients[1]	2.2MM
Peak market share[2]	13%
Treatment revenue/year/patient[3]	$475
Peak sales[4]	$300MM
Launch	2014
Peak sales year	2018
Use patent expires[5]	2027
Discount rate	15%
Risk-adjusted NPV[6]	$200MM
NPV per share	$7
Additional value drivers (fetal gender determination, HPV testing)	$80MM
Total enterprise value	$280MM
Cash and cash equivalent balance at end-1Q 2014	$60MM
Shares Outstanding at end-1Q 2014 (in millions)	28
Cash per share	$2
15-Month Target Price	$12.00

Notes on assumptions:

[1] Patients carrying relevant mutations (K-ras, B-raf, PIK3CA) - United States only (Source: American Cancer Society, National Cancer Institute)

[2] Peak market share - factoring in competition from other molecular diagnostics

[3] Revenue/year/patient - estimated based on projected pricing in the $400 - $600 per test range

[5] Peak sales - test revenue / year / patient x diagnosed patients x peak market share

[6] Final patent on transrenal nucleic acid-based analysis expires 2027

[7] Cash flow fully taxed at 35%; net operating loss carryforwards not forecast to offset taxes

Source: Company reports; Aegis Capital Corp. estimates

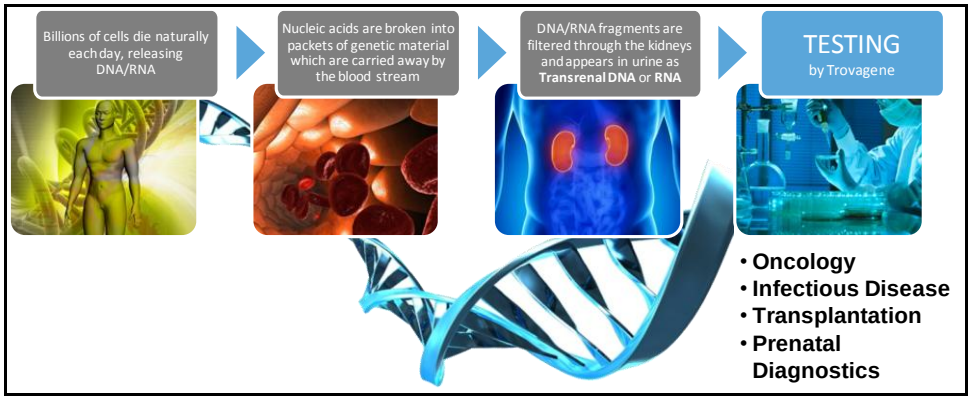
We note that, although TrovaGene currently has roughly $20 million in net operating loss carry-forwards, we are not factoring the impact of these into our valuation because of the ownership changes that occurred according to the company. This approach may be conservative if it turns out that some of these NOLs can in fact be used to offset future taxes. We are currently assuming a 35% corporate tax rate from the outset.

Company Overview

TrovaGene, Inc. is a specialized molecular diagnostics company focusing on the development and commercialization of proprietary diagnostic tests in the domain of oncology, as well as other areas. The firm's core strength is its industry-leading expertise in the field of transrenal nucleic acids, which have recently been observed to have substantial potential in the development of non-invasive molecular diagnostics. The company was originally founded in 1999, with a focus on developing non-invasive diagnostic approaches aimed at quantifying the extent of disease in a wide array of pathological conditions. In the cell, genes are expressed through information carried from DNA by messenger RNAs, or mRNAs, which is in turn translated into proteins (the so-called "central dogma" of biology).

Proteins are the building blocks of all living cells. The type of cell, its function, and the timing of its death are determined by which proteins are produced in the cell, and at what quantities and time they are produced. However, the proteins are the end product of a complex process which begins with the genetic code present in DNA. Before a protein is expressed, or produced, relevant parts of the DNA are copied into an mRNA strand. Each mRNA holds a code with instructions on how to build a specific protein using a process called translation. DNA and RNA molecules are released – in relatively intact form – by dying cells in the body. These nucleic acids are "shed" into the bloodstream and wind up in the urine of the patient by traveling through the renal filtration pathway. As shown in the schematic flow chart below, TrovaGene's aim is to utilize the presence of transrenal nucleic acids in order to develop and commercialize an entire suite of non-invasive diagnostic tests, which rely upon the detection and analysis of these nucleic acids that are found in the urine of patients being assessed.

Figure 1: Principles of Transrenal Nucleic Acid-Based Diagnostics



Source: TrovaGene

Although historically the levels of intact nucleic acids in urine were too small to permit sensitive detection and analysis, recent advances in the efficiency and accuracy of nucleic acid amplification techniques has permitted the levels of intact nucleic acids in urine samples to be rendered sufficient for the development of reliable diagnostic tests. In addition, high-throughput sequencing and multiplex polymerase chain reaction (PCR) allows for rapid analysis of millions of sequences, making this approach a reality.

Urine also provides the unique advantage of being collectable in massive volumes – unlike blood – and thus even very scarcely-expressed nucleic acid species can be amplified by using a combination of both nucleic acid amplification techniques as well as volume collection of the urine in order to pool the sample and concentrate the target nucleic acid species, if necessary.

The company is currently advancing diagnostic development programs in cancer and other areas, to potentially enable accurate diagnosis and improve patient care management worldwide. TrovaGene's core business strategies are as follows:

- Leverage its knowledge to develop body fluid-based (specifically urine) diagnostic tests. The company has recently prioritized the discovery projects of potential transrenal nucleic acid biomarkers for new indications within the oncology domain.
- Maximize sales of the firm's first commercial tests through the establishment of a proprietary sales force or a sales team accessed through a partnership with a contract sales organization (CSO).
- Build and maintain a strong intellectual property position. In our view, TrovaGene's patent portfolio is one of the most attractive aspects of the company, as this firm was the first commercial enterprise to focus on the emerging field of transrenal nucleic acids and assess the possibility of developing non-invasive diagnostic tests using urine as the primary analyte. We also believe that TrovaGene possesses key, fundamental IP in the area of developing optimized nucleic acid amplification and detection methods designed for use with urine samples.
- Leverage the firm's intellectual property position and transrenal nucleic acid-based diagnostic test design expertise to continue to establish strategic collaborations. The company intends to continue to establish strategic collaborations with leading clinical diagnostic and pharmaceutical companies to further develop and commercialize transrenal nucleic acid-based diagnostics.

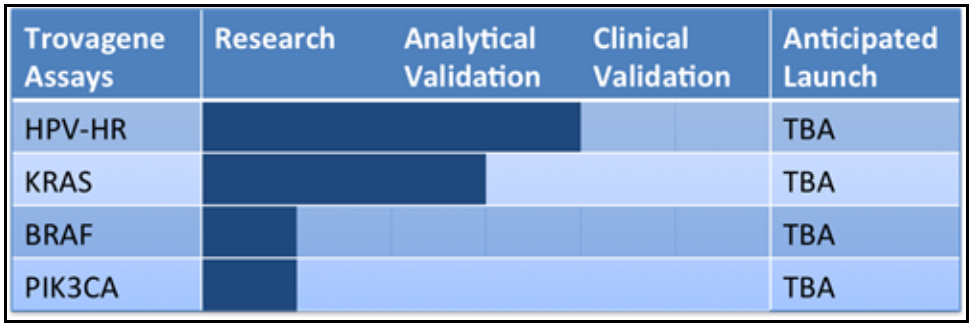
Leadership

The firm's leadership comprises several individuals, notably the company's CEO, Antonius Schuh, CFO Steve Zaniboni, and Chief Technology Officer Charlie Rodi, who have worked together for many years and whose collaboration spans multiple previous employers. In addition, these individuals have launched tests, established strategic partnerships and consummated acquisition transactions in the diagnostics arena. Furthermore, the company's Board of Directors is exceptionally strong, in our view, including individuals such as Gabriele Cerrone, who has a well-known track record in the life sciences sector after having executed several high-profile acquisition transactions.

Product Pipeline

This pipeline of proprietary tests is shown below. Our current valuation methodology only accounts for TrovaGene's oncology-focused diagnostics, and does not ascribe any value to the firm's proven diagnostic capabilities in other arenas, such as fetal gender determination and infectious diseases (e.g. human papillomavirus infection). Such applications could provide substantial future upside to our projections and valuation.

Figure 2: TrovaGene Proprietary Diagnostic Test Pipeline



Source: TrovaGene

Current Corporate Partnerships

TrovaGene is unusual for a company its size in that it has already put in place a relatively broad network of corporate partnerships. The agreements that have been executed thus far provide TrovaGene with ongoing licensing income. However, in our view none of these partnerships is as yet a pan-validating arrangement. We would expect TrovaGene to pursue the consummation of additional partnerships with established diagnostic and pharmaceutical firms in order to optimize the commercialization of its tests and broaden the recognition of the value inherent in its proprietary technology platform. TrovaGene's current royalty-bearing licensing agreements largely focus on the firm's rights to the nucleophosmin 1 (NPM1) marker, which TrovaGene originally in-licensed in 2006, as a way to diagnose and monitor patients with acute myeloid leukemia (AML). Among the firm's strategic arrangements are the following:

- Ipsogen S.A. In August 2007, TrovaGene entered into a sublicense agreement with Ipsogen S.A. Ipsogen is obligated to develop, seek registration and sell licensed products derived from the NPM1 patent rights. Ipsogen is obligated to pay a royalty in the teens with annual minimum royalties of $10,000 for the first year, $25,000 for the second year, $40,000 for the third and fourth year and $50,000 thereafter and milestone payments with a potential aggregate of $230,000. The term of the license ends on October 28, 2025, which is the date of expiration of the issued patent rights.

- Asuragen, Inc. In October 2007, TrovaGene entered into a Co-Exclusive Sublicensing Agreement with Asuragen, Inc. on NPM1 patent rights. Asuragen is obligated to pay a single digit royalty on a sliding scale based on sales volume with annual minimum royalties of $10,000 for the first year, $25,000 for the second year and $50,000 thereafter and milestone payments with a potential aggregate of $300,000. The term of the license ends on October 28, 2025 which is the date of expiration of the issued patent rights.

- Laboratory Corporation of America Holdings (LabCorp). In August 2008, TrovaGene entered into a sublicense agreement with LabCorp relating to the NPM1 patent rights. LabCorp is obligated to pay a royalty in the teens with annual minimum royalties of $10,000 for the first and second year, $15,000 for the second year, $20,000 for the third year and $25,000 thereafter.

On January 18, 2011, TrovaGene acquired a hybridoma able to produce a monoclonal antibody targeting the NPM1 biomarker for $10,000. The firm agreed to pay the seller of the hybridoma – for a period of seven years commencing with the first sale of the antibody – annual royalties on a country by country basis in the aggregate amount of 10% of all royalties received from licensees pursuant to any licenses of rights to the antibody. Thus far, no such royalties have been received. TrovaGene agreed to pay (i) 10% of all cash consideration from licensees as upfront license fees and (ii) 7% of all cash consideration received by the firm from licensees as milestone payments.

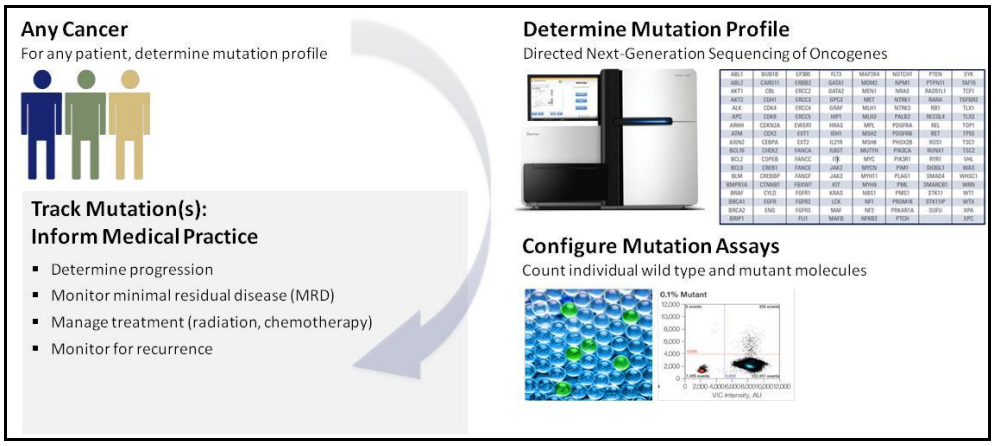
In October 2011, TrovaGene entered an exclusive license agreement on a specific gene mutation (SF3B1) with potential prognostic value in chronic lymphoblastic leukemia (CLL). The term of the license runs until September 29, 2031. In December 2011, TrovaGene also licensed the rights to the use of a specific B-raf mutation in diagnosis of hairy cell leukemia (HCL). The term runs until May 10, 2021. Both of these agreements involve the payment of single-digit royalties on sales of diagnostics derived from these markers. Thus far, no royalties have been paid by TrovaGene under these agreements. While at this juncture we have not modeled out sales of diagnostic tests using these markers, we note that the hematological malignancies represent a potentially substantial opportunity for TrovaGene and that these markers may thus provide value in the future.

CLIA Laboratory Acquisition

In order to facilitate early availability and use of the firm's products and technologies, on February 1, 2012, TrovaGene acquired the CLIA laboratory assets of MultiGEN Diagnostics, Inc. The acquisition included CLIA (Clinical Laboratory Improvement Amendments of 1998) approval and licensing documentation, laboratory procedures, customer lists and marketing materials.

A CLIA lab is a clinical reference laboratory that can perform high complexity diagnostic assays (e.g. those requiring PCR amplification). Through this CLIA laboratory, TrovaGene is able to offer laboratory-developed tests (LDTs) in compliance with CLIA guidelines, and, depending on the diagnostic assay, without the need for FDA review of each individual test. This is intended to make TrovaGene's diagnostic solutions directly available to physicians, and in turn generate revenue.

Figure 3: Envisaged Cancer Mutation Tracking Paradigm



Source: TrovaGene

In connection with the acquisition, TrovaGene issued 750,000 shares of restricted common stock to MultiGEN. In addition, up to an additional $3.7 million in common stock and cash may be paid to MultiGEN upon achievement of specific sales and earnings targets. In addition, TrovaGene entered a Reagent Supply Agreement dated as of February 1, 2012 pursuant to which MultiGEN will supply and deliver to TrovaGene reagents to be used in connection with the CLIA lab. The reagents are being sold to TrovaGene in an amount equal to cost per unit plus 20%.

The company is currently engaged in conducting validation analysis aimed at establishing the predictive and prognostic value of its lead oncology-focused diagnostic tests. The firm believes that, once favorable accuracy data have been generated in a prospective manner with these tests, the commercialization of such products is likely to be relatively straightforward. We believe that there is ample current market data that demonstrates the validity of this strategy. Several companies currently operating in the molecular diagnostics field have not only managed to successfully commercialize tests that are only regulated as LDTs, but have also secured value-based pricing for these tests based on their high levels of sensitivity and specificity, which have been accepted by reimbursement agencies as indicative of pharmacoeconomic benefit. For example, Genomic Health – a molecular diagnostics firm – currently sells the Oncotype DX test, which is an LDT used to establish the likelihood of breast cancer recurrence. Even though this test is only considered to be roughly 70% – 80% accurate, it is still reimbursed in the region of $3,000 – $4,000 per test. Accordingly, therefore, we believe that the prospects for value-based pricing in the case of TrovaGene's tests are relatively strong, since the tests do not have to be 100% accurate in order to qualify.

Over the course of the past decade, TrovaGene has built a substantial IP estate in the domain of transrenal nucleic acids. We note that one particularly advantageous aspect of the firm's IP estate is its breadth; regardless of the specific nature of the diagnostic test, if it involves the analysis of transrenal nucleic acids it is likely to be covered by TrovaGene's IP estate. This gives TrovaGene substantial strategic flexibility. We note that the company has spent only about $40 million since its inception in 1999, which we consider to be clear evidence of its capital-efficient approach. The firm also holds rights to a highly sensitive complementary metal-oxide semiconductor (CMOS)-based approach that permits the detection of nucleic acids in samples without a requirement for prior amplification. In our view, this technology could provide TrovaGene with a significant advantage vs. other firms focusing on the detection of nucleic acid-based biomarkers.

The CLIA laboratory that TrovaGene currently owns is licensed by the State of California, which enables the firm to provide testing services to residents of most states. The company plans to obtain licenses from other states as required. TrovaGene's laboratory is also accredited by the College of American Pathologists (CAP). The CAP Laboratory Accreditation Program is an internationally recognized program, and accreditation by CAP can also be used to meet CLIA and state certification requirements.

Molecular Diagnostics Acquisition Transactions

Given the fact that Gabriele Cerrone is on the TrovaGene Board of Directors and has played a pivotal role in the company's recent strategic moves, and considering the fact that he has a lengthy track record of successfully consummating acquisition transactions, we feel it would be appropriate for investors to be aware of recent acquisition activity in the molecular diagnostics sector. Three transactions in particular stand out, in our view:

- The acquisition of Clarient, a developer of cancer diagnostic tools, by GE Healthcare (a division of General Electric) in October 2010 for $587 million – this represented a revenue multiple of roughly 5x on projected 2010 revenues of $115 million
- The acquisition of Genoptix, a hematology- and oncology-focused diagnostics firm, by Novartis in January 2011 for $470 million – this represented a revenue multiple of approximately 2.5x on projected 2010 revenues of roughly $190 million
- The acquisition of Third Wave Technologies, a firm focused on women's health diagnostics, by Hologic in 2008 for $580 million

Perspectives

We believe that investors should take note of the following key points:

- TrovaGene has demonstrated the validity of its approaches by confirming the accuracy of several transrenal nucleic acid-based tests in various different contexts:
  - → Infectious disease diagnosis (human papillomavirus (HPV) infection)
  - → Fetal gender determination
  - → Oncology-focused diagnosis of minimal residual disease
- TrovaGene possesses a significant amount of strategic flexibility because it owns its own CLIA-certified laboratory for sample processing
- The company has a significant pipeline of diagnostic tests, which are currently not being ascribed substantial value by investors, in our view; this provides risk mitigation and diversification
- TrovaGene possesses a significant amount of valuable and fundamental IP in the domain of transrenal nucleic acids, which, in our view, could make it an attractive partner for other diagnostics-focused firms as well as a possible acquisition target for either established diagnostics firms seeking to commercialize non-invasive tests or established pharmaceutical companies aiming to develop theranostic solutions

Firm History

TrovaGene was originally incorporated in the State of Florida on April 26, 2002 as Used Kar Parts, Inc. and planned to develop an on-line marketplace for used car parts. In an effort to develop that business, the company originally entered into a contract with a web hosting service on a month-to-month basis to provide storage for website development and transaction processing.

On February 24, 2004, Jeannine Karklins, the firm's former President, Treasurer, and Secretary, as well as the principal shareholder, entered into a Capital Stock Purchase Agreement with Panetta Partners Ltd., a limited partnership affiliated with the company's former co-chairman and current director, Gabriele M. Cerrone, pursuant to which Panetta purchased an aggregate of 2,000,000 restricted shares of the company's common stock from Ms. Karklins for $386,400 which represented approximately 97% of the company's outstanding shares of common stock at the time. Pursuant to the agreement, Ms. Karklins resigned as an officer and director of the company and no longer has any involvement in the firm's business affairs.

On July 2, 2004, the firm acquired Xenomics, a California company, which was developing transrenal nucleic acid-based technology and which held the principal patents on the use of urine as an analyte for nucleic acid-based diagnostic testing. As part of the acquisition, the company changed its corporate name to Xenomics, Inc. In 2007, the firm changed its fiscal year end from January 31 to December 31. In January 2010, the company relocated its state of incorporation from Florida to Delaware and changed its name to TrovaGene, Inc. At the time, the firm's shares were traded on the OTC Bulletin Board. Subsequently, they traded on the Pink Sheets.

On August 6, 2010, TrovaGene acquired all of the outstanding common stock of Etherogen, Inc., in exchange for 12,262,782 shares of TrovaGene common stock pursuant to the terms of the merger agreement dated August 10, 2010 among TrovaGene, E ACQ Corp. and Etherogen. The fair value of the shares issued to effect the merger was approximately $2.8 million, based on the fair value of TrovaGene's common stock on the date of the merger. This transaction provided TrovaGene with ownership of a detection method for nucleic acids that does not require amplification, as described earlier.

On May 24, 2012, the Board of Directors approved a 1-for-6 reverse stock split of TrovaGene's issued and outstanding common stock effective. Following the 1-for-6 reverse split, TrovaGene shares began trading on the NASDAQ Capital Markets exchange. On May 30, 2012, TrovaGene completed an underwritten public offering in which an aggregate of 1.15 million units, with each unit consisting of two shares of its common stock and one warrant to purchase one share of common stock, were sold at a purchase price of $8.00 per unit. On June 13, 2012, the underwriters exercised their overallotment option in full for an additional 172,500 units. The firm raised a total of $9.1 million in net proceeds after deducting underwriting and offering expenses of $1.4 million. Each warrant has an exercise price of $5.32 per share, and expires five years from the closing of the offering. Warrants issued in connection with the underwritten public offering and sale of units in May 2012 are not considered derivatives based on the firm's analysis of the criteria of ASC 815, as the firm is not required to make any cash payments or net cash settlement to holders in lieu of issuance of warrant shares.

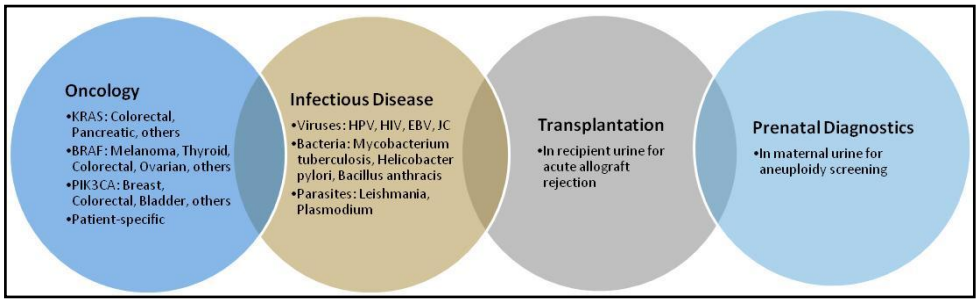
Currently, the firm has three dedicated scientists located in its main office in San Diego, CA. The company plans to continue to grow this organization to 10 – 15 talented individuals. Such a group is intended to represent a mix of senior lead researchers and scientists, laboratory associates, and experts in clinical development and regulatory affairs relevant to the domain of molecular diagnostics.

Transrenal Nucleic Acid Technology Overview

TrovaGene's primary focus is to leverage its urine-based (i.e. transrenal) testing platform to facilitate improvements in the management of cancer and women's health. Transrenal DNAs and RNAs are fragments of nucleic acids derived from dying cells inside the body[1]. The intact DNA is fragmented in dying cells and released into the blood stream. These fragments have been shown to cross the kidney barrier and can be detected in urine[2]. In addition, there is evidence that some species of RNA or their fragments are stable enough to cross the renal barrier[3]. These RNA molecules can also be isolated from urine, detected and analyzed.

Thus far, TrovaGene has demonstrated the feasibility of conducting transrenal nucleic acid-based analysis using urine as an analyte. The firm's initial studies have proven that sufficient intact nucleic acid material is present in a patient's urine to permit a wide array of genetic analyses. In addition, the urine sample is stable for several days, even at room temperature, permitting flexibility in transportation and sample turnaround. TrovaGene has also filed patents on the use of its transrenal nucleic acid-based approaches in oncology, infectious disease, transplant rejection monitoring, and prenatal diagnostics. In addition, the firm has pending applications in the domains of cell-free nucleic acid isolation from body fluids, diagnostic applications of microRNAs from urine and other bodily fluids, and methods for detection of "ultra short" DNA sequences.

Figure 4: Applications For Transrenal Nucleic Acid Diagnostics



Source: TrovaGene

Oncology-Focused Applications

It is anticipated that transrenal nucleic acid-based analysis may be useful for detecting and monitoring various primary cancers. Such testing could serve to help the physician choose a treatment regimen offering the highest likelihood of a successful outcome and monitor response to these treatments and check for disease recurrence. By testing transrenal DNA for the appropriate genetic markers, it may also be possible to carry out pre-cancerous screening.

As a case in point, transrenal DNA technology was evaluated in a cancer clinical study at Thomas Jefferson University, funded jointly by the National Institute of Health (NIH) and the National Cancer Institute (NCI). The study demonstrated that DNA fragments carrying a specific mutation (K-ras) and released from pre-cancerous colon polyps can be detected in the urine of patients. Studies have shown that cancer patients who have K-ras mutations do not respond successfully to treatment with anti-epidermal growth factor receptor (anti-EGFR) drugs such as Erbitux (cetuximab), Iressa (gefitinib), Tarceva (erlotinib), Tykerb (lapatinib) and Vectibix (panitumumab). These anti-EGFR agents

[1] Su *et al*., Annals of the New York Academy of Sciences 1022: 81-89 (2004)
[2] Melkonyan *et al*., Annals of the New York Academy of Sciences 1137: 73-81 (2008)
[3] Lichtenstein *et al*., Methods in Molecular Biology 336: 145-154 (2006)

represent mainstays of current colorectal cancer treatment[4]. It has been estimated that 17% – 25% of all human cancers have been found to harbor K-ras mutations, with mutation rates as high as 59% – 90% in pancreatic cancers and 35% – 40% in colorectal cancers. These tumors will most likely not respond to EGFR-targeting drugs[5].

By first testing for these K-ras mutations, oncologists would potentially be able to better manage their patients and avoid costly treatments that are not likely to have a positive clinical response. Screening and monitoring for K-ras and other key biomarker mutations (i.e. B-raf, PIK3CA, EGFR, etc.) using urine-based tests would provide a simple, non-invasive, quick, cost effective and convenient (i.e. at-home testing) diagnostic alternative for physicians and patients. The number of patients who could potentially benefit from such a simple urine-based testing approach is substantial, as there are roughly 141,000 and 44,000 new cases of colorectal and pancreatic cancer in the U.S. per year, respectively, according to the National Cancer Institute. All of these cases are at risk for K-ras mutations. Transrenal nucleic acid testing could also be applicable in lung cancer (221,000 new cases per year) and breast cancer (230,000 new cases per year) wherein the screening and monitoring for mutations is also crucial.

Infectious Disease-Focused Applications

In addition to pinpointing endogenous mutations inherent to the genetic makeup of the patient, transrenal nucleic acids can also reveal the presence of pathogens. In particular, TrovaGene and other groups have demonstrated the utility of transrenal nucleic acid screening in the detection and monitoring of various viral infections, as well as fungal (e.g. *Aspergillus*) and bacterial (e.g. *Borrelia*, the cause of Lyme disease) pathogens.

Human papillomavirus (HPV) screening and monitoring is one of TrovaGene's core priority areas. This specifically relates to the company's development-stage urine-based HPV test. The rationale for screening HPV is that high-risk subtypes cause virtually all cases of cervical cancer. Cervical cancer is the third most commonly diagnosed cancer, and the fourth leading cause of cancer deaths in women worldwide. Deaths due to cervical cancer are still a huge global problem, especially in the developing world where screening practices are far from ideal. More than 85% of these cases and deaths occur in developing countries, which typically have poor screening practices. India alone accounts for 27% (77,100) of the total cervical cancer deaths globally. A recent clinical trial in rural India found that a single round of HPV DNA testing was associated with about a 50% reduction in risk of developing advanced cervical cancer and associated deaths. In the U.S., where there is much better patient compliance and screening guidelines, there were an estimated 13,000 cases in 2011, resulting in only about 4,000 deaths. The major drivers for poor screening in these developing regions are cultural, limited resources/economics and poor cytology proficiency. Further exacerbating the compliance hurdles is the fact that the primary screening mechanism involves an invasive cervical scraping (e.g. Pap smear). It is generally agreed that the early detection of cervical cancer leads to much higher cure rates and lower rates of invasive disease.

Several independent groups have demonstrated the ability to detect the presence of Mycobacterium tuberculosis, the bacterial agent that causes the lung disease tuberculosis, in urine[6]. Thus, groups not affiliated with TrovaGene have proven that the transrenal nucleic acid-based detection approach can be applied to the identification and screening of bacterial pathogens. In our view, there is a wide array of potential infectious disease screening applications for the technology, several of which have been well-validated.

[4] Lopez-Chavez *et al*., Current Opinion on Investigational Drugs 10: 1305-1314 (2009)
[5] Weickhardt *et al*., Current Cancer Drug Targets 10: 824-833 (2010)
[6] Green *et al*., Lancet Infectious Disease 9: 505-511 (2008)

Non-Invasive Prenatal Diagnostics

TrovaGene has demonstrated its potential in the domain of non-invasive prenatal diagnostics (NIPDs) by showing how fetal gender determination can be performed using transrenal nucleic acids. As we shall discuss in a later section of this report, the company has conducted feasibility assessments that demonstrated the presence of fetal DNA in maternal urine – at the same proportions seen in maternal plasma – and that also showed how sequences derived from the Y chromosome could be detected in maternal urine, thereby determining that the fetus was male. With a female fetus, no Y chromosome-derived genetic sequences would be detectable.

Should a gender determination test prove feasible, it could also permit prenatal screening for a range of sex-linked genetic disorders. Some of these disorders have severe symptoms – Klinefelter syndrome, otherwise known as XXY syndrome, renders males with the condition completely sterile. The same is true of single X syndrome, wherein girls are born with only a single copy of the X chromosome. These girls are rendered infertile, and suffer from cataracts and diabetes, along with heart, thyroid and kidney disorders. They may also suffer from learning difficulties. Furthermore, many couples often desire to know the genders of their babies during pregnancy, since this permits certain choices – such as what color to paint the baby's room – to be made in advance.

TrovaGene could also utilize its diagnostic approach to detect chromosomal abnormalities – in particular, Down syndrome. In our view, such a diagnostic could be priced at roughly $750 per test, which compares favorably to the cost of amniocentesis. In January 2007, the American College of Obstetricians and Gynecologists recommended mandatory NIPD testing for all women, regardless of their perceived risk for carrying fetuses with Down syndrome or other defects. This represents a major acknowledgement of the utility of NIPDs and their market potential. We note that six million pregnancies occur every year in the United States alone, so this is a substantial market opportunity. In addition, the competitive landscape appears favorable since all the other molecular diagnostics are at least minimally invasive (amniocentesis, blood tests, etc.) A urine-based test would likely trump all of these from the convenience and safety perspective.

Transplantation Monitoring

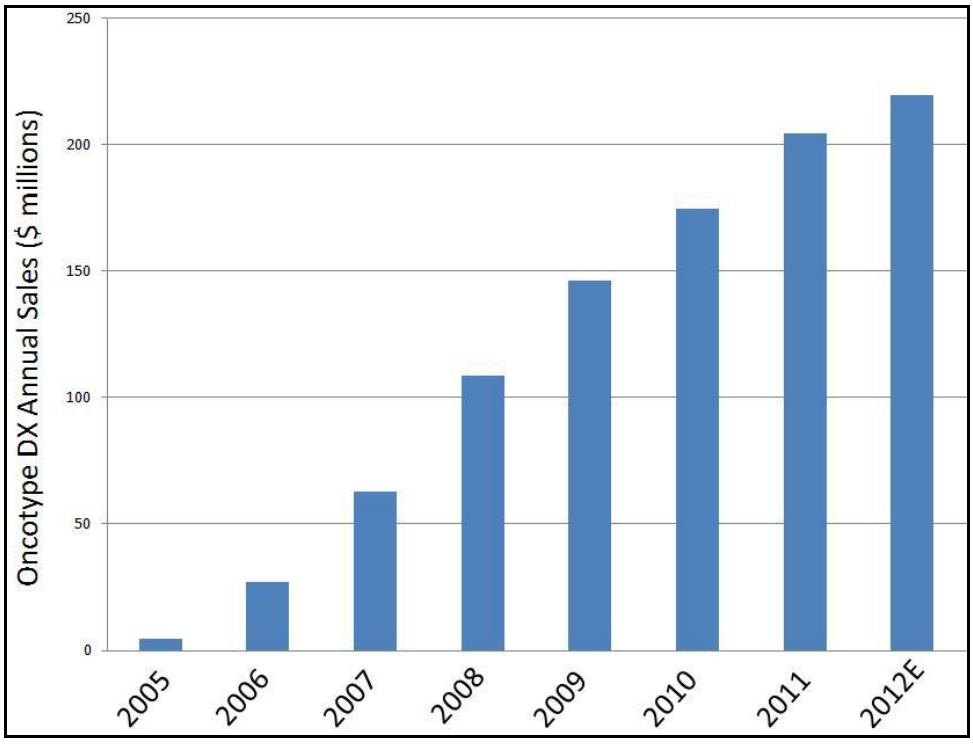
A final area in which TrovaGene's technology platform could prove useful is in the domain of transplant monitoring. Following an organ transplant, it is often the case that patients experience tissue rejection, which is a condition in which the patient's immune system attacks the transplanted organ because it is recognized as foreign. Transplant rejection is a significant issue because it could eventually result in organ failure, systemic inflammation and the eventual death of the patient. A diagnostic approach that could permit minimally invasive or non-invasive monitoring of the patient following a transplant could have significant benefits, including the ability to proactively treat the signs of rejection before irreversible tissue or organ damage has occurred.

According to government statistics, there are approximately 28,000 solid organ transplants performed in the U.S. annually. Post-transplant monitoring for organ rejection episodes currently requires a highly invasive tissue biopsy. Approximately 10 such biopsies are taken over a period of one year per patient. Because organ rejection is marked by early death of the cells, an early indication of rejection can be identified by measuring a unique series of genetic markers characteristic of the organ donor that can be easily detected in random urine specimens from the transplant recipient. Given the annual number of transplants performed in the U.S. and the annual number of corresponding biopsies performed per patient, this would equate to a market opportunity in the U.S. of roughly 300,000 urine-based tests/year.

Oncology Diagnostics Market Model

We have modeled sales for TrovaGene's diagnostic test products solely in the U.S. for the diagnosis of cancer. In our view, the firm would need to seek commercialization partners outside the U.S. in order to sell its products in those territories; while such partnerships could materialize in the future, we conservatively do not project revenue contributions from ex-U.S. territories at all at this juncture. We note that even companies that have marketed a single diagnostic test via the CLIA route (i.e. no formal test-specific FDA approval) have managed to generate substantial revenue, as shown by the example of the sales ramp for the Onco*type* DX test from Genomic Health:

Figure 5: Onco*type* DX Sales Ramp (2006 – 2012E)



Source: Company Reports; Aegis Capital Corp. estimates

We have modeled sales of three diagnostic tests – namely, the K-ras mutation test, the B-raf test, and the PIK3CA test. K-ras mutations are well-known in a wide range of cancers and occur frequently, particularly in malignancies such as lung, colorectal and pancreatic cancers. B-raf mutations are likewise well-validated in arenas such as melanoma, where an agent known as vemurafenib (Zelboraf), developed by Roche, was recently launched with a companion diagnostic that screens for a specific mutation in the B-raf gene. Finally, the PIK3CA gene encodes a protein known as p110α, which is classified as a catalytic subunit of phosphoinositol-3-kinase (PI3K). These kinases are well-validated targets in oncology. Mutations in the PIK3CA gene have been characterized in a wide array of malignancies, including breast, colorectal, bladder, ovarian and stomach cancers.

For the purposes of modeling, we have assumed pricing in the $400 – $600 range at steady-state. In our view, considering the presence of current tests such as the Oncotype DX diagnostic in the $3,000 – $4,000 range, the pricing assumptions we have used in our model appear quite conservative and defensible. Even at these levels, TrovaGene's gross margins are likely to be in excess of 90%, in our view. We project peak sales of $300 million from the three oncology-focused tests in 2018, the first year of patent expiry.

Table 3: Transrenal Diagnostic Test Sales Estimates – Oncology Market Size Model

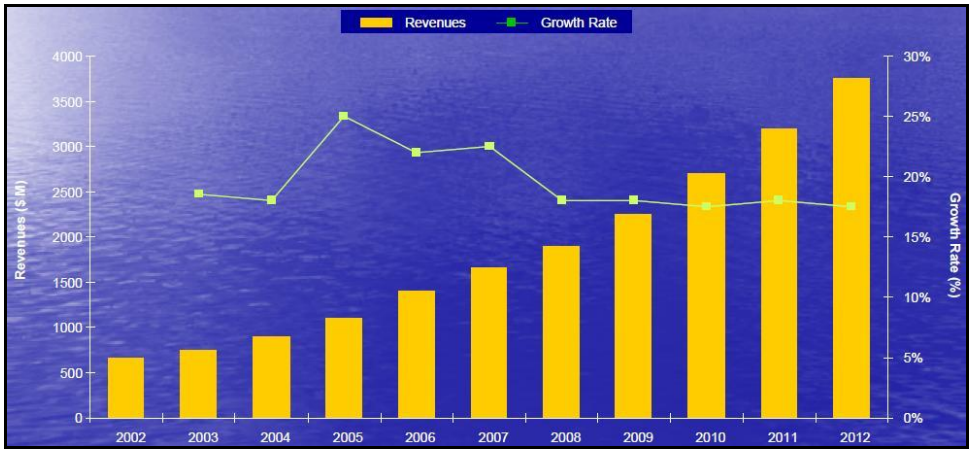
US market	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Total solid tumor patients	16,800,000	17,010,000	17,222,625	17,369,017	17,516,654	17,665,546	17,815,703	17,967,136	18,119,857	18,273,876	18,429,204	18,585,852	18,743,831	18,903,154	19,063,831	18,903,154	19,063,831	19,225,873	19,389,293
Breast cancer	*2,688,000*	*2,721,600*	*2,755,620*	*2,779,043*	*2,802,665*	*2,826,487*	*2,850,512*	*2,874,742*	*2,899,177*	*2,923,820*	*2,948,673*	*2,973,736*	*2,999,013*	*3,024,505*	*3,050,213*	*3,024,505*	*3,050,213*	*3,076,140*	*3,102,287*
Colorectal cancer	*1,680,000*	*1,701,000*	*1,722,263*	*1,736,902*	*1,751,665*	*1,766,555*	*1,781,570*	*1,796,714*	*1,811,986*	*1,827,388*	*1,842,920*	*1,858,585*	*1,874,383*	*1,890,315*	*1,906,383*	*1,890,315*	*1,906,383*	*1,922,587*	*1,938,929*
Melanoma	*840,000*	*850,500*	*861,131*	*868,451*	*875,833*	*883,277*	*890,785*	*898,357*	*905,993*	*913,694*	*921,460*	*929,293*	*937,192*	*945,158*	*953,192*	*945,158*	*953,192*	*961,294*	*969,465*
Bladder cancer	*672,000*	*680,400*	*688,905*	*694,761*	*700,666*	*706,622*	*712,628*	*718,685*	*724,794*	*730,955*	*737,168*	*743,434*	*749,753*	*756,126*	*762,553*	*756,126*	*762,553*	*769,035*	*775,572*
Pancreatic cancer	*504,000*	*510,300*	*516,679*	*521,071*	*525,500*	*529,966*	*534,471*	*539,014*	*543,596*	*548,216*	*552,876*	*557,576*	*562,315*	*567,095*	*571,915*	*567,095*	*571,915*	*576,776*	*581,679*
Ovarian cancer	*336,000*	*340,200*	*344,453*	*347,380*	*350,333*	*353,311*	*356,314*	*359,343*	*362,397*	*365,478*	*368,584*	*371,717*	*374,877*	*378,063*	*381,277*	*378,063*	*381,277*	*384,517*	*387,786*
K-ras Mutation Detection Test																			
Patients carrying relevant mutations	*425,000*	*430,313*	*435,691*	*439,395*	*443,130*	*446,896*	*450,695*	*454,526*	*458,389*	*462,286*	*466,215*	*470,178*	*474,174*	*478,205*	*482,270*	*486,369*	*490,503*	*494,672*	*498,877*
Penetration % in pancreatic and colorectal cancer	0%	0.5%	1%	2.5%	5%	8%	10%	9%	8%	7%	6%	5%	4.5%	4%	3%	2.5%	1%	0.5%	0.5%
Total eligible patients tested	0	2,152	4,357	10,985	22,156	35,752	46,422	40,907	36,671	32,360	27,973	23,509	21,338	19,128	14,468	12,159	4,905	2,473	2,494
Price per test	$0	$250	$400	$412	$424	$437	$450	$464	$478	$492	$507	$522	$538	$554	$570	$554	$570	$587	$605
Number of tests per year	0	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Sales from K-ras test ($MM)	0	1	3	9	19	31	42	38	35	32	28	25	23	21	17	13	6	3	3
B-raf Mutation Test																			
Patients carrying relevant mutations	700,000	708,750	717,609	723,709	729,861	736,064	742,321	748,631	754,994	761,411	767,883	774,410	780,993	787,631	794,326	801,078	807,887	814,754	821,680
Penetration % in melanoma, colorectal and ovarian	0%	0%	1%	3%	7%	11%	15%	13%	12%	11%	10%	9%	8%	7%	6%	3%	2%	1%	0.5%
Total eligible patients tested	0	0	7,176	21,711	51,090	80,967	112,833	97,322	90,599	83,755	76,788	69,697	62,479	55,134	47,660	24,032	16,158	8,148	4,108
Price per test	$0	$0	$500	$515	$530	$546	$563	$580	$597	$615	$633	$652	$672	$692	$713	$692	$713	$734	$756
Number of tests per year	0	0	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Sales from B-raf test ($MM)	0	0	4	11	27	44	63	56	54	52	49	45	42	38	34	17	12	6	3
PIK3CA Test																			
Patients carrying relevant mutations	970,000	982,125	994,402	1,002,854	1,011,378	1,019,975	1,028,645	1,037,388	1,046,206	1,055,099	1,064,067	1,073,112	1,082,233	1,091,432	1,100,709	1,110,065	1,119,501	1,129,017	1,138,613
Penetration % in breast, colorectal, bladder, ovarian	0%	0%	1%	3%	7%	12%	15%	14%	13%	12%	11%	10%	9%	7%	6%	5.5%	3%	1%	0.2%
Total eligible patients tested	0	0	9,944	30,086	70,796	122,397	157,383	145,234	136,007	126,612	117,047	107,311	97,401	76,400	66,043	61,054	33,585	5,645	2,277
Price per test	$0	$0	$550	$567	$583	$601	$619	$638	$657	$676	$697	$718	$739	$761	$784	$761	$784	$808	$832
Number of tests per year	0	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Sales from PIK3CA test ($MM)	0	0	11	34	83	147	195	185	179	171	163	154	144	116	104	93	53	9	4
Total annual sales ($MM)	0	1	18	54	129	223	300	280	268	255	240	224	209	176	154	123	70	18	10

Source: Company Reports and Aegis Capital Corp. estimates

Competitive Landscape

As shown below, the molecular diagnostics market has seen substantial growth over the course of the past decade, and we expect this trend to continue. In an era of personalized medicine and theranostics, this market seems poised for even further expansion.

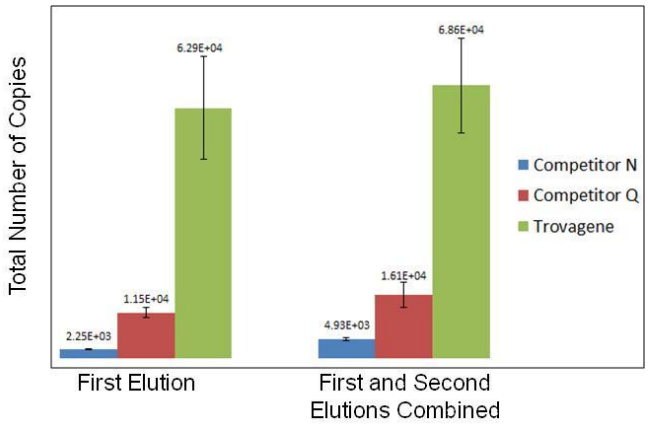
Figure 6: Molecular Diagnostics Market Sales



Source: Frost & Sullivan

We note that, in many cases, the competitive landscape for TrovaGene's tests appears to be relatively attractive. Firstly, the typical modality for minimally invasive molecular diagnostic tests in the current market environment involves the use of a blood sample. Drawing blood is substantially more onerous than simply having the patient urinate into a cup. In addition, when assessing very rare genetic transcripts, the amount of blood required to obtain sufficient nucleic acid for an accurate diagnosis becomes prohibitive. For example, recent data indicates that the identification of mutations such as those in the K-ras gene in colorectal cancer could require a blood draw with a volume of 50mL[7]. Such testing is simply not feasible on an ongoing basis, and has major disadvantages vs. urine-based analysis. Below, we show data from TrovaGene showing the firm's ability to detect a 50-base pair nucleic acid species spiked into a 10mL urine sample.

Figure 7: Competitive Benchmarking



Source: TrovaGene

[7] Diehl *et al*., Gastroenterology 135: 489-495 (2008)

Additional Diagnostic Tests

Unlike many molecular diagnostics-focused companies, TrovaGene has generated substantial proof-of-concept for its technology platform in an array of areas, including infectious disease (specifically HPV infections) and prenatal diagnostics (specifically fetal gender determination). In this section, we review the proof-of-concept clinical data that has thus far been generated by TrovaGene in these sectors, which lie beyond the company's core strategic focus on cancer diagnostics.

Human Papillomavirus (HPV) Infection

As mentioned earlier, the importance of HPV screening lies in the fact that infection with high-risk subtypes of HPV is correlated with the development of malignancy (particularly penile cancer in males and cervical cancer in females). Particularly in developing nations, where HPV infection screening is not routinely performed and there is little access to vaccines, cervical cancer rates continue to climb. TrovaGene performed a feasibility study on 320 individuals, the initial results of which (shown below) demonstrated a 78% concordance with existing screening techniques.

Figure 8: HPV Screening Initial Urine Test Results

High Risk vs Low Risk HPV, # patients			
	QIAGEN hc2 Results High Risk	QIAGEN hc2 Results Low Risk	Total
Trovagene Urine-HPV Results – High Risk	102	38	140
Trovagene Urine-HPV Results – Low Risk	34	146	180
Total	136	184	320

Initial Concordance 77.5% (CI 95%, 72-81%) Kappa 0.53

Source: TrovaGene

Final results from the feasibility study conducted on the HPV urine-based test demonstrated that the test was highly accurate, particularly when compared to the Qiagen hc2 test. In our view, accuracy established at the >90% range on both sensitivity and specificity should permit value-based pricing for this test, were it to be commercialized.

Figure 9: HPV Screening Initial Urine Test Results

Urine HPV Test	High Risk	Low Risk	Total
High Risk	102 + 31 = 133	7	140
Low Risk	10	146 + 24 = 170	180
Total	**143***	**177***	**320**

	Trovagene	QIAGEN
Sensitivity:	93.0%	78.3%
Specificity:	96.0%	86.4%

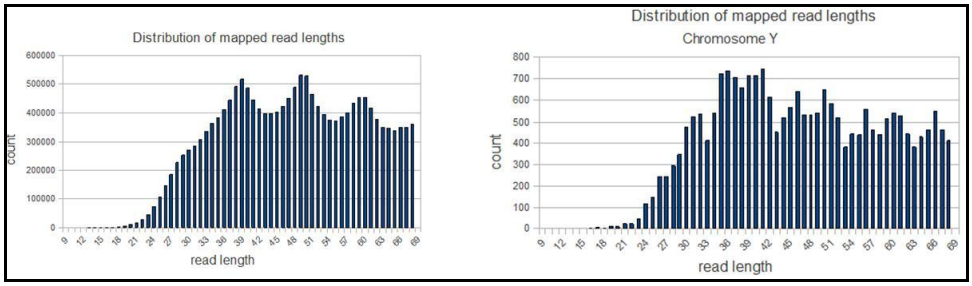
Source: TrovaGene

Although currently TrovaGene's priority remains focused on its oncology-based tests, we believe that the HPV test represents a valuable strategic asset. TrovaGene could generate interest from strategic partners as well as explore the possibility of commercializing the test independently going forward.

Fetal Gender Determination

The non-invasive prenatal diagnostics market represents a significant commercial opportunity. Approximately 6 million pregnancies occur every year in the U.S. alone. A substantial number of diagnostic tests are often carried out routinely in order to assess the health of the fetus. Among the most popular are tests for chromosomal abnormalities, such as Down syndrome (trisomy 21, or a condition in which there are three copies of chromosome 21 rather than the normal two); genetic defects, such as spina bifida; and sex chromosome-based abnormalities, such as Klinefelter syndrome (two copies of the X chromosome in a fetus that also carries the Y chromosome, or an XXY genotype). However, many parents also want to know the gender of the baby prior to birth. In this case, the diagnostic paradigm is extremely simple – non-invasive tests simply aim to detect the presence of genetic sequences associated with the Y chromosome in the bodily fluids of the mother. Since the mother herself cannot carry a Y chromosome, if Y chromosome-derived sequences are detected, the fetus must be male. The figure below shows that Y chromosomal sequences can be detected in the urine of pregnant women.

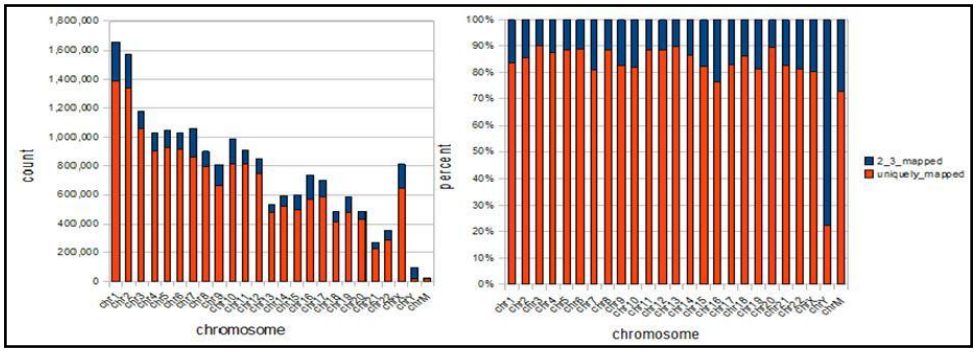
Figure 10: Y Chromosomal Signal in Maternal Urine



Source: TrovaGene

The figure below shows the result of next-generation high-throughput sequencing. Tens of thousands of sequencing reads for each chromosome confirm overall genomic representation in the nucleic acids present trans-renally. Fetal DNA is estimated to constitute 14% of the cell-free DNA found in urine, which implies that the percentage of fetal DNA in urine is comparable to that found in plasma.

Figure 11: Genome Representation in Maternal Urine



Source: TrovaGene

Intellectual Property Portfolio

The TrovaGene portfolio includes a total of six issued U.S. patents and one issued European patent, along with multiple pending applications worldwide.

Table 4: TrovaGene Intellectual Property

Patent Number	Title	Expiry Date	Country	Description
6251638	Methods for Detection of Nucleic Acid Sequences in Urine	5/29/2018*	United States	Detection of transrenal nucleic acids in urine
6287820	Methods for Detection of Nucleic Acid Sequences in Urine	5/29/2018*	United States	Detection of transrenal nucleic acids in urine
6492144	Methods for Detection of Nucleic Acid Sequences in Urine	5/29/2018*	United States	Detection of transrenal nucleic acids in urine
RE39920	Methods for Detection of Nucleic Acid Sequences in Urine	5/29/2018*	United States	Detection of transrenal nucleic acids in urine
920539	Methods for Detection of Nucleic Acid Sequences in Urine	5/29/2018	European Union	Detection of transrenal nucleic acids in urine
Published	Methods for Detection of Nucleic Acid Sequences in Urine		PCT (International)	Detection of transrenal nucleic acids in urine
1634966	Methods for Detection of Nucleic Acid Sequences in Urine	5/29/2018	European Union	Detection of transrenal nucleic acids in urine
1088363	Methods for Detection of Nucleic Acid Sequences in Urine	5/29/2018	HK-Hong Kong	Detection of transrenal nucleic acids in urine
2216116	Methods for Detection of Nucleic Acid Sequences in Urine	5/29/2018	European Union	Detection of transrenal nucleic acids in urine
7973154	Kits for Diagnosis and Monitoring of Viral Infection by Analytes of Viral Transrenal Nucleic Acids in Urine	2/16/2026*	United States	Viral transrenal nucleic acids
	Method for Diagnosis and Monitoring of Viral Infection by Analysis of Viral Transrenal Nucleic Acids in Urine		United States	Viral transrenal nucleic acids
2006214096	Compositions and Methods for Detecting Viral Specific Nucleic Acids in Urine	2/16/2026	Australia	Viral transrenal nucleic acids
	Compositions and Methods for Detecting Viral Specific Nucleic Acids in Urine		China	Viral transrenal nucleic acids
allowed (16 minimum countries)	Method for Diagnosis and Monitoring of Viral Infection by Analysis of Viral Transrenal Nucleic Acids in Urine		European Union	Viral transrenal nucleic acids
	Method for Diagnosis and Monitoring of Viral Infection by Analysis of Viral Transrenal Nucleic Acids in Urine		Hong Kong	Viral transrenal nucleic acids
	Compositions and Methods for Detecting Viral Specific Nucleic Acids in Urine		India	Viral transrenal nucleic acids
Published	Method for Diagnosis and Monitoring of Viral Infection by Analysis of Viral Transrenal Nucleic Acids in Urine		PCT (International)	Viral transrenal nucleic acids
7803929	Kits for Diagnosis and Monitoring of Pathogenic Infection by Analysis of Cell-Free Pathogenic Nucleic Acids in Urine	5/25/2025*	United States	Viral transrenal nucleic acids
7914982	Methods for Detecting Pathogen Specific Nucleic Acids in Urine	5/25/2025*	United States	Viral transrenal nucleic acids
2006214444	Method for Diagnosis and Monitoring of Pathogenic Infection by Analysis of Pathogenic Transrenal Nucleic Acids in Urine		Australia	Viral transrenal nucleic acids
	Method for Diagnosis and Monitoring of Pathogenic Infection by Analysis of Pathogenic Transrenal Nucleic Acids in Urine		European Union	Viral transrenal nucleic acids
1359648	Method for Diagnosis and Monitoring of Pathogenic Infection by Analysis of Pathogenic Transrenal Nucleic Acids in Urine	2/17/2025	Italy	Viral transrenal nucleic acids
Published	Method for Diagnosis and Monitoring of Pathogenic Infection by Analysis of Pathogenic Transrenal Nucleic Acids in Urine		PCT (International)	Viral transrenal nucleic acids
	Compositions, Methods and Kits for Isolating Nucleic Acids from Body Fluids Using Anion Exchange Media		United States	Anion Exchange Media
	Compositions, Methods and Kits for Isolating Nucleic Acids from Body Fluids Using Anion Exchange Media		European Union	Anion Exchange Media
Published	Compositions, Methods and Kits for Isolating Nucleic Acids from Body Fluids Using Anion Exchange Media		PCT (International)	Anion Exchange Media
8222370	Nucleophosmin Protein (NPM) Mutants, Corresponding Gene Sequences and Uses Thereof	10/28/2025*	United States	Nucleophosmin (NPM) protein diagnostics
	NPM Mutants, Corresponding Gene Sequences and Uses Thereof		United States	Nucleophosmin (NPM) protein diagnostics
	NPM Mutants, Corresponding Gene Sequences and Uses Thereof		China	Nucleophosmin (NPM) protein diagnostics
	NPM Mutants, Corresponding Gene Sequences and Uses Thereof		European Union	Nucleophosmin (NPM) protein diagnostics
Published	NPM Mutants, Corresponding Gene Sequences and Uses Thereof		PCT (International)	Nucleophosmin (NPM) protein diagnostics
	Methods of Using Urinary MicroRNA for Detection of In Vivo Cell Death		United States	MicroRNA
	Methods of Using Urinary MicroRNA for Detection of In Vivo Cell Death		China	MicroRNA
allowed (likely 16 minimum countries as in 0501-22__ series)	Methods of Using Urinary MicroRNA for Detection of In Vivo Cell Death		European Union	MicroRNA
	Methods of Using Urinary MicroRNA for Detection of In Vivo Cell Death		Japan	MicroRNA
Published	Methods of Using Urinary MicroRNA for Detection of In Vivo Cell Death		PCT (International)	MicroRNA
	Methods of PCR-Based Detection of "Ultra Short" Nucleic Acid Sequences		United States	Ultra Short Nucleic Acids
	Methods of PCR-Based Detection of "Ultra Short" Nucleic Acid Sequences		European Union	Ultra Short Nucleic Acids
Published	Methods of PCR-Based Detection of "Ultra Short" Nucleic Acid Sequences		PCT (International)	Ultra Short Nucleic Acids
	Genetic Marker for Detection of Human Papillomavirus (HPV)		United States	Ultra Short Nucleic Acids
	Genetic Marker for Detection of Human Papillomavirus (HPV)		European Union	Ultra Short Nucleic Acids
	Genetic Marker for Detection of Human Papillomavirus (HPV)		Japan	Ultra Short Nucleic Acids
Published	Genetic Marker for Detection of Human Papillomavirus (HPV)		PCT (International)	Ultra Short Nucleic Acids
	Conjugate Probes and Optical Detection of Analytes		United States	Complementary metal-oxide semiconductor (CMOS) methodology for high-throughput nucleic acid detection
	Conjugate Probes and Optical Detection of Analytes		European Union	CMOS approach
4672966	Conjugate Probes and Optical Detection of Analytes	3/11/2022	Japan	CMOS approach
	Conjugate Probes and Optical Detection of Analytes		European Union	CMOS approach

Source: Company reports

Capital Structure and Financing History

The table below depicts the current capital structure of TrovaGene. Investors should note that the company went through a lengthy period of dormancy until 2011, at which point the firm successfully consummated a number of strategic moves that culminated in its changing its name and reincorporating in Delaware. Furthermore, TrovaGene subsequently acquired a CLIA laboratory in California and generated proof-of-concept data validating its unique and proprietary approach to the development of accurate, non-invasive molecular diagnostics.

The two most recent financing transactions occurred in May 2012 and December 2012; the gross proceeds raised in the first transaction were $10.5 million, leaving the company with approximately $9.5 million in cash (*pro forma*). In conjunction with this registered direct offering, TrovaGene conducted a 1-for-6 reverse split of its common stock. Thereafter, the company had roughly 14.2 million shares outstanding, along with approximately 5.7 million warrants and 3.8 million options. In December 2012, the firm raised gross proceeds of $3.8 million in an independently conducted unit offering, consisting of 940,000 units with each unit consisting of one share of common stock priced at $4.00 per share and one five-year warrant, with an exercise price of $5.32. When taking account of all outstanding options and warrants, we derive a fully-diluted share count of roughly 25.4 million shares at this juncture.

Table 5: TrovaGene Capital Structure (11/30/2012)

	Number of Shares	Weighted Average Exercise Price	Expiration Date	Total Cash
Cash, cash equivalents and marketable securities				$10,515,128
Common Stock	15,241,934			
Preferred Stock	95,600			$0
Options	3,295,833	$4.74		$15,622,248
Warrants	6,791,754	$4.61	5/30/2017 - 12/31/2018	$31,309,986
				$0
Fully Diluted Shares	**25,425,121**			**$57,447,362**

Source: Company reports

The table below lists the various transactions that TrovaGene has consummated in its existence as a public company. While the firm had previously conducted several highly-dilutive funding rounds, we note that the current cash – assuming a $1.2 – 1.5 million-a-quarter burn rate – should be sufficient to last the firm for the next 12 months.

Table 6: TrovaGene Financing History

		Net Proceeds	Shares	Price	Notes
Public Company					
	Private Placement 2004	$ 2,512,950	2,645,210	$ 0.95	
	Private Placements 2005	$ 5,444,410	2,986,102	$ 1.95	746,527 warrants issued
	Private Placements 2006	$ 1,943,401	1,754,721	$ 1.11	877,361 warrants issued
	Private Placements 2007	$ 794,750	1,700,000	$ 0.50	100,000 warrants issued
	Private Placements 2008	$ 1,145,000	1,984,091	$ 0.58	777,045 warrants issued
	Private Placements 2009	$ 1,369,775	2,930,000	$ 0.50	2,930,000 warrants issued
	Exchange Agreement	$ 164,550	413,379	$ 0.40	418,854 warrants issued
	Private Placements 2010	$ 1,621,945	3,469,400	$ 0.50	3,469,400 warrants issued
	Private Placements 2011	$ 2,406,223	5,147,000	$ 0.50	5147,000 warrants issued
	Private Placements January - March 2012	$ 889,500	1,900,000	$ 0.50	1,900,000 warrants issued
	Underwritten Public Offering	$ 9,100,000	2,645,000	$ 4.00	1,322,500 warrants issued
Total Amount		$ 27,392,503	27,574,903		

Source: Company reports

Financial Review and Outlook

Revenue: We forecast $1.2 million in revenue in 2013 and $14.2 million in 2014. Management does not provide guidance.

- **K-ras Mutation Detection Test Revenue Trajectory:** We forecast that K-ras test-based revenue growth could begin to accelerate in late 2013, reflecting the impact of TrovaGene's generation of supportive data validating the accuracy of the test in a prospective manner. Ex-U.S. revenue to TrovaGene is likely to remain relatively low for the foreseeable future, in our view. We believe that the firm would need to ink ex-U.S. distribution agreements in order to extract value from international territories, since it is unlikely to build a sales force outside the U.S.

- **Additional Test Reimbursement Decisions:** Significant further upside beyond the revenue ramp for the K-ras test could come from favorable reimbursement decisions on TrovaGene's other diagnostic tests. In our view, these decisions could occur later in 2013 or early in 2014, pending positive accuracy data.

- **Other Value Drivers:** We believe that the company could potentially license certain rights to its extensive IP portfolio for use in the development of therapeutics.

Gross Margins: We project that the gross margins on the K-ras test could exceed 90%. Historical margins associated with product sales in the high-value molecular diagnostics space have been in the 90% range; we expect this to remain sustainable. However, net margins may be impacted by increased sales promotional spending going forward.

Operating Expenses: For 2012 and 2013, we estimate operating expense levels that are $5 million and $7.6 million respectively. We estimate R&D of $1.9 million in 2012, as the firm continues development work on its transrenal nucleic acid-based platform.

Taxes: As of end-2011, TrovaGene had net operating loss carry-forwards (NOLs) of approximately $20 million, which begin to expire in 2019. However, because the firm has determined that ownership changes occurred pursuant to Internal Revenue Code Section 382, we believe that the company's ability to utilize these NOLs to offset future taxes is likely to be limited. We project that revenues will be taxed at the statutory 35% U.S. corporate tax rate.

Share Count: The outstanding share count stands at approximately 15.2 million shares, excluding 3.3 million options and 6.8 million warrants, the bulk of which expire in the 2017 – 2018 timeframe.

EPS: We forecast diluted losses per share of $0.49 and $0.34 for 2012 and 2013, respectively. If the K-ras test and other oncology-focused diagnostics perform commercially according to expectations, TrovaGene could potentially attain cash flow break-even status in early 2015, and become sustainably profitable shortly thereafter.

Balance Sheet: The firm held $7.8 million in cash, short-term and long-term investments as of end-September 2012.

Cash Flow: We believe that TrovaGene has sufficient cash to fund operations for at least 12 months, given the current burn rate of roughly $1.2 million per quarter. No immediate-term equity or debt financing need is anticipated.

Guidance: TrovaGene does not provide revenue or earnings guidance.

Management Team

The TrovaGene management team includes several individuals with significant expertise in molecular diagnostics. The company's Chief Executive Officer has previously headed several diagnostics-focused companies. In addition, TrovaGene benefits from the substantial experience of several other senior management team members in the domains of cancer biomarker discovery and laboratory-based diagnostic services.

Antonius Schuh, Ph.D.
Chief Executive Officer
Antonius Schuh joined Trovagene in October 2011 as CEO and was elected as a Director in December 2011. Dr. Schuh co-founded Sorrento Therapeutics, Inc., a publicly traded biopharmaceutical company developing monoclonal antibodies, in January 2006. From such time until April 2011, he served as Chairman of the Board and CEO from November 2008 to April 2011. From April 2006 to September 2008, Dr. Schuh served as Chief Executive Officer of AviaraDx (now bioTheranostics, Inc., a bioMerieux company), a molecular diagnostic testing company that is focused on clinical applications in oncology. From March 2005 to April 2006, Dr. Schuh was Chief Executive Officer of Arcturus Bioscience Inc., a developer of laser capture microdissection and reagent systems for microgenomics. From December 1996 to February 2005, Dr. Schuh was employed by Sequenom Inc., a publicly traded diagnostic testing and genetics analysis company. He started with Sequenom as a Managing Director and was promoted to Executive Vice President, Business Development and Marketing, and from May 2000 to February 2005, served as Sequenom's President and CEO. He also previously served as the Head of Business Development at Helm AG, an international trading and distribution firm focusing on chemical and pharmaceutical products, and in medical and regulatory affairs positions with Fisons Pharmaceuticals (now part of Sanofi S.A., formerly Sanofi-Aventis, which is one of the world's largest pharmaceutical companies). Since March 2009, Dr. Schuh has been appointed to the board of directors of Diogenix, Inc., a privately held molecular diagnostic company, and since May 2009, he has served as a director of Transgenomic, Inc., a public biotechnology company focused on genetic analysis and molecular diagnostics. Dr. Schuh is a certified pharmacist and earned his Ph.D. in pharmaceutical chemistry from the University of Bonn in Germany.

Stephen Zaniboni, M.B.A., C.P.A.
Chief Financial Officer
Stephen Zaniboni joined TrovaGene as CFO in January 2012. Prior to joining TrovaGene, since June 2010, Mr. Zaniboni has served as the CFO of Awarepoint Corporation, a leading provider of healthcare software. Prior to joining Awarepoint Corporation, Mr. Zaniboni served as the CFO of XIFIN Inc., the leading provider of revenue cycle management for diagnostic service providers, from January 2009 through June 2010. Prior to joining XIFIN Inc. Mr. Zaniboni served as the CFO of Sorrento Therapeutics, Inc. from January 2006, and as a director from November 2008 through September 2009. From May 2006 to September 2008, Mr. Zaniboni served as the CFO of AviaraDx (now bioTheranostics, a bioMerieux company), a molecular diagnostics-focused cancer profiling company. From October 2005 to April 2006, Mr. Zaniboni was CFO of Arcturus Bioscience (acquired by Molecular Devices Corp., now MDS). He joined Arcturus from Sequenom, Inc., a publicly-traded diagnostic testing and genetics analysis firm, where he served as CFO from May 1997 to September 2005. Mr. Zaniboni has also held various financial management positions at Aspect Medical Systems, Behring Diagnostics, and Boston Scientific. He and Dr. Schuh have had a lengthy working partnership across multiple firms. Mr. Zaniboni was previously a practicing Certified Public Accountant with Arthur Andersen and holds a BS in accounting from Boston University and an M.B.A. from Boston College.

Charles Rodi, Ph.D.
Vice President & Chief Technology Officer
Charlie Rodi was appointed Vice President and Chief Technology Officer of Trovagene, Inc. in February, 2012. He previously served as Vice President, Research and Development/Collaborations at Sorrento Therapeutics, Inc., where he led early development of the company's technology to generate fully human monoclonal antibody libraries and established critical collaborations to support the company's entry into infectious diseases. Previously, Dr. Rodi established the use of digital PCR in rare allele detection in circulating nucleic acids and transcript profiling in circulating tumor cells at a firm called ICx Biosystems. Prior to that, Dr. Rodi founded Rodi Pharma, Inc., dedicated to the discovery of cancer biomarkers and target discovery. From 1999 to 2002 Dr. Rodi held executive positions at Sequenom, Inc., including Executive Vice President, Genomics, and led the development of a suite of technologies for the discovery, scoring, and determination of allelic frequency of disease SNPs (single nucleotide polymorphisms). While at Monsanto/G.D. Searle, Dr. Rodi was the Director of the Monsanto Genome Sequencing Center; served on both the Genomics Leadership Team and the Genomics Business Team; led the New Technologies Initiative; and introduced the use of nucleic acid biomarkers for product safety assessment. Dr. Rodi received his doctorate in Cellular and Developmental Biology from the University of Minnesota and served as a Senior Staff Fellow at the National Institutes of Allergy and Infectious Diseases (NIAID), a division of the National Institutes of Health (NIH).

Joseph R. Voland, M.D.
Medical & Laboratory Director
Dr. Voland is currently the medical and laboratory director for TrovaGene and has also served in a management role in several other molecular laboratories developing and providing new diagnostics tests for cancer and infectious disease. In 1995, he established Scientific Pathology Consultants, providing pathology and laboratory management services to a range of prestigious clients including Amylin, Clarient and Novartis, with a focus on autoimmune disease, cardiovascular disease and cancer, including the immunotherapy of melanoma. Dr. Voland received his M.D. degree from the Ohio State University in 1978. He originally trained in anatomic and pediatric pathology at The University of California at San Diego (UCSD) and The Children's Hospital of Los Angeles. Dr. Voland is board-certified in Anatomic Pathology. He spent 15 years at the UCSD Cancer Center where he studied immunology, pregnancy and cancer. Dr. Voland is the author of over 40 published scientific papers, articles and book chapters.

B. Keith McCormick, M.B.A.
Vice President, Commercial Operations
Mr. McCormick joined Trovagene to lead commercialization efforts of the company's emerging portfolio of proprietary testing services. Most recently, he served as director of sales and marketing, and later senior director of sales operations, for AviaraDx (now bioTheranostics). While at AviaraDx, Mr. McCormick led the successful commercial launch of two molecular assays, CancerTYPE ID and Breast Cancer Index. Previously, he held positions of increasing responsibility in sales, sales management, marketing, market research and commercial operations at Biogen Idec and Schering-Plough (now part of Merck & Co.), focused on the oncology marketplace. These two firms were at the time among the largest and highest-profile companies operating in the cancer arena. Mr. McCormick began his career at Dianon Systems, a specialty laboratory providing cancer and genetic testing services to physicians. He holds a bachelor's degree in business administration from Stetson University in DeLand, FL, and an M.B.A. from Jacksonville State University in Jacksonville, AL.

Board of Directors

In our view, the TrovaGene Board of Directors represents an asset for the company because of the presence of a number of individuals with substantial strategic backgrounds and illustrious track records in the healthcare industry. We would draw investors' attention in particular to the fact that TrovaGene's Chairman, Dr. Thomas Adams, has been a director of IRIS International, Inc., a successful and profitable diagnostics firm, for several years. IRIS was recently acquired by the industrial and medical conglomerate Danaher Corp. In addition, one of TrovaGene's other directors, Gabriele Cerrone, has a lengthy track record in the healthcare industry, notably including his success as a serial entrepreneur. Among Mr. Cerrone's recent successes is the sale of Inhibitex to Bristol-Myers Squibb for $2.5 billion in early 2012. From our perspective, the presence of these individuals on TrovaGene's board sets the company apart from many of its peers in the molecular diagnostics sector.

Thomas Adams, Ph.D.
Chairman of the Board
Thomas H. Adams has been the Chairman of the Board of Directors for TrovaGene since April 2009. Since June 2005, Dr. Adams has served as a director of IRIS International, Inc., a diagnostics company, and as Chief Technology Officer of IRIS since April 2006. Dr. Adams served as Chairman and CEO of Leucadia Technologies, a privately-held medical device company, from 1998 to April 2006, when Leucadia was acquired by IRIS. In 1989, Dr. Adams founded Genta, Inc., a publicly-held biotechnology company in the field of antisense technology, and served as its CEO until 1997. Dr. Adams founded Gen-Probe, Inc. in 1984 and served as its CEO and Chairman until its acquisition by Chugai Biopharmaceuticals, Inc. in 1989. Before founding Gen-Probe, Dr. Adams held management positions at Technicon Instruments and the Hyland Division of Baxter Travenol. He has significant public-company experience serving as a director of Biosite Diagnostics, Inc., a publicly held medical research firm, from 1989 to 1998 and as a director of Invitrogen, a publicly held company that develops, manufactures and markets research tools and products, from 2000 to 2002. Dr. Adams is currently a director of Synergy Pharmaceuticals, Inc., a biotechnology company. He obtained a Ph.D. in biochemistry from the University of California, at Riverside.

Antonius Schuh, Ph.D.
Director, President & Chief Executive Officer
See management biographies above.

John P. Brancaccio, C.P.A.
Director
John Brancaccio, a retired C.P.A., has served as a director of TrovaGene since December 2005. Since April 2004, Mr. Brancaccio has been the CFO of Accelerated Technologies, Inc., an incubator for medical device companies. From May 2002 until March 2004, Mr. Brancaccio was the CFO of Memory Pharmaceuticals Corp., a biotechnology company that was acquired by Roche in 2008. From 2000 to 2002, Mr. Brancaccio was the Chief Financial Officer/Chief Operating Officer of Eline Group, an entertainment and media company. Mr. Brancaccio is currently a director of Tamir Biotechnology, Inc. (formerly known as Alfacell Corp.), as well as a director of Synergy Pharmaceuticals, Inc. and Callisto Pharmaceuticals, Inc. (which recently merged with Synergy Pharmaceuticals).

Gabriele M. Cerrone, M.B.A.
Director
Gabriele M. Cerrone has served as a director of TrovaGene since February 2010. Since July 2008, Mr. Cerrone has served as Chairman of the Board of Directors for and as a consultant to Synergy Pharmaceuticals, Inc., a biotechnology company. From March

1999 to January 2005 Mr. Cerrone served as a Senior Vice President of Investments of Oppenheimer & Co. Inc., a financial services firm. In May 2001, Mr. Cerrone led the restructuring of SIGA Technologies, Inc., a biotechnology company, and served on its board of directors from May 2001 to May 2003. Mr. Cerrone also co-founded FermaVir Pharmaceuticals, Inc., a biotechnology company, and served as Chairman from August 2005 to September 2007, when the company was acquired by Inhibitex, Inc., a biotechnology company. Mr. Cerrone served as a director of Inhibitex, Inc. from September 2007 until February 2012 when it was acquired by Bristol-Myers Squibb Company. Since 2003, Mr. Cerrone has been Chairman of Callisto Pharmaceuticals, Inc., a biotechnology company, and has served as a consultant to Callisto since 2005. In 2012, Callisto was merged into Synergy Pharmaceuticals. He is also the managing partner of Panetta Partners Ltd., a limited partnership that is a private investor in both public and private venture capital in the life sciences and technology arena as well as real estate.

Gary Jacob, Ph.D.
Director
Gary S. Jacob has served as a director on the TrovaGene board since February 2009. Since July 2008, Dr. Jacob has been President, CEO and a member of the Board of Directors of Synergy Pharmaceuticals Inc. and as Chairman of a subsidiary of Synergy from October 2003 until July 2008. Dr. Jacob has over 25 years of experience in the pharmaceutical and biotechnology industries across multiple disciplines including research & development, operations and business development. Prior to 1999, Dr. Jacob served as a Monsanto Science Fellow, specializing in the field of glycobiology, and from 1997 to 1998 was Director of Functional Genomics, Corporate Science & Technology, at Monsanto. Dr. Jacob also served from 1990 to 1997 as Director of Glycobiology at G.D. Searle Pharmaceuticals Inc., a major life sciences firm, which is now part of Pfizer Inc. During 1986 – 1990, he was Manager of the G.D. Searle Glycobiology Group at Oxford University, England.

Stanley Tennant, M.D.
Director
Dr. Tennant has served as a director of TrovaGene since December 2010. Since 1983, he has been a cardiologist in Greensboro, NC. Dr. Tennant graduated from Wake Forest University School of Medicine in 1978 and completed postgraduate training in Internal Medicine and Cardiology at Vanderbilt University in 1983.

Scientific Advisory Board

One of TrovaGene's strategic advantages centers on the involvement of its scientific advisory board, which includes a number of well-known individuals with lengthy track records in the diagnostics arena, particularly with respect to the oncology domain. In our view, this prestigious group of individuals should be capable of providing value-added and timely guidance to the company as it seeks to optimize the commercialization of its proprietary diagnostic approaches.

Carlo Croce
Director, Institute of Genetics, Ohio State University Comprehensive Cancer Center
Dr. Croce is globally recognized for his groundbreaking research into the genetic mechanisms involved in the development of cancer. During his career he has discovered and characterized numerous oncogenes and established the role of microRNAs in cancer development and progression. Dr. Croce is the principal investigator on seven federal research grants, and has authored or co-authored more than 875 peer-reviewed publications. He is the recipient of numerous prestigious awards including the Henry M. Stratton Medal from the American Society of Hematology, the Albert Szent-Györgyi Prize for Progress in Cancer Research, and most recently the 2008 Leopold Griffuel Prize

awarded by the French Association for Cancer Research. He has played a critical role in the formation and development of numerous successful biotechnology companies, most notably as a co-founder of Centocor Inc. which was acquired by Johnson & Johnson in 1999 for $4.9 billion in stock. Dr. Croce is the current Chairman of the Department of Molecular Virology, Immunology and Medical Genetics at Ohio State University, and also holds the John W. Wolfe Chair in Human Cancer Genetics at this institution.

Riccardo Dalla-Favera, M.D.
Director, Institute for Cancer Genetics ad Herbert Irving Comprehensive Cancer Center Columbia University, New York
A Columbia faculty member for more than 15 years, Dr. Dalla-Favera helped found and has led the Institute for Cancer Genetics at Columbia University since 1999. He joined Columbia's College of Physicians and Surgeons in the Department of Pathology in 1989, after completing a fellowship at the National Cancer Institute (NCI). Dr. Dalla-Favera was previously a faculty member at New York University School of Medicine. From 1992 to 1998, he served as the Deputy Director of the HICCC. He is the Percy and Joanne Uris Professor of Pathology and Professor of Genetics & Development at the Columbia University College of Physicians and Surgeons. The author of more than 250 publications, Dr. Dalla-Favera has made pioneering contributions to the study of cancer - particularly lymphoma, whose incidence has doubled in the last 35 years. He discovered most of the genes responsible for lymphoma development, including a gene that stimulates tumor growth in most types of B cell lymphoma.

Mark Erlander, Ph.D.
Chief Scientific Officer, bioTheranostics, Inc.
Mark Erlander, Ph.D., has more than 18 years of experience directing and leading research and development for gene discovery, with a strong focus on molecular diagnostics. Prior to joining bioTheranostics, Dr. Erlander was a group leader and subsequently a research fellow at the R.W. Johnson Pharmaceutical Research Institute (Johnson & Johnson). He was also an assistant member and postdoctoral fellow at The Scripps Research Institute in the Department of Molecular Biology. Dr. Erlander holds a B.S. degree in Biochemistry from the University of California, Davis; an M.S. degree in Biochemistry from Iowa State University; and a Ph.D. in Neuroscience from the University of California, Los Angeles (UCLA). He is an accomplished researcher with 32 issued U.S. patents and 38 U.S. patent applications, and is a lead or contributing author on more than 70 scientific papers and review articles.

Brunangelo Falini, M.D.
Director, Institute of Hematology, University of Perugia, Italy
Dr. Falini is a professor of hematology at Perugia University. He is a discoverer of and an expert on new nucleophosmin protein (NPM) mutants, corresponding gene sequences and relative uses thereof for diagnosis, monitoring of minimal residual disease; prognostic evaluation and therapy of acute myeloid leukemia (AML). In our view, Dr. Falini's unique expertise in hematological malignancies could enable TrovaGene to explore the development of proprietary diagnostic tests for liquid cancers as well as solid tumors (such as lung and colorectal cancers).

Sinuhe Hahn, M.D.
Head of Research, Prenatal Medicine, University of Basel, Switzerland
Sinuhe Hahn is a recognized expert in the domain of prenatal medicine and is a key participant in TrovaGene's initiative to develop non-invasive prenatal diagnostics. He has an extensive scientific record, spanning nearly 150 peer-reviewed publications. Dr. Hahn has been a member of the Scientific Advisory Board at TrovaGene since April 2010.

Public Companies Mentioned in this Report:

Affymetrix (AFFX/NASDAQ – $3.34)

Danaher Corp. (DHR/NYSE – $53.53)

EXACT Sciences (EXAS/NASDAQ – $10.35)

Fluidigm Corp. (FLDM/NASDAQ -- $14.43)

GenMark Diagnostics (GNMK/NASDAQ – $9.42)

General Electric (GE/NYSE – $21.51)

Genomic Health (GHDX/NASDAQ – $27.85)

Johnson & Johnson (JNJ/NYSE – $71.10)

NeoGenomics (NEO/NASDAQ – $3.00)

Novartis (NVS/NYSE – $63.20)

Pacific Biosciences of California (PACB/NASDAQ – $1.67)

Pfizer (PFE/NYSE – $25.64)

Response Genetics (RGDX/NASDAQ – $1.38)

Rosetta Genomics (ROSG/NASDAQ – Buy – $4.26)

Sanofi S.A. (SNY/NYSE – $46.91)

Sequenom (SQNM/NASDAQ – $4.82)

TrovaGene (TROV/NASDAQ – $4.61)

Vermillion (VRML/NASDAQ – $1.36)

Table 7: TrovaGene, Inc. (TROV) – Historical Income Statements, Financial Projections

FY end December 31

$ in thousands, except per share data

		2012E					2013E					
	2011A	1QA	2QA	3QA	4QE	2012E	1QE	2QE	3QE	4QE	2013E	2014E
Revenue												
Product revenue	-	-	-	-	-	-	-	-	250	750	1,000	14,000
Royalty income	228	34	42	42	42	159	50	50	50	50	200	220
License fees	30	-	-	170	170	340	170	170	170	170	680	680
Total revenue	258	34	42	212	212	499	220	220	470	970	1,880	14,900
Expenses												
Cost of product and service revenue	-	-	-	-	-	-	-	-	-	-	-	-
Research & development	911	337	477	511	550	1,876	600	650	700	750	2,700	3,750
Selling and marketing	-	-	-	-	-	-	-	250	500	800	1,550	8,100
General and administrative	2,324	827	810	739	750	3,126	700	750	850	1,000	3,300	6,000
Total expenses	3,234	1,164	1,287	1,250	1,300	5,002	1,300	1,650	2,050	2,550	7,550	17,850
Gain (loss) from operations	(2,977)	(1,130)	(1,246)	(1,039)	(1,089)	(4,503)	(1,080)	(1,430)	(1,580)	(1,580)	(5,670)	(2,950)
Other income/expense												
Interest income/expense	(56)	-	-	-	-	-	-	5	8	7	20	10
Gain on debt extinguishment	623	-	-	-	-	-	-	-	-	-	-	-
Change in fair value of derivative instruments	171	(32)	(2,181)	389		(1,825)	-	-	-	-	-	-
Other income/expense	-	-	-	-	-	-	-	-	-	-	-	-
Total investment income and other	738	(32)	(2,181)	389	-	(1,825)	-	5	8	7	20	10
Loss before provision for income taxes	(2,239)	(1,163)	(3,426)	(650)	(1,089)	(6,328)	(1,080)	(1,425)	(1,572)	(1,573)	(5,650)	(2,940)
Preferred stock dividend	-	(10)	(10)	(10)	(10)	(38)	(10)	(10)	(10)	(10)	(38)	(38)
Net loss/income	(2,239)	(1,172)	(3,436)	(660)	(1,098)	(6,366)	(1,090)	(1,435)	(1,582)	(1,583)	(5,688)	(2,978)
Net loss per share (basic)	(0.23)	(0.11)	(0.28)	(0.05)	(0.07)	(0.49)	(0.07)	(0.09)	(0.09)	(0.09)	(0.34)	(0.17)
Net loss per share (diluted)	(0.23)	(0.11)	(0.28)	(0.05)	(0.07)	(0.49)	(0.07)	(0.09)	(0.09)	(0.09)	(0.34)	(0.17)
Weighted average number of shares outstanding (basic)	9,711	11,002	12,087	14,179	14,711	12,994	15,291	16,391	17,491	17,591	16,691	17,841
Weighted average number of shares outstanding (diluted)	9,711	11,002	12,087	14,179	14,711	12,994	15,291	16,391	17,491	17,591	16,691	17,841

Source: Company Reports and Aegis Capital Corp. estimates

Required Disclosures

Price Target

Our 15-month price target is $12.00 per share.

Valuation Methodology

We utilize a Net Present Value (rNPV) analysis to determine our price target objective. Using a discounted cash flow analysis, we derive an rNPV-based total firm value of roughly $340 million, which translates into a price per share of $12.00, assuming 28 million fully-diluted shares outstanding and $60 million in cash as of the end of 1Q 2014.

Risk Factors

Issues that could prevent the achievement of our price objective include, but are not limited to, clinical, regulatory, competitive, reimbursement and financial risks. Diagnostic tools in clinical development may not advance due to inadequate safety. Regulatory agencies may decline to approve regulatory submissions in a timely manner, or may not approve a product candidate at all. The firm may require substantial funding to advance the clinical progress of its diagnostic products, which could be dilutive to current shareholders. Sales of the firm's products could depend upon reimbursement from private, as well as public, reimbursement agencies.

For important disclosures go to www.aegiscap.com.

We, Raghuram Selvaraju and Yi Chen, the authors of this research report, certify that the views expressed in this report accurately reflect our personal views about the subject securities and issuers, and no part of our compensation was, is, or will be directly or indirectly tied to the specific recommendations or views contained in this research report.

Research analyst compensation is dependent, in part, upon investment banking revenues received by Aegis Capital Corp.

Aegis Capital Corp. intends to seek or expects to receive compensation for investment banking services from the subject company within the next three months.

Aegis Capital Corp. has performed investment banking services for and received fees from Trovagene, Inc. and Rosetta Genomics within the past 12 months.

Rating	Percent	Investment Banking Services/Past 12 Mos. Percent
BUY [BUY]	95.45	33.33
HOLD [HOLD]	4.55	0.00
SELL [SELL]	0.00	0.00

Meaning of Ratings

A) A Buy rating is assigned when we do not believe the stock price adequately reflects a company's prospects over 12-18 months.
B) A Hold rating is assigned when we believe the stock price adequately reflects a company's prospects over 12-18 months.
C) A Sell rating is assigned when we believe the stock price more than adequately reflects a company's prospects over 12-18 months.

Other Disclosures

The information contained herein is based upon sources believed to be reliable but is not guaranteed by us and is not considered to be all inclusive. It is not to be construed as an offer or the solicitation of an offer to sell or buy the securities mentioned herein. Aegis Capital Corp., its affiliates, shareholders, officers, staff, and/or members of their families, may have a position in the securities mentioned herein, and, before or after your receipt of this report, may make or recommend purchases and/or sales for their own accounts or for the accounts of other customers of the Firm from time to time in the open market or otherwise. Opinions expressed are our present opinions only and are subject to change without notice. Aegis Capital is under no obligation to provide updates to the opinions or information provided herein. Additional information is available upon request.

Aegis Capital Corp.
(212) 813-1010
810 Seventh Avenue, 18th Floor
New York, New York 10019