



April 1, 2013

Key Metrics

TROV - NASDAQ	\$6.26
Pricing Date	Mar 28 2013
Price Target	\$14.00
52-Week Range	\$8.96 - \$1.86
Shares Outstanding (mm)	14.2
Market Capitalization (\$mm)	\$88.9
3-Mo Average Daily Volume	89,621
Institutional Ownership	3%
Debt/Total Capital	NM
ROE	NM
Book Value/Share	\$0.35
Price/Book	17.9x
Dividend Yield	NM
LTM EBITDA Margin	NM

EPS (\$ FY: December

	2012E	Prior 2013E	Curr. 2013E	Prior 2014E	Curr. 2014E
1Q-Mar	(0.11)A	--	(0.07)E	--	(0.05)E
2Q-Jun	(0.28)A	(0.09)E	(0.07)E	--	(0.03)E
3Q-Sep	(0.05)A	(0.09)E	(0.06)E	--	0.00E
4Q-Dec	(0.07)E	(0.09)E	(0.05)E	--	0.02E
FY	(0.49)E	(0.34)E	(0.26)E	--	(0.05)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 Launches HPV Test - Raising Price Target****Investment Highlights:**

- **Trovagene Launches First Urine-Based Test.** Last week, Trovagene announced the launch of its first laboratory-developed test (LDT) using its proprietary cell-free nucleic acid detection approach optimized for use with urine as the analyte. This test is aimed at detection of high-risk human papillomavirus (HPV) infections, which are implicated in the incidence of cervical and penile cancers, among other malignancies. In the wake of this announcement, we reiterate our Buy rating and raise our 12-month price target from \$12.00 to \$14.00 per share on TROV shares.
- **HPV Test Validation Achieved.** In previous clinical assessments, the non-invasive HPV test developed by Trovagene has been shown to accurately identify the presence or absence of 15 known high-risk HPV strains using proprietary DNA sequences. Sensitivity and specificity were both measured at >90%. The Trovagene HPV-HR DNA test is a non-invasive option that may improve the adoption and acceptance rate of HPV testing. Carrier testing for HPV can help raise awareness and encourage use of preventative measures to reduce transmission of the virus. For women who require ongoing monitoring for their HPV status but who do not want repeated physical exams, a urine-based HPV-HR DNA test can facilitate more comprehensive continuous patient assessment.
- **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. We anticipate the launches of the firm's first oncology-focused tests, aimed at detection of B-raf and K-ras mutations, over the course of the next 3-4 months. In our view, with the B-raf and K-ras mutation analysis tests on the market along with the HPV test, Trovagene should be able to attain cash flow-positive status in the second half of 2014.
- **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 \$90mm, a significant discount to our risk-adjusted Net Present Value (rNPV)-based total firm value estimate of \$385mm, which factors in exercise of 3.3mm options and 6.8mm warrants currently outstanding.

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. As of September 30th, 2012, TrovaGene had \$7.8 million in cash and equivalents. 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 18 months in order to reach sustainable profitability. 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 sooner than expected. 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 \$14 per share, given our estimate of a \$320 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 \$325 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 3/28/2013	Shares (MM)	Market cap (\$MM)	Cash (\$MM)	Debt (\$MM)	Enterprise value (\$MM)
Marketed	Molecular Diagnostics / Life Science Tools	Affymetrix	AFFX	Not Rated	\$4.72	71	335	35	162	462
Marketed	Molecular Diagnostics	EXACT Sciences	EXAS	Not Rated	\$9.80	64	627	108	2	521
Marketed	Life Science Tools	Fluidigm Corp.	FLDM	Not Rated	\$18.51	25	468	80	0	388
Marketed	Molecular Diagnostics	Genomic Health	GHDX	Not Rated	\$28.28	30	852	99	0	753
Marketed	Molecular Diagnostics	GenMark Diagnostics	GNMK	Not Rated	\$12.92	33	423	51	1	372
Marketed	Molecular Diagnostics	NeoGenomics	NEO	Not Rated	\$3.93	45	178	2	14	190
Marketed	Molecular Diagnostics	Response Genetics	RGDX	Not Rated	\$1.32	33	43	9	1	35
Marketed	Molecular Diagnostics	Rosetta Genomics	ROSG	Buy	\$4.34	9	39	31	0	9
Marketed	Molecular Diagnostics	Sequenom	SQNM	Not Rated	\$4.15	115	476	176	157	458
Marketed	Molecular Diagnostics	Vermillion	VRML	Not Rated	\$1.20	15	18	8	1	11
		Average					346			323
								Discrepancy		
Current valuation	Molecular Diagnostics	Trovagene	TROV	Buy	\$6.26	14	89	8	0	81
Derived 12-month compa-month comparable value										
Target valuation (12-month)	Molecular Diagnostics	Trovagene	TROV	Buy	\$14.00	28	385	62	0	323

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 \$14 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 \$120 million in value, or roughly \$4.30 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)	\$120MM
Total enterprise value	\$320MM
Cash and cash equivalent balance at end-1Q 2014	\$62MM
Shares Outstanding at end-1Q 2014 (in millions)	28
Cash per share	\$2
15-Month Target Price	\$14.00
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	
⁴ Peak sales - test revenue / year / patient x diagnosed patients x peak market share	
⁵ Final patent on transrenal nucleic acid-based analysis expires 2027	
⁶ 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.

Table 3: TrovaGene, Inc. (TROV) – Historical Income Statements, Financial Projections

FY end December 31

\$ in thousands, except per share data

	2011A	2012E	2013E				2013E	2014E				2014E
			1QE	2QE	3QE	4QE		1QE	2QE	3QE	4QE	
Revenue												
Product revenue	-	-	-	250	750	1,400	2,400	2,200	3,300	4,500	6,000	16,000
Royalty income	228	159	50	50	50	50	200	55	55	55	55	220
License fees	30	340	170	170	170	170	680	195	195	195	195	780
Total revenue	258	499	220	470	970	1,620	3,280	2,450	3,550	4,750	6,250	17,000
Expenses												
Cost of product and service revenue	-	-	-	-	-	-	-	-	-	-	-	-
Research & development	911	1,876	600	650	700	750	2,700	800	850	900	1,200	3,750
Selling and marketing	-	-	-	250	500	800	1,550	1,250	1,850	2,200	2,800	8,100
General and administrative	2,324	3,126	700	750	850	1,000	3,300	1,200	1,400	1,600	1,800	6,000
Total expenses	3,234	5,002	1,300	1,650	2,050	2,550	7,550	3,250	4,100	4,700	5,800	17,850
Gain (loss) from operations	(2,977)	(4,503)	(1,080)	(1,180)	(1,080)	(930)	(4,270)	(800)	(550)	50	450	(850)
Other income/expense												
Interest income/expense	(56)	-	-	5	8	7	20	4	3	2	1	10
Gain on debt extinguishment	623	-	-	-	-	-	-	-	-	-	-	-
Change in fair value of derivative instruments	171	(1,825)	-	-	-	-	-	-	-	-	-	-
Other income/expense	-	-	-	-	-	-	-	-	-	-	-	-
Total investment income and other	738	(1,825)	-	5	8	7	20	4	3	2	1	10
Loss before provision for income taxes	(2,239)	(6,328)	(1,080)	(1,175)	(1,072)	(923)	(4,250)	(796)	(547)	52	451	(840)
Preferred stock dividend	-	(38)	(10)	(10)	(10)	(10)	(38)	(10)	(10)	(10)	(10)	(38)
Net loss/income	(2,239)	(6,366)	(1,090)	(1,185)	(1,082)	(933)	(4,288)	(806)	(557)	42	441	(878)
Net loss per share (basic)	(0.23)	(0.49)	(0.07)	(0.07)	(0.06)	(0.05)	(0.26)	(0.05)	(0.03)	0.00	0.02	(0.05)
Net loss per share (diluted)	(0.23)	(0.49)	(0.07)	(0.07)	(0.06)	(0.05)	(0.26)	(0.05)	(0.03)	0.00	0.02	(0.05)
Weighted average number of shares outstanding (basic)	9,711	12,994	15,291	16,391	17,491	17,591	16,691	17,691	17,791	17,891	17,991	17,841
Weighted average number of shares outstanding (diluted)	9,711	12,994	15,291	16,391	17,491	17,591	16,691	17,691	17,791	17,891	17,991	17,841

Source: Company Reports and Aegis Capital Corp. estimates

Required Disclosures

Price Target

Our 12-month price target is \$14.00 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 \$385 million, which translates into a price per share of \$14.00, 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.

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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	Investment Banking Services/Past 12 Mos.	
	Percent	Percent
BUY [BUY]	82.86	24.14
HOLD [HOLD]	17.14	16.67
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

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