

## Healthcare: Biotechnology

# TrovaGene, Inc. | TROV - \$6.62 - NASDAQ | Buy

### Company Update

Estimates Changed

#### Stock Data

52-Week Low - High	\$2.09 - \$8.96
Shares Out. (mil)	15.62
Mkt. Cap.(mil)	\$103.4
3-Mo. Avg. Vol.	65,291
12-Mo.Price Target	\$11.00
Cash (mil)	\$9.2
Tot. Debt (mil)	\$0.0

#### EPS \$

Yr Jan	—2012—	—2013E—		—2014E—	
		Curr	Prev	Curr	Prev
1Q	(0.09)A	(0.07)A	(0.12)E	-	-
2Q	(0.28)A	(0.13)E	(0.10)E	-	-
3Q	(0.05)A	(0.21)E	(0.14)E	-	-
4Q	(0.43)A	(0.18)E	(0.14)E	-	-
YEAR	(0.89)A	(0.61)E	(0.49)E	(0.57)E	(0.46)E
P/E	NM	NM	NM	NM	NM

#### Revenue (\$ millions)

Yr Jan	—2012—	—2013E—		—2014E—	
		Curr	Prev	Curr	Prev
1Q	0.0A	0.1A	0.1A	-	-
2Q	0.0A	0.1E	0.2E	-	-
3Q	0.2A	0.2E	0.2E	-	-
4Q	0.2A	0.2E	0.3E	-	-
YEAR	0.5A	0.6E	0.9E	1.4E	1.6E

TROV One-Year Price and Volume History



## TROV: 1Q13 - Product Developments Are in High Gears

TROV reported 1Q13 results with a net loss of (\$1.1M) or (\$0.07)/share. By netting out non-cash change in fair value of derivative instruments / warrants, the net loss was (\$2.4M) or (\$0.15)/share. The company ended the quarter with cash and equivalents of \$9.2M; sufficient for operations into 2014, in our opinion

- We are encouraged by TROV's R&D collaboration with PerkinElmer Health Sciences to co-develop and design assay for determining the risk of a patient to develop hepatocellular carcinoma, based on TROV's transrenal nucleic acids (TrNA) technology. In addition to validation of the TrNA technology and the recognition that TROV is a legitimate player in the space, we believe there are more potential diagnostics collaborations with TROV going forward. Given TrNA-based diagnostics can be used in a broad array of diseases, TROV could potentially consummate different non-exclusive partnerships with multiple players to create shareholder value.
- With the recent launch of HPV test and pilot sales and marketing efforts were already in place, we believe 2013 could be a major development year for TROV for launches of HPV and several other oncology diagnostic tests. On the oncology side, launches of KRAS, BRAF and PIK3CA plus hepatocellular carcinoma-related HBV/p53 tests are expected in 2Q13, 3Q13 and 4Q13, respectively. We anticipate modest product revenue growth in 2013 given it is the initial stage for product launch; and potential sales force expansion could start in 4Q13.
- **ASCO presence could be valuable.** TROV is scheduled to set up a booth at the upcoming ASCO annual conference (May 31 -- June 4) to expand the awareness of TrNA-based diagnostics to a large number of oncologists.
- **Continued R&D efforts.** Management pointed out during our recent discussion that the company is continuing product configuration improvements and clinical validation studies by major medical centers. As such, we believe the company could further strengthen its product offering going forward.

#### Action:

Materialization of the encouraging outlook for TrNAs-based diagnostics could drive TROV share value beyond the current valuation, in our view. We reiterate our Buy rating and our \$11 price target, supported by peer comparable analysis, to long-term, risk tolerant investors.

Figure 1 Estimated and reported 1Q13 results

Table 1: 1Q13 Estimates and Reported Results			
(\$ MM)	ROTH Estimate	Actual	Consensus
<b>Total revenue</b>	\$0.1	\$0.1	\$0.1
<b>Total op. profit (loss)</b>	(\$1.6)	(\$2.4)	(\$1.4)
R&D	\$0.7	\$0.8	
SG&A	\$1.1	\$1.7	
<b>EPS</b>	(\$0.12)	(\$0.07)	(\$0.10)
Net income (loss)	(\$1.7)	(\$1.1)	(\$1.5)

Source: The company report and ROTH Capital research

## VALUATION

Given TrovaGene's products are in mid-to-early development stage, it is more difficult to project the future revenue stream with sufficient accuracy. As such, we believe a peer comparable analysis is a more appropriate method to value TROV shares. Accordingly, we have derived a 12-month target price of \$11, based on a peer comparable analysis with molecular diagnostic peers.

Factors that could impede shares of TROV from achieving our price target include: 1) despite its novelty and potential benefits, TrNAs-based diagnostic test remain untested as a commercially-viable product; 2) despite promising outcomes from analytical and early clinical validation studies, it remains uncertain as to whether or not actual clinical utilities of these tests can be established by upcoming clinical validation studies; 3) other possible TrNAs-based diagnostic tests could outperform TrovaGene's products; 4) commercial outlook of TrNAs-based diagnostic tests might not meet expectations; 5) lack of sufficient cash could impede corporate development; and 6) limited trading liquidity limits shareholder options.

## RISKS

**Despite its novelty and potential benefits, the TrNAs-based diagnostic test remains untested as a commercially viable product.** Although the TrNAs-based diagnostic test has the potential to become one of the more sensitive diagnostic platforms, with possible broad clinical utility, the platform itself remains in a nascent development stage without any commercialization. As such, risks still exist as to whether or not TrNAs-based diagnostic tests could become a commercial alternative until a successful precedent has been established.

**Despite promising outcomes from analytical and early clinical validation studies, it remains uncertain as to whether or not actual clinical utility of these tests can be established by upcoming clinical validation studies.** It remains too early for the test to be rapidly adapted by large number of physicians until clinical utility has been established by additional successful clinical validation studies. Many of such prospective studies might take a while before a potential positive outcome is reported. It is difficult to handicap the outcome of potential future validation studies. If not robust, the commercial potential of the KRAS or any other tests could be limited.

**Other possible TrNAs-based diagnostic tests could potentially outperform TrovaGene's products.** Although TrovaGene's platform has comprised several superior technologies and is potentially protected by patents, it is possible that competitors could develop other similar or even better TrNAs-based diagnostic products without infringing TrovaGene's patents, since no company has a monopoly on the TrNAs-based platform.

**Commercial outlook of TrNAs-based diagnostic tests might not meet expectations.** Despite potentially successful clinical validation results that establish clinical utility for the test, the sales performance might be difficult to forecast, depending on the level of physician and payer buy-in as well as marketing and sales execution by the company or potential commercialization partners.

**Lack of sufficient cash could impede corporate development.** If the company cannot amass sufficient capital via non-dilutive sources to advance its pipeline development, TROV's shares could decline.

**Limited trading liquidity limits shareholder options.** With a relatively illiquid trading volume, shareholders wanting to increase or reduce positions may face constraints.

## COMPANY DESCRIPTION

TrovaGene is a development-stage molecular diagnostic company that focuses on the development and marketing of transrenal nucleic acids (TrNAs)-based diagnostic tests for patient / disease screening and monitoring. The company's internal development focuses on oncology with KRAS, BRAF and PIK3CA as lead diagnostic markers. The company expects to conduct multiple clinical validation studies in 2013 and beyond to further advance oncology diagnostic tests with revenue growth potentially to start in 2014.

### Anticipated milestones in 2013 and beyond

Program	Indication	Event	Timing
KRAS	Pancreatic cancer	Completion of clinical validation by CLIA lab and product release	2Q13
		Potential releases data of the MD Anderson Cancer Center clinical study	2013
		Commencement of additional clinical studies with other medical insitutions	2013
BRAF	Multiple cancers	Completion of clinical validation by CLIA lab and product release	3Q13
PIK3CA	Multiple cancers	Completion of clinical validation by CLIA lab and product release	4Q13
		Potential clinical collaboration	4Q13
Commercial sales and marketing plan		Potential initiate oncology pilot launch	2Q13
		Potential Expand sales force expansion	4Q13
		Participation at the ASCO conference	May 31 - June 4, 2013

*ROTH Capital Partners, and company presentation (May 2013)*

Trovagene, Inc. – Income Statement										
('000 \$)	2009	2010	2011	2012	1Q13	2Q13E	3Q13E	4Q13E	2013E	2014E
Royalty income	154	256	228	175	119	123	125	131	498	598
Milestone fees	-	-	-	150	-	-	-	-	-	-
Product revenue	-	-	-	-	-	-	25	50	75	825
License fees	500	10	30	125	-	0	-	-	0	0
<b>Total Revenue</b>	<b>654</b>	<b>266</b>	<b>258</b>	<b>450</b>	<b>119</b>	<b>123</b>	<b>150</b>	<b>181</b>	<b>573</b>	<b>1,423</b>
Cost of goods sold	-	-	-	-	-	-	-	-	-	-
Gross profit	654	266	258	450	119	123	150	181	573	1,423
Research and development expenses	562	1,024	911	1,920	802	907	997	1,087	3,793	4,362
Purchased in process research and development	-	2,667	-	-	-	-	-	-	-	-
General and administrative expenses	1,661	1,954	2,324	3,379	1,707	1,604	1,701	1,803	6,814	7,836
<b>Operating expense</b>	<b>2,223</b>	<b>5,645</b>	<b>3,234</b>	<b>5,299</b>	<b>2,509</b>	<b>2,511</b>	<b>2,698</b>	<b>2,890</b>	<b>10,607</b>	<b>12,198</b>
Excess amount of participation in research and development from third party	-	-	-	-	-	-	-	-	-	-
<b>Operating income</b>	<b>(1,569)</b>	<b>(5,379)</b>	<b>(2,977)</b>	<b>(4,849)</b>	<b>(2,390)</b>	<b>(2,388)</b>	<b>(2,548)</b>	<b>(2,708)</b>	<b>(10,034)</b>	<b>(10,775)</b>
Interest income	0.0	0.2	0.2	4	-	-	-	-	-	-
Interest expense	(161)	(116)	(57)	-	-	-	-	-	-	-
Amortization of deferred debt costs and original issue discount	(203)	(221)	-	-	-	-	-	-	-	-
Change in fair value of derivative instruments—warrants	273	267	171	(6,721)	1,279	300	(850)	(263)	466	559
Gain on extinguishment of debt	-	-	623	-	-	-	-	-	-	-
Liquidated damages and other forbearance agreement settlement costs	(824)	-	-	-	-	-	-	-	-	-
<b>Income (loss) before taxes</b>	<b>(2,484)</b>	<b>(5,449)</b>	<b>(2,239)</b>	<b>(11,566)</b>	<b>(1,111)</b>	<b>(2,088)</b>	<b>(3,398)</b>	<b>(2,971)</b>	<b>(9,568)</b>	<b>(10,216)</b>
Income tax expense	0.0	(0)	-	-	-	-	-	-	-	-
Preferred stock dividend	(38)	(38)	(38)	(38)	(6)	(6)	(6)	(6)	(24)	(24)
<b>Net income</b>	<b>(2,522)</b>	<b>(5,487)</b>	<b>(2,277)</b>	<b>(11,604)</b>	<b>(1,117)</b>	<b>(2,094)</b>	<b>(3,403)</b>	<b>(2,977)</b>	<b>(9,591)</b>	<b>(10,239)</b>
Dividend in respect of reduction in exercise price of certain Warrants	0.0	0.0	-	-	-	-	-	-	-	-
<b>Net income attributable to common shareholders</b>	<b>(\$2,522)</b>	<b>(\$5,487)</b>	<b>(\$2,277)</b>	<b>(\$11,604)</b>	<b>(\$1,117)</b>	<b>(\$2,094)</b>	<b>(\$3,403)</b>	<b>(\$2,977)</b>	<b>(\$9,591)</b>	<b>(\$10,239)</b>
Net Earnings (Losses) Per Share—Basic	(\$0.08)	(\$0.13)	(\$0.20)	(\$0.89)	(\$0.07)	(\$0.13)	(\$0.21)	(\$0.18)	(\$0.61)	(\$0.57)
Net Earnings (Losses) Per Share—Diluted	(\$0.08)	(\$0.13)	(\$0.20)	(\$0.89)	(\$0.07)	(\$0.13)	(\$0.21)	(\$0.18)	(\$0.61)	(\$0.57)
Shares outstanding—basic	31,178	42,953	11,654	13,067	15,510	15,710	15,910	16,110	15,810	17,810
Shares outstanding—diluted	31,178	42,953	11,654	13,067	15,510	15,710	15,910	16,110	15,810	17,810
<b>Margin Analysis (% of Sales/Revenue)</b>										
COGS	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
R&D	86%	386%	353%	427%	673%	739%	664%	599%	662%	307%
MG&A	254%	735%	902%	751%	1433%	1308%	1133%	994%	1188%	551%
Operating Income (loss)	-240%	-2025%	-1155%	-1077%	-2006%	-1946%	-1697%	-1493%	-1750%	-757%
Pretax	-380%	-2051%	-869%	-2569%	-932%	-1702%	-2263%	-1638%	-1669%	-718%
Tax Rate	NA	0%	NA	NA	NA	NA	NA	NA	NA	NA
Net Income	-386%	-2066%	-884%	-2578%	-937%	-1707%	-2267%	-1641%	-1673%	-720%
<b>Financial Indicator Growth Analysis (YoY%)</b>										
Total Revenue		-59%	-3%	75%	253%	-52%	340%	337%	171%	148%
Cost of goods sold		N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
R&D expenses		82%	-11%	111%	138%	90%	95%	83%	98%	15%
Purchased in process research and development		N.A.	-1000%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
G&A		18%	19%	45%	106%	98%	130%	80%	102%	15%
Operating expense		154%	-43%	64%	115%	95%	116%	81%	100%	15%
Operating Incomes (Losses)		243%	-45%	63%	111%	92%	145%	89%	107%	7%
Pretax Income		119%	-45%	417%	-4%	-39%	423%	-53%	-17%	7%
Net Income		118%	-58%	409%	-5%	-39%	416%	-53%	-17%	7%
EPS - Basic		58%	53%	354%	-19%	-53%	360%	-57%	-32%	-5%
EPS - Diluted		58%	53%	354%	-19%	-53%	360%	-57%	-32%	-5%
Source: Roth Capital Partners Research and Trovogene's SEC filings										
Yale Jen, Ph.D. 646-358-1916										

Regulation Analyst Certification ("Reg AC"): The research analyst primarily responsible for the content of this report certifies the following under Reg AC: I hereby certify that all views expressed in this report accurately reflect my personal views about the subject company or companies and its or their securities. I also certify that no part of my compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

## Disclosures:

ROTH makes a market in shares of TrovaGene, Inc. and as such, buys and sells from customers on a principal basis.

On September 28, 2010, ROTH changed its rating system in order to replace the Hold rating with Neutral.

On May 26, 2011, ROTH changed its rating system in order to incorporate coverage that is Under Review.



Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years. **Distribution Ratings/IB Services** shows the number of companies in each rating category from which Roth or an affiliate received compensation for investment banking services in the past 12 month.

### Distribution of IB Services Firmwide

Rating	Count	Percent	IB Serv./Past 12 Mos. as of 05/14/13	
			Count	Percent
Buy [B]	184	74.80	84	45.65
Neutral [N]	38	15.45	5	13.16
Sell [S]	3	1.22	2	66.67
Under Review [UR]	21	8.54	10	47.62

Our rating system attempts to incorporate industry, company and/or overall market risk and volatility. Consequently, at any given point in time, our investment rating on a stock and its implied price movement may not correspond to the stated 12-month price target.

Ratings System Definitions - ROTH employs a rating system based on the following:

**Buy:** A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return of at least 10% over the next 12 months.

**Neutral:** A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return between negative 10% and 10% over the next 12 months.

**Sell:** A rating, which at the time it is instituted and or reiterated, that indicates an expectation that the price will depreciate by more than 10% over the next 12 months.

**Under Review [UR]:** A rating, which at the time it is instituted and or reiterated, indicates the temporary removal of the prior rating, price target and estimates for the security. Prior rating, price target and estimates should no longer be relied upon for UR-rated securities.

**Not Covered [NC]:** ROTH does not publish research or have an opinion about this security.

ROTH Capital Partners, LLC expects to receive or intends to seek compensation for investment banking or other business relationships with the covered companies mentioned in this report in the next three months. The material, information and

facts discussed in this report other than the information regarding ROTH Capital Partners, LLC and its affiliates, are from sources believed to be reliable, but are in no way guaranteed to be complete or accurate. This report should not be used as a complete analysis of the company, industry or security discussed in the report. Additional information is available upon request. This is not, however, an offer or solicitation of the securities discussed. Any opinions or estimates in this report are subject to change without notice. An investment in the stock may involve risks and uncertainties that could cause actual results to differ materially from the forward-looking statements. Additionally, an investment in the stock may involve a high degree of risk and may not be suitable for all investors. No part of this report may be reproduced in any form without the express written permission of ROTH. Copyright 2013. Member: FINRA/SIPC.