

Healthcare: Biotechnology

TrovaGene, Inc. | TROV - \$6.18 - NASDAQ | Buy

Company Update

Estimates Changed

Stock Data

52-Week Low - High	\$1.86 - \$8.96
Shares Out. (mil)	14.18
Mkt. Cap.(mil)	\$87.6
3-Mo. Avg. Vol.	88,928
12-Mo.Price Target	\$11.00
Cash (mil)	\$10.8
Tot. Debt (mil)	\$0.0

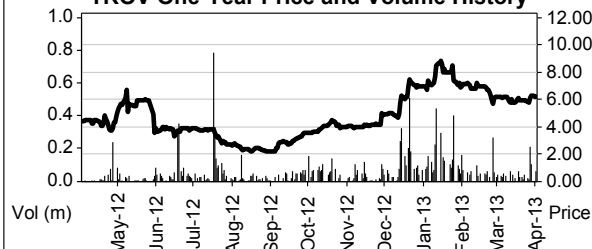
EPS \$

Yr Jan	—2012—	—2013E—		—2014E—
		Curr	Prev	Curr
1Q	(0.09)A	(0.12)E	(0.10)E	-
2Q	(0.28)A	(0.10)E	(0.08)E	-
3Q	(0.05)A	(0.14)E	(0.12)E	-
4Q	(0.43)A	(0.14)E	(0.13)E	-
YEAR	(0.89)A	(0.49)E	(0.43)E	(0.46)E
P/E	NM	NM	NM	NM

Revenue (\$ millions)

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

TROV One-Year Price and Volume History



TROV: 4Q12 - 2013 Would Be The Year of Development

TROV reported 4Q12 and 2012 full year financial results via 10K filed April 1st with 4Q12 and 2012 net losses of (\$6.3M) or (\$0.43)/share and (\$11.6M) or (\$0.89) /share, respectively. By netting out non-cash item of "change in fair value of derivative instruments / warrants", the net losses was (\$1.4M) or (\$0.10)/share and (\$4.9M) or (\$0.37)/share, respectively.

- Since top-line performance is not the near term key investment focus of TROV shares; the value driver is the successful progression of product development and initial launches of several oncology diagnostic tests to gain greater traction among oncologists.
- With the recent launch of HPV test (3/17/'13), we believe 2013 could be the major development year for TROV for initial launches of several other oncology diagnostic tests. The company expects to launch KRAS, BRAF and PIK3CA plus hepatocellular carcinoma related HBV/p53 tests in 2Q13, 3Q13 and 4Q13, respectively. For 2013, we only anticipate very modest product revenue growth given it is the initial stage for product launch and more material revenue growth, in our opinion, could start in 2014 as accumulated clinical utility information could provide physician-specific utility applicable to various diagnostic tests.
- With the HPV test formerly launched in March, the company already geared up its pilot effort to target ~600 OB-Gyns in Southern California with direct mail, which includes web-based activities, to promote awareness and trial and followed by sales for potential securing new accounts (currently reps n=2). Further, we expect the company to expand the pilot effort into oncology starting in 2Q13 after former launch of KRAS diagnostic test. After the launches of additional oncology tests, the company plans to expand its sales force, potentially up to 12 for greater selling and marketing effort possibly in 4Q13.

Action:

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

Intraday price: \$6.24 at 2:10pm ET 4/2/2013

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 (April 2013)

Trovagene, Inc. – Income Statement														
('000 \$)	2009	2010	2011	1Q12	2Q12	3Q12	4Q12	2012	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E
Royalty income	154	256	228	34	42	42	58	175	62	64	65	69	261	313
Milestone fees	-	-	-	-	-	150	-	150	-	-	-	-	-	-
Product revenue	-	-	-	-	-	-	-	-	-	40	100	200	340	1020
License fees	500	10	30	-	-	20	105	125	63	67	72	77	280	313
Total Revenue	654	266	258	34	42	212	163	450	125	172	238	346	880	1,646
Cost of goods sold	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Gross profit	654	266	258	34	42	212	163	450	125	172	238	346	880	1,646
Research and development expenses	562	1,024	911	337	477	511	594	1,920	677	765	872	968	3,283	3,775
Purchased in process research and development	-	2,667	-	-	-	-	-	-	-	-	-	-	-	-
General and administrative expenses	1,661	1,954	2,324	827	810	739	1,003	3,379	1,073	1,138	1,206	1,278	4,695	5,399
Operating expense	2,223	5,645	3,234	1,164	1,287	1,250	1,597	5,299	1,750	1,903	2,078	2,246	7,978	9,174
Excess amount of participation in research and development from third party	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating income	(1,569)	(5,379)	(2,977)	(1,130)	(1,246)	(1,039)	(1,434)	(4,849)	(1,625)	(1,731)	(1,841)	(1,901)	(7,097)	(7,528)
Interest income	0.0	0.2	0.2	-	-	-	4	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	(32)	(2,181)	389	(4,896)	(6,721)	(100)	300	(250)	(263)	(313)	(376)
Gain on extinguishment of debt	-	-	623	-	-	-	-	-	-	-	-	-	-	-
Liquidated damages and other forbearance agreement settlement costs	(824)	-	-	-	-	-	-	-	-	-	-	-	-	-
Income (loss) before taxes	(2,484)	(5,449)	(2,239)	(1,163)	(3,426)	(650)	(6,326)	(11,566)	(1,725)	(1,431)	(2,091)	(2,164)	(7,410)	(7,904)
Income tax expense	0.0	(0)	-	-	-	-	-	-	-	-	-	-	-	-
Preferred stock dividend	(38)	(38)	(38)	(10)	(10)	(10)	(10)	(38)	(10)	(10)	(10)	(10)	(38)	(38)
Net income	(2,522)	(5,487)	(2,277)	(1,172)	(3,436)	(660)	(6,336)	(11,604)	(1,735)	(1,441)	(2,100)	(2,173)	(7,449)	(7,942)
Dividend in respect of reduction in exercise price of certain Warrants	0.0	0.0	-	-	-	-	-	-	-	-	-	-	-	-
Net income attributable to common shareholders	(\$2,522)	(\$5,487)	(\$2,277)	(\$1,172)	(\$3,436)	(\$660)	(\$6,336)	(\$11,604)	(\$1,735)	(\$1,441)	(\$2,100)	(\$2,173)	(\$7,449)	(\$7,942)
Net Earnings (Losses) Per Share—Basic	(\$0.08)	(\$0.13)	(\$0.20)	(\$0.09)	(\$0.28)	(\$0.05)	(\$0.43)	(\$0.89)	(\$0.12)	(\$0.10)	(\$0.14)	(\$0.14)	(\$0.49)	(\$0.46)
Net Earnings (Losses) Per Share—Diluted	(\$0.08)	(\$0.13)	(\$0.20)	(\$0.09)	(\$0.28)	(\$0.05)	(\$0.43)	(\$0.89)	(\$0.12)	(\$0.10)	(\$0.14)	(\$0.14)	(\$0.49)	(\$0.46)
Shares outstanding—basic	31,178	42,953	11,654	13,202	12,087	14,179	14,716	13,067	14,916	15,116	15,316	15,516	15,216	17,216
Shares outstanding—diluted	31,178	42,953	11,654	13,202	12,087	14,179	14,716	13,067	14,916	15,116	15,316	15,516	15,216	17,216
Margin Analysis (% of Sales/Revenue)														
COGS	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
R&D	86%	386%	353%	988%	1150%	242%	364%	427%	540%	446%	367%	280%	373%	229%
MG&A	254%	735%	902%	2421%	1951%	349%	615%	751%	856%	663%	507%	369%	533%	328%
Operating Income (loss)	-240%	-2025%	-1155%	-3309%	-3001%	-491%	-880%	-1077%	-1297%	-1009%	-775%	-549%	-806%	-457%
Pretax	-380%	-2051%	-869%	-3404%	-8256%	-307%	-3881%	-2569%	-1376%	-834%	-880%	-625%	-842%	-480%
Tax Rate	NA	0%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Net Income	-386%	-2066%	-884%	-3432%	-8279%	-312%	-3887%	-2578%	-1384%	-840%	-884%	-628%	-846%	-482%
Financial Indicator Growth Analysis (YoY%)														
Total Revenue		-59%	-3%	-62%	-48%	285%	383%	75%	271%	-33%	596%	734%	316%	87%
Cost of goods sold		N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
R&D expenses		82%	-11%	31%	233%	155%	93%	111%	101%	60%	71%	63%	71%	15%
Purchased in process research and development		N.A.	-1000%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
G&A		18%	19%	50%	39%	26%	66%	45%	30%	40%	63%	27%	39%	15%
Operating expense		154%	-43%	44%	77%	59%	75%	64%	50%	48%	66%	41%	51%	15%
Operating Incomes (Losses)		243%	-45%	57%	92%	42%	63%	63%	44%	39%	77%	33%	46%	6%
Pretax Income		119%	-45%	111%	663%	-7115%	407%	417%	48%	-58%	222%	-66%	-36%	7%
Net Income		118%	-58%	109%	649%	226630%	404%	409%	48%	-58%	218%	-66%	-36%	7%
EPS - Basic		58%	53%	111%	467%	160082%	384%	354%	31%	-66%	195%	-67%	-45%	-6%
EPS - Diluted		58%	53%	111%	467%	160082%	384%	354%	31%	-66%	195%	-67%	-45%	-6%
Source: Roth Capital Partners Research and Trovagene's SEC filings														
Yale Jen, Ph.D. 646-358-1916														

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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 04/02/13	
			Count	Percent
Buy [B]	183	74.09	82	44.81
Neutral [N]	39	15.79	3	7.69
Sell [S]	2	0.81	1	50.00
Under Review [UR]	22	8.91	11	50.00

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.

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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.

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