ROTH Capital Partners

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Healthcare: Biotechnology

TrovaGene, Inc. | TROV - $5.75 - NASDAQ | *Buy*

Company Update

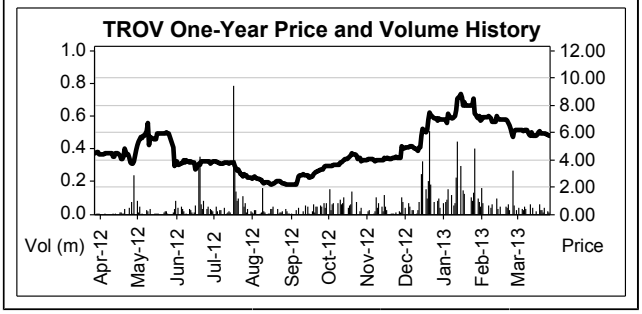
Stock Data	
52-Week Low - High	$1.86 - $8.96
Shares Out. (mil)	14.18
Mkt. Cap.(mil)	$81.5
3-Mo. Avg. Vol.	87,973
12-Mo.Price Target	$11.00
Cash (mil)	$10.8
Tot. Debt (mil)	$0.0

EPS $

Yr Jan	—2011—	—2012E—	—2013E—
		Curr	Curr
1Q	(0.04)A	(0.09)A	(0.10)E
2Q	(0.05)A	(0.28)A	(0.08)E
3Q	0.00A	(0.05)A	(0.12)E
4Q	(0.09)A	(0.10)E	(0.13)E
YEAR	(0.20)A	(0.50)E	(0.43)E
P/E	NM	NM	NM

Revenue ($ millions)

Yr Jan	—2011—	—2012E—	—2013E—
		Curr	Curr
1Q	0.1A	0.0A	0.1E
2Q	0.1A	0.0A	0.1E
3Q	0.1A	0.2A	0.1E
4Q	0.0A	0.1E	0.1E
YEAR	0.3A	0.4E	0.3E



TROV: HPV Test Launched

Trovagene announced this morning, March 27, the commercial launch of urine (TrNAs)-based HPV-HR (high-risk) assay as a non-invasive molecular test to identify the presence or absence of 15 known high-risk human papillomavirus (HPV) based on strains proprietary DNA sequences test.

Details:

The potential benefit of the HPV-HR DNA test is to improve the adoption and acceptance rate of HPV testing. Although standard Pap smear or liquid cytology sample are the standard tests detecting HPV for women in cervical cancer screening, less than 40 percent of them underwent additional supportive HPV DNA testing. TROV's TrNAs-based HPV-diagnostic test could help women who wish to avoid repeated physical exams, but still need monitoring for their HPV status.

Implications:

As scheduled, TrovaGene launched the TrNAs-based HPV-HR DNA test diagnostic test as the first major product in 1Q13. The test targets the E1 region of HPV as a screening test for high-risk HPV carriers. E1 is a viral protein, with function as a DNA helicase/ATPase, which is involved in initiating viral DNA replication. The company has conducted a laboratory study, comparing its TrNAs-based HPV diagnostic test with commercially available hc2 developed by Qiagen; and demonstrated that TrovaGene's TrNAs-based HPV diagnostic test has performed better than the competitor. For sensitivity of the accuracy for identifying high risk PV carriers, the urine-based test was 93% vs. 78% for the hc2 test. The specificity was 96% and 86% for the urine-based test and hc2 test, respectively. For 2013, we anticipate modest revenue contribution by the HPV-HR DNA test as the product is only in its early phase of commercialization. Further, the company has forged several collaborations with ex-U.S. partners to validate its TrNAs-based HPV diagnostic.test; which include the PIO XII Foundation of Barretos Cancer Hospital in Brazil, and Strand Life Sciences Pvt Ltd., of Bangalore, India.

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: $6.08 at 11:14am ET 3/27/2013

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 $10, 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.

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

			IB Serv./Past 12 Mos. as of 03/27/13	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**183**	**74.09**	**82**	**44.81**
Neutral [N]	**41**	**16.60**	**5**	**12.20**
Sell [S]	**1**	**0.40**	**0**	**0**
Under Review [UR]	**22**	**8.91**	**11**	**50.00**

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.

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