Zacks Small-Cap Research

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Atossa Genetics (ATOS-NASDAQ)

ATOS: Significant revenue growth from Pharmacogenomics testing in 1Q15, which convinces us revenue growth will accelerate in the coming quarters– Buy

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	12/16/2014
Current Price (05/13/15)	$1.42
Twelve- Month Target Price	**$9.50**

OUTLOOK

Atossa is a pure play breast health company with a focused growth strategy. The Company has three products/tests on the market now.

The company just reported significant revenue growth for 1Q15, which convinces us that revenue growth will accelerate in the coming quarters. We see total revenue growing at 126% CAGR from 2014 to 2020, with the Company turning profitable in 2018 with EPS of $0.05. We see EPS grow to $0.63 in 2020.

We think downside risk is low while upside potential is high at this time. We rate Atossa shares Buy.

SUMMARY DATA

52-Week High	**$2.51**
52-Week Low	**$0.82**
One-Year Return (%)	**10.40**
Beta	**1.55**
Average Daily Volume (sh)	**706,161**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$47**
Short Interest Ratio (days)	**0.68**
Institutional Ownership (%)	**3**
Insider Ownership (%)	**22**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A**
Type of Stock	**N/A**
Industry	**Med Instruments**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	0.02 A	0.01 A	0.00 A	0.49 A	0.53 A
2015	1.87 A	2.05 E	2.25 E	2.60 E	8.77 E
2016					13.50 E
2017					22.00 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.10 A	-$0.13 A	-$0.13 A	-$0.15 A	-$0.51 A
2015	-$0.13 A	-$0.12 E	-$0.11 E	-$0.11 E	-$0.47 E
2016					-$0.34 E
2017					-$0.16 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

- ***Atossa reports significant revenue growth for 2Q15;***
- ***Revenue growth will accelerate in the rest of 2015 and beyond;***
- ***Atossa Shares are undervalued;***

Atossa Reports Significant Revenue Growth for 1Q15

Total revenue for 1Q15 was $1.9 million, mainly from pharmacogenomics testing, compared to $24,124 for 1Q14 from additional cash collections on NAF cytology tests.

Total revenue also blew out our estimate of $1.0 million for the 1Q15.

Total cost of revenue for 1Q15 was $1.2 million, which derived mainly from pharmacogenomics testing services, compared to $0 for the same period in 2014.

Gross profit for 1Q15 was $665,314, compared to $24,124 gross profit in the same period in 2014.

SG&A expenses for 1Q15 were $3.2 million, companied to $2.0 million for 1Q14.

R&D expenses for 1Q15 were $0.8 million, compared to $0.4 million for 1Q14.

Total operating expenses for 1Q15 were $3.9 million, compared to $2.4 million for 1Q14.

As of March 31, 2015, Atossa held $9.7 million in cash and cash equivalents.

We are impressed with the significant revenue growth from pharmacogenomics testing in the first quarter of 2015. It's even more impressive when we consider that the company achieved this in such a short period of time since the test is launched in late 2014.

Revenue Growth Will Accelerate in the Coming Quarters

Significant revenue growth in 1Q15, especially revenue from pharmacogenomics testing, convinces us that revenue growth will accelerate in the rest of 2015 and beyond.

Atossa has three revenue resources in 2015: pharmacogenomics (PG) testing services, FullCYTE Breast Aspirator sales in the US, and ForeCYTE Breast Aspirator sales in the EU.

The PG testing will generate decent revenue for Atossa in 2015

Pharmacogenomics testing is a subgroup of molecular testing. PG test has become an emerging market with great potential for growth over the next 10 years. Pharmacogenomics involves testing an individual's genetic make-up to determine which drug regimen will best benefit his or her condition.

The PG test was launched in late October 2014 and Atossa performed 527 tests in 2014, which generated revenue of $525,954. In the first quarter of 2015, revenue from PG testing increased to $1.9 million, which is significant in our view.

Current capacity at Atossa's subsidiary, the National Reference Laboratory for Breast Health (NRLBH), can process approximately 5,000 pharmacogenetics tests per month and can increase capacity by hiring additional employees and adding additional equipment to its facility.

In order to accelerate the growth of the PG test, Atossa has retained **BioVentive Inc**. as its sales and marketing partner for the pharmacogenetics tests in the US. Going forward, BioVentive's experienced sales and marketing team of over 85 women's health sales representatives will greatly raise the visibility of the PG tests for Atossa.

Atossa plans to utilize its **third-party reimbursement** firms, FedMed, MultiPlan, Xifin and HealthSmart, to maximize the amount and speed of collections and help ensure that insurance companies that are members of these organizations pay for this test for their covered patients.

The PG testing at Atossa already has gained traction since its launch in late October 2014 and it's our belief that the PG testing will grow strongly in fiscal 2015. With the help of BioVentive, Atossa can maximize the revenue and profitability of the pharmacogenetics testing to help finance the company's broader business. Revenue from the pharmacogenomics testing should add substantially to the company's top and bottom line and help finance its therapeutic development and device business in a **non-dilutive** manner.

The FullCYTE Breast Aspirator Launched in the US

In late March, 2015, Atossa launched the **FullCYTE Breast Aspirator** in the United States. This is in line with our expectations. As we discussed in our previous reports, the company has shifted its focus to FullCYTE Breast Aspirator after its voluntary recall of the ForeCYTE Breast Aspirator in 2013.

Background

In October 2013 Atossa initiated a voluntary recall of the ForeCYTE Breast Health Test and Mammary Aspirate Specimen Cytology Test (MASCT) device from the US market. This was in response to concerns the FDA had made that Atossa had made changes in the device that required submission of a new 510(k) Pre-Market Notification.

In December 2013 Atossa submitted a new 510(k) for the ForeCYTE device but in September 2014 the FDA determined that it did not meet the criteria for substantial equivalence. Atossa intends to request a pre-submission meeting with the FDA to reach agreement on the new clinical studies FDA is seeking and then intends to perform those studies and submit a new 510(k) notification for the ForeCYTE Breast Aspirator to the FDA.

Focus Shifted to FullCYTE Test in the US

With the delay of ForeCYTE breast aspirator re-launch in the US market, Atossa plans to now commercialize in the US an alternative breast aspirator, called the **FullCYTE Breast Aspirator**. The FullCYTE Breast Aspirator is an FDA-cleared device that was acquired by Atossa in 2012 and is a subset of Atossa's FullCYTE Microcatheter which Atossa has been preparing for commercialization over the past 12 months. Atossa will now prioritize the commercial launch of the FullCYTE Breast Aspirator in the US market, which serves as the **second revenue source** for Atossa in 2015 and beyond.

The FullCYTE Breast Aspirator is designed to collect a nipple aspirate specimen for cytological testing. .

The FullCYTE **Microcatheter** involves collecting **ductal lavage samples** from each of the five to seven individual breast milk ducts using the Company's patented and FDA-cleared **Mammary Ductal Microcatheter System** and analyzing the samples by cytological examination.

The aspirator device is comprised of a rigid polycarbonate cup which is placed around the breast nipple. The polycarbonate cup is attached to a user supplied standard syringe, which is used to pull a gentle vacuum to express breast ductal fluid. This fluid can be placed directly into a non-gyn liquid-based cytology fixative for transport to a pathology laboratory. The FullCYTE Breast Aspirator device is intended for single patient use only.

FullCYTE was acquired in April 2012 from **Hologic, Inc.** Atossa paid an up-front fee and is obliged to pay royalties between 2% and 6% on aggregate net sales in the countries with issued patents.

Two Deals will Accelerate FullCYTE Sales Growth

We are very pleased to see the scheduled launch of the FullCYTE device in the US and believe this product will generate significant top line growth for the company in the coming quarters.

In Feb, 2015, Atossa announced two important deals with the two large, prestigious diagnostic companies in the US.

The deal with **Thermo Fisher Scientific** was announced in early Feb and the deal with **Henry Schein Medical** was announced in late Feb.

While the agreement with Thermo allows for Thermo to distribute FullCYTE Breast Aspirator in a **hospital setting** including breast clinics and women's health centers, the agreement with Henry allows for the company to distribute FullCYTE Breast Aspirator in OB/GYNs offices and smaller healthcare facilities.

Access to both the hospital market and smaller healthcare facilities is a critical part of Atossa's launch strategy for the FullCYTE Breast Aspirator in the US.

The two deals give us confidence that launch is likely to be successful and initial sales ramp for FullCYTE Breast Aspirator may be better than we thought before.

The ForeCYTE Breast Aspirator Launched in the EU

In early March, 2015, Atossa launched the ForeCYTE Breast Aspirator and Collection Kit within the European Union (EU). The initial focus is on the Netherlands, Germany, Switzerland, and the United Kingdom.

The ForeCYTE Breast Aspirator device is a reusable, hand-held pump device intended for the collection of a small amount of nipple aspirate fluid (NAF) from a woman's breast for cytological testing. Atossa received **CE Mark** from the European Medical Device Directive (MDD) for its **ForeCYTE Breast Aspirator** in October 2014, which allows for Atossa to distribute the device in the European Union and its member states.

Atossa contracted in early December 2014 with **Rhenus Advanced Services BV** to provide comprehensive logistics services and support in European markets. Rhenus will provide Atossa with logistics services and support throughout European markets from its facilities located in Tilburg, The Netherlands, including warehousing, packaging, shipping, invoicing and collections.

According to management, Atossa has accepted an initial order for ForeCYTE Breast Aspirators and Collection Kits from the University Medical Center Utrecht, The Netherlands.

The ForeCYTE Breast Aspirator will serve as **the third revenue source** for Atossa in 2015 and beyond.

Atossa Shares are Undervalued

We maintain our Buy rating for Atossa Genetics and reiterate our 12-month price target of $9.50 per share.

Atossa is an emerging medical diagnostics company with a focus on breast care. The Company currently has three sources for revenue generation: pharmacogenomics testing, FullCYTE breast aspirator in the US and ForeCYTE breast aspirator in the EU.

We think revenue will accelerate in the coming years thanks to its focused marketing strategy and continued new products/services offering. We see total revenue growing at an impressive 126% compound annual growth rate (CAGR) from fiscal 2014 to 2020 according to our financial model. We model that the Company will become profitable in fiscal 2018 with earnings per share (EPS) of $0.05 based on total revenue of $34.0 million. We forecast EPS will grow to $0.63 per share based on revenue of $70 million in fiscal 2020. This is impressive considering the relatively short history of the operations and the small size of the Company.

Based on Atossa's strong fundamentals, we think the Company's shares are undervalued. Currently, Atossa shares are trading at about $1.4 per share which values the Company at $38 million in terms of market cap based on 27 million shares outstanding. This is a deep discount compared to its peers. We think Atossa shares should trade at 38 x P/E multiple which is similar to the biotech industry average P/E ratio. If we use this P/E multiple, coupled with our estimated EPS of $0.63 in 2020, discounted at 20% for five years, we come up with a price target of $9.50 per share.

One wild card for Atossa valuation is that the Company could be an acquisition target for big players. The clinical lab testing industry is quite fragmented currently, and merger & acquisition activity is looming. We all know that big players LabCorp and Quest Diagnostics are increasingly acquiring smaller players in this field. Qiagen NV, a research service company based in Netherland, entered into molecular diagnostics market in 2007 by acquiring Digene Corp. Since then, Qiagen has been quite aggressive in acquisition of other small genetic/molecular testing companies.

With the increased activity in M&A in the industry, Atossa could be an easy target for acquisition. If acquired by big players, share price of Atossa may soar.

We are optimistic about the Company's prospect. With a rapidly growing market worldwide, combined with its unique technology and broad range of product offering, the Company is well positioned to boost its top line and bottom line in the coming years. We think at this time, downside risk for Atossa is relatively low while upside potential is high.

PROJECTED INCOME STATEMENT

					2014A (Dec)	2015E (Dec)					2016E (Dec)	2017E (Dec)	2018E (Dec)	2019E (Dec)	2020E (Dec)
$ in million except per share data	Q1	Q2	Q3	Q4	FYA	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE	FYE	FYE
Laboratory Services	$0.02	$0.01	$0.00	$0.49	$0.53	$1.87	$1.90	$2.00	$2.20	$7.97	$12.00	$18.50	$27.00	$37.00	$55.00
Medical Device sales	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.15	$0.25	$0.40	$0.80	$1.50	$3.50	$7.00	$10.00	$15.00
Total Revenues	**$0.02**	**$0.01**	**$0.00**	**$0.49**	**$0.53**	**$1.87**	**$2.05**	**$2.25**	**$2.60**	**$8.77**	**$13.50**	**$22.00**	**$34.00**	**$47.00**	**$70.00**
YOY Growth	-86.8%	-97.0%	-95.5%	934.7%	-16.9%	7665.2%	20659.5%	65574.3%	432.2%	1568.1%	53.9%	63.0%	54.5%	38.2%	48.9%
CoGS	0.00	0.00	0.00	0.34	0.34	1.21	1.20	1.25	1.35	5.01	5.50	7.00	9.50	10.20	15.00
Gross Income	**$0.02**	**$0.01**	**$0.00**	**$0.15**	**$0.19**	**$0.67**	**$0.85**	**$1.00**	**$1.25**	**$3.77**	**$8.00**	**$15.00**	**$24.50**	**$36.80**	**$55.00**
Gross Margin	100.0%	100.0%	100.0%	30.3%	35.2%	35.5%	41.5%	44.4%	48.1%	42.9%	59.3%	68.2%	72.1%	78.3%	78.6%
SG&A	$2.01	$2.69	$2.33	$2.87	$9.90	$3.15	$3.20	$3.20	$3.40	$12.95	$14.50	$16.50	$18.00	$18.50	$19.50
% SG&A	8342.5%	27196.4%	67878.3%	588.3%	1881.8%	168.3%	156.1%	142.2%	130.8%	147.6%	107.4%	75.0%	52.9%	39.4%	27.9%
R&D	$0.42	$0.51	$0.92	$0.72	$2.58	$0.80	$0.80	$0.85	$0.90	$3.35	$3.50	$4.00	$4.50	$5.00	$6.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($2.4)**	**($3.2)**	**($3.2)**	**($3.4)**	**($12.3)**	**($3.3)**	**($3.2)**	**($3.1)**	**($3.1)**	**($12.5)**	**($10.0)**	**($5.5)**	**$2.0**	**$13.3**	**$29.5**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-25.00%	5.88%	28.30%	42.14%
Other Net	$0.0	$0.0	$0.0	($2.4)	($2.4)	($0.1)	$0.0	$0.0	$0.0	($0.1)	($0.1)	($0.1)	($0.1)	($0.1)	($0.1)
Pre-Tax Income	**($2.4)**	**($3.2)**	**($3.2)**	**($5.8)**	**($14.7)**	**($3.3)**	**($3.2)**	**($3.1)**	**($3.1)**	**($12.6)**	**($10.1)**	**($5.6)**	**$1.9**	**$13.2**	**$29.4**
Income taxes(benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($2.4)**	**($3.2)**	**($3.2)**	**($5.8)**	**($14.7)**	**($3.3)**	**($3.2)**	**($3.1)**	**($3.1)**	**($12.6)**	**($10.1)**	**($5.6)**	**$1.9**	**$13.2**	**$29.4**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-134.9%	582.5%	122.4%
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-			
Diluted Shares Out	24.4	24.4	24.5	22.8	24.0	24.9	27.0	27.5	28.0	26.9	30.0	35.0	40.0	45.0	50.0
Reported EPS	**($0.10)**	**($0.13)**	**($0.13)**	**($0.26)**	**($0.61)**	**($0.13)**	**($0.12)**	**($0.11)**	**($0.11)**	**($0.47)**	**($0.34)**	**($0.16)**	**$0.05**	**$0.29**	**$0.59**
One time charge	*$0.00*	*$0.00*	*$0.00*	*$2.37*	*$2.37*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$1.00*	*$2.00*
Non GAAP Net Income	**($2.4)**	**($3.2)**	**($3.2)**	**($3.4)**	**($12.3)**	**($3.3)**	**($3.2)**	**($3.1)**	**($3.1)**	**($12.6)**	**($10.1)**	**($5.6)**	**$1.9**	**$14.2**	**$31.4**
Non GAAP EPS	**($0.10)**	**($0.13)**	**($0.13)**	**($0.15)**	**($0.51)**	**($0.13)**	**($0.12)**	**($0.11)**	**($0.11)**	**($0.47)**	**($0.34)**	**($0.16)**	**$0.05**	**$0.32**	**$0.63**

Source: Company filing and Zacks estimates

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