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Zacks Small-Cap Research

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CombiMatrix Corporation (CBMX-NASDAQ)

CBMX: Several Recent Events Could Catalyze Additional Growth

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	07/07/2014
Current Price (04/20/16)	$3.49
Target Price	**$20.00**

OUTLOOK

Molecular diagnostics company CBMX has offered a variety of genetic tests for various indications but just recently shifted the majority of its focus for growth on chromosomal microarray analysis (CMA) in the prenatal setting. A relatively novel genetic testing method, CMA has gained more attention due to two recent NEJM-published studies and a recommendation from an influential trade association supporting its use in prenatal analysis. CBMX is positioning itself to exploit an industry shift away from the current standard testing method towards CMA by expanding distribution, beefing up their sales force, launching new products, entering into key partnerships and leveraging competitive advantages. Recent favorable insurance coverage decisions, new product launch and additional positive recommendations from industry associations could fuel additional growth.

SUMMARY DATA

52-Week High	**$28.49**
52-Week Low	**$3.18**
One-Year Return (%)	**-88.05**
Beta	**0.27**
Average Daily Volume (sh)	**35,669**
Shares Outstanding (mil)	**1**
Market Capitalization ($mil)	**$4**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**22.5**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Value**
Industry	**Instru-Scientfc**

ZACKS ESTIMATES

Revenue
(in 000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	2,329 A	2,549 A	2,526 A	2,684 A	10,088 A
2016	2,751 E	2,984 E	2,987 E	3,087 E	11,808 E
2017					14,025 E
2018					16,465 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$2.24 A	-$1.91 A	-$2.00 A	-$1.82 A	-$7.95 A
2016	-$1.92 E	-$1.76 E	-$1.61 E	-$1.46 E	-$6.68 E
2017					-$2.50 E
2018					-$1.88 E

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

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WHAT'S NEW….

Several Recent Events Could Catalyze Additional Revenue Growth Including; Updated Prenatal Testing Guidelines, Beneficial Revisions to Insurers' Coverage Policies and Launch of New IVF Test…

Several events over the last few weeks have the potential to make a meaningful contribution to steepening and elongating CBMX's revenue curve, two of which relate to additional recognition of the benefits of prenatal and miscarriage CMA testing. Another recent significant event being CMBX's launch of a new IVF-related test.

Perhaps the most significant recent event in terms of potential positive effect for CBMX were the updates to the Practice Bulletins of the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM). Practice Bulletins summarize current clinical evidence to provide up-to-date information for the clinical management of obstetrics and gynecology and are used by clinicians to guide diagnosis and treatment decisions.

ACOG / SMFM Updated Recommendations Provide Further Support for Use of CMA
On March 1, 2016 ACOG and SMFM released two Practice Bulletins; *Prenatal Diagnostic Testing for Genetic Disorders*, which replaces a December 2007 Bulletin, and *Screening for Fetal Aneuploidy*, which replaces a January 2007 Bulletin. The updated information provides greater clarity on the potential risks of chorionic villous sampling (CVS) / amniocentesis and updated recommendations for the use of CMA as well as for confirmatory testing following a positive result from a screening test (such as NIPT).

Amniocentesis and CVS sampling involves inserting a needle or thin catheter into the uterus where a sample of amniotic fluid or placental tissue is taken. These samples are then analyzed for chromosomal abnormalities using techniques such as CMA and karyotyping. While sampling directly from amniotic fluid and placental tissue provides greater and more accurate information than less invasive techniques such as NIPT which analyze cell-free fetal DNA (cfDNA) from the mother's blood, the invasive nature comes with risks - the most significant of which is pregnancy loss (i.e. miscarriage). Given the risk of miscarriage, some clinicians have recommended that amniocentesis or CVS only be considered for women older than 35 years of age or are otherwise at higher risk of having a baby with aneuploidy.

While there has not been a consensus from national governing bodies in terms of the degree of risk of pregnancy loss due to amniocentesis and CVS, it has been believed to be as high as 1.5% or more. However, a recent meta-analysis (*Procedure-related risk of miscarriage following amniocentesis and CVS: a systematic review and meta-analysis)* by R. Akolekar et al. published in the journal Ultrasound in Obstetrics and Gynecology which looked at studies aggregating a total of almost 43k women which underwent amniocentesis and almost 9k who underwent CVS found the risk of pregnancy loss was much lower than previously believed. The meta-analysis found that "the added procedure-related risks of miscarriage following amniocentesis and CVS are in the region of 0.1% and 0.2%, respectively". The authors also note that, "It may be that these risks are unrelated to the invasive procedure, but instead may reflect the pregnancy characteristics of the women undergoing invasive testing. It is essential that pregnant women should be provided with accurate estimates of procedure-related risks associated with invasive testing to allow them to make appropriate choices rather than provide them with exaggerated risks based on historical data, which may unnecessarily deter women from testing." [1]

This study and the lowered risk of amnio/CVS-related miscarriage are cited in the updated ACOG and SMFM Practice Bulletins as is a recommendation that all pregnant women be offered prenatal assessment for aneuploidy by screening or diagnostic testing regardless of age. Given that risk of miscarriage has been the most significant concern associated with amnio and CVS procedures, findings by this study and subsequent recognition by ACOG and SMFM of substantially less risk than previously believed could result in facilitation of greater use of CMA, including that offered by CBMX. The Bulletins also recommend pre- and post-test counseling be offered to patients – which has been a focus for CBMX in an effort to help drive adoption of CMA as well as to differentiate themselves from competing CMA providers.

And other recommendations in the Practice Bulletins also support the use of CMA as the most definitive technology to identify aneuploidy. The benefits of CMA, as noted in the Bulletins include;

[1] R. Akolekar et al. Procedure-related risk of miscarriage following amniocentesis and chorionic villus sampling: a systematic review and meta-analysis. Ultrasound Obstet Gynecol 2015; 45: 16–26

- "chromosomal microarray analysis can be performed either directly on uncultured tissue or on cultured cells" (while karyotyping requires samples to be cultured)
- "chromosomal aberrations that are smaller than the resolution of conventional karyotype also can result in phenotypic anomalies; these copy number variants can be detected in the fetus using chromosomal microarray analysis"
- "when structural abnormalities are detected by prenatal ultrasound examination, chromosomal microarray will identify clinically significant chromosomal abnormalities in approximately 6% of the fetuses that have a normal karyotype. For this reason, chromosomal microarray analysis should be recommended as the primary test (replacing conventional karyotype) for patients undergoing prenatal diagnosis for the indication of fetal structural abnormality detected by ultrasound examination"
- "chromosomal microarray analysis has been found to detect a pathogenic (or likely pathogenic) copy number variant in approximately 1.7% of patients with a normal ultrasound examination and a normal karyotype, and it is recommended that a chromosomal microarray analysis be made available to any patient choosing to undergo invasive diagnostic testing"

In regard to cfDNA screening tests, the Bulletins note their potential for false-positive and false-negative results (the risk of which has been widely cited in numerous studies) and therefore;

- cfDNA should not be used as a substitute for diagnostic testing (i.e. CMA)
- "all women with a positive cfDNA test result should have a diagnostic procedure [such as CMA] before any irreversible action, such as pregnancy termination, is taken"
- "women whose cfDNA screening test results are not reported, are indeterminate, or are uninterpretable should receive further genetic counseling and be offered comprehensive ultrasound evaluation and diagnostic testing because of an increased risk of aneuploidy"
- women with a positive screening test result for fetal aneuploidy should be offered further detailed counseling and testing"

Insurers Revise Policies to Define CMA as 'Medically Necessary' for Recurrent Pregnancy Loss
During the first quarter of this year six insurers revised their policies to include coverage of recurrent pregnancy testing. This includes major and mid-tier payers. CBMX cited Cigna Health Services, BC/BS of North Carolina, Premera BC/BS and Life Wise of Oregon as revising their medical policies to include CMA as 'medically necessary' for the evaluation of pregnancy loss. 'Medically necessary' essentially means that there is no ambiguity in terms of whether the procedure will be covered. If this trend continues with other insurers revising policies for specific coverage of CMA for pregnancy loss, it would almost certainly be a meaningful benefit to CBMX and demand for their miscarriage analysis tests.

We also note that spotty or otherwise inconsistent insurance coverage has been somewhat of a headwind and was one of the reasons why CBMX expanded their portfolio to include products such as the CombiPGS IVF test which is cash-pay and unaffected by insurers policy decisions. It was also a reason why CBMX picked their spots geographically – focusing on areas of the country where insurance coverage was more favorable. So anything that improves the third-party payor environment as it relates to CMA and reproductive health has the potential to have a direct and positive benefit on CBMX and demand for their products.

CombiPGD Looks to Build On Success of CombiPGS
CBMX launched CombiPGS (IVF – preimplantation genetic screening test) last year in order to grow and diversify revenue and not be so beholden to insurers' coverage decisions. By all measures the test has been a success, growing from 30 tests processed in the quarter of launch (Q2) to 127 in Q3 and 202 in Q4. CombiPGS contributed $371k in revenue in the second half of 2015, more than 7% of total diagnostic services revenue in that period. And that's just after only a very brief period in marketing the product. We expect PGS to be a much more significant revenue catalyst in 2016.

Management is clearly looking to build on the success of PGS with the introduction of CombiPGD – launch of which they announced earlier this month. Both PGS and PGD test embryos prior to IVF implantation in order to minimize chance of selecting an embryo with a genetic disorder and increase the chance of a successful pregnancy. While PGS is a screen – testing for aneuploidy (i.e. abnormal number of chromosomes), which is the most common cause of genetic disorders, PGD is a diagnostic - testing the embryo for specific genetic disorders or genetic abnormalities based on the genetic status of the parents (which may be carriers of certain genetic abnormalities). Similar to PGS, CBMX will offer customers the opportunity to purchase PGD on a per-embryo or multicycle basis. If PGD receives a similarly warm welcome as PGS has, it will be needle-mover for CBMX – this will be something to keep on eye on.

Scientific Advisory Board Formed And Tasked With Facilitating Growth Opportunities

To help implement CBMX's growth plans, including bringing additional products to market, expand adoption and entry into new markets and leverage new opportunities the company brought on a scientific advisory board consisting of five physicians/academics, all with significant experience in the reproductive health segment.

FINANCIAL MODEL

CombiMatrix Corporation

	2015 A	Q1E	Q2E	Q3E	Q4E	2016 E	2017 E	2018 E	2019 E
Diagnostic Svcs	$9,941.0	$2,711.4	$2,943.5	$2,946.4	$3,046.8	$11,648.1	$13,865.0	$16,305.0	$19,799.8
YOY Growth	*25.95%*	*18.56%*	*16.6%*	*18.8%*	*15.0%*	*17.17%*	*19.03%*	*17.60%*	*21.43%*
Royalties	$147.0	$40.0	$40.0	$40.0	$40.0	$160.0	$160.0	$160.0	$160.0
YOY Growth	*-1.34%*	*-4.76%*	*60.0%*	*-11.1%*	*14.3%*	*8.8%*	*0.0%*	*0.0%*	*0.0%*
Total Revenues	$10,088.0	$2,751.4	$2,983.5	$2,986.4	$3,086.8	$11,808.1	$14,025.0	$16,465.0	$19,959.8
YOY Growth	*25.4%*	*18.1%*	*17.0%*	*18.2%*	*15.0%*	*17.1%*	*18.8%*	*17.4%*	*21.2%*
Cost of Services	$5,444.0	$1,461.5	$1,627.8	$1,650.0	$1,620.9	$6,360.1	$7,154.3	$8,201.4	$9,345.5
Gross Income	$4,644.0	$1,290.0	$1,355.7	$1,336.4	$1,465.9	$5,448.0	$6,870.7	$8,263.6	$10,614.3
Services Margin	*46.0%*	*46.1%*	*44.7%*	*44.0%*	*46.8%*	*46.2%*	*48.4%*	*49.7%*	*52.8%*
R&D	$466.0	$162.0	$112.0	$140.0	$125.0	$539.0	$628.0	$667.0	$738.0
% R&D	*4.6%*	*5.9%*	*3.8%*	*4.7%*	*4.0%*	*4.6%*	*4.5%*	*4.1%*	*3.7%*
SG&A	$10,519.0	$2,735.2	$2,813.0	$2,845.5	$2,910.2	$11,303.9	$12,077.2	$12,812.6	$14,510.8
% SG&A	*104.3%*	*99.4%*	*94.3%*	*95.3%*	*94.3%*	*95.7%*	*86.1%*	*77.8%*	*72.7%*
Patent amort. & royalties	$100.0	$25.0	$25.0	$25.0	$25.0	$100.0	$110.0	$110.0	$0.0
Goodwill impairment	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($6,441.0)	($1,632.2)	($1,594.3)	($1,674.1)	($1,594.3)	($6,494.9)	($5,944.6)	($5,326.0)	($4,634.5)
Operating Margin	*-63.8%*	*-59.3%*	*-53.4%*	*-56.1%*	*-51.6%*	*-55.0%*	*-42.4%*	*-32.3%*	*-23.2%*
Total Other income	($63.0)	($15.0)	($15.0)	($15.0)	($15.0)	($60.0)	($125.0)	($150.0)	($150.0)
Pre-Tax Income	($6,601.0)	($1,647.2)	($1,609.3)	($1,689.1)	($1,609.3)	($6,554.9)	($6,069.6)	($5,476.0)	($4,784.5)
Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Preferred Dividends	$0	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	($6,601.0)	($1,647.2)	($1,609.3)	($1,689.1)	($1,609.3)	($6,554.9)	($6,069.6)	($5,476.0)	($4,784.5)
YOY Growth	*-24.2%*	*-6.7%*	*-0.2%*	*0.1%*	*4.7%*	*-0.7%*	*-7.4%*	*-9.8%*	*-12.6%*
Net Margin	*-65.4%*	*-59.9%*	*-53.9%*	*-56.6%*	*-52.1%*	*-55.5%*	*-43.3%*	*-33.3%*	*-24.0%*
EPS	($7.95)	($1.92)	($1.76)	($1.61)	($1.46)	($6.68)	($2.50)	($1.88)	($1.52)
YOY Growth	*-32.9%*	*-14.5%*	*-7.8%*	*-19.4%*	*-19.5%*	*-15.9%*	*-62.6%*	*-24.9%*	*-19.0%*
Diluted Shares O/S	831	858	915	1,050	1,100	981	2,430	2,920	3,150

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Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 28.7%, Hold/Neutral- 49.5%, Sell/Underperform – 14.9%. Data is as of midnight on the business day immediately prior to this publication.