Zacks Small-Cap Research

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CombiMatrix Corporation (CBMX-NASDAQ)

CBMX: Largest Study To-Date Reinforces Superiority of CMA

We use a 10-year DCF model to value CBMX. We model revenue to grow from $10.1M in 2015 to $20M in 2019. Other key inputs into our DCF include a 9% discount rate and 2% terminal growth rate. Based on our DCF model, CBMX is valued at approximately $16/share.

Current Price (06/28/16)	$2.65
Valuation	**$16.00**

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. Largest study to-date, published in June 2016 further reinforces support of CMA over karyotyping. 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	**$26.40**
52-Week Low	**$2.62**
One-Year Return (%)	**-88.73**
Beta	**0.32**
Average Daily Volume (sh)	**226,716**
Shares Outstanding (mil)	**1**
Market Capitalization ($mil)	**$4**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**33**
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	2329 A	2549 A	2526 A	2684 A	10088 A
2016	2970 A	2927 E	3070 E	3190 E	12159 E
2017					14519 E
2018					16944 E

EPS

	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	-$3.63 A	-$1.39 E	-$1.21 E	-$1.15 E	-$5.33 E
2017					-$2.05 E
2018					-$1.52 E

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

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Largest Study To-Date Further Reinforces CMA Superiority Over Karyotyping
While several studies over the last number of years, including the widely cited Reddy et al and Wapner et al studies which have positively influenced reimbursement policy, have all indicated that chromosomal microarray analysis (CMA) is the preferred genetic testing modality versus karyotyping due to the former's proven greater accuracy, that it provides more substantive clinical information and is able to be used on fresh as well as preserved (i.e. FFPE) tissue, none was as large as CBMX's recently published study which included over 8k samples.

The study, published (in advance online) in Genetics Medicine on June 23, 2016 and titled *Comprehensive genetic analysis of pregnancy loss by chromosomal microarrays: outcomes, benefits, and challenges*, further reinforced the superiority of CMA over karyotyping and could be another catalyst to driving demand for CBMX's CMA testing products and services.

Lead by Dr. Trilochan Sahoo, CBMX's VP of Clinical Affairs and Director of Cytogenetics, investigators collected 8,298 tissue samples - most of which were due to recurrent pregnancy loss but also due to fetal demise, stillbirth, neonatal death and certain fetal structural abnormalities. Of the 8,118 samples that were eventually tested (most were tested with CBMX's SNP-based microarray) ;

- 6,196 (76%) were fresh POC samples
- 1,823 (23%) were FFPE samples
- 99 (1%) were a variety including amniotic fluid, cultured cells, DNA and cord blood

Of the 8,118 samples that were tested by CMA;

- 91% (7,396) were successfully processed (the most common reason for test failure was insufficient or no fetal tissue) which included;
  - 92% (5,725 / 6,196) of the fresh POC samples
  - 86% (1,575 / 1,823) of the FFPE samples
  - 97% (96 / 99) of other non-FFPE samples

This 91% success rate further supports the use of CMA and compares to a historical rate (as established in various other clinical trials) as low as 60% to 80% with karyotyping, which has been considered the standard pregnancy loss testing methodology. The relatively low success rate of karyotyping relates to culture failure and significant false-positive rates due to maternal cell contamination (MCC).

Culture failure (i.e. tissue dies) occurs in as many as 20% - 55% of products of conception, making karyotyping much less reliable than CMA given that the latter analyzes DNA extracted directly from tissue, can analyze non-living tissue and usually does not require culturing. MCC relates to cells of the mother cross-contaminating the fetal culture which can produce erroneous results with karyotyping. False-negative results due to MCC have been reported as high as 50% or more. As CMA can detect and differentiate the maternal DNA, MCC is much less likely to cause erroneous results.

Other well-documented drawbacks of karyotyping is the relatively long turnaround time for performing the test and that it can not be used with tissue that has been preserved with formalin-fixed, paraffin-embedded (FFPE).

Results:
As noted, 91%)7,396) of samples were successfully processed. Abnormal results were found in 54% (3,975) and normal results in 44% (3,272) of all samples. 2% (149) of all samples showed variants of unknown significance.

Of the 5,821 fresh and non-FFPE samples, 45% had an abnormal result. Of the 1,575 FFPE samples (which karyotyping would be unable to process), 49% were abnormal.

Results	Fresh tissue/ non-FFPE (*N* = 5,821)	FFPE (*N* = 1,575)
Normal/variants of uncertain significance	2,611 (44.9%)	810 (51.3%)
Abnormal	3,210 (55.1%)	765 (48.7%)

SOURCE: T. Sahoo, et al. Genetics in Medicine (2016) doi:10.1038/gim.2016.69

Perhaps particularly noteworthy is that the investigators found approximately 94% of results which had abnormalities would be expected to have been cause for pregnancy loss or fetal demise. In addition, the SNP-array was able to provide additional information compared to traditional testing methods including whole-genome uniparental isodisomy or molar pregnancy. The investigators surmised that approximately 5.6% of cases with reportable findings would not have been identifiable with karyotype or FISH analysis. And when taking into account the 21% of reportable samples which were FFPE and that MCC could provide erroneous results with those traditional testing methods, the authors note that**, "it is reasonable to suggest that the outcomes from microarray analysis are significantly superior to those of conventional cytogenetics".**

Abnormality	Number of abnormal cases (3,975)[a]	Frequency of abnormality (among abnormal cases)	Overall frequency (7,396 cases)
Single trisomy[b]	2,516	63.3%	34%
Multiple trisomy[b]	129	3.2%	1.7%
Monosomy X[b]	446	11.2%	6%
Monosomy X + trisomy[b]	33	0.8%	0.4%
Monosomy (autosome)[b]	26	0.6%	0.35%
Triploidy[b]	468	11.8%	6.3%
Hypertriploidy or hypotriploidy[b]	86	2.2%	1.2%
Whole-genome uniparental isodisomy (complete mole)[b]	37	1%	0.5%
Tetraploidy[b]	2	0.04%	0.02%
Deletions/duplications[c]	127	3.2%	1.7%
Terminal deletion + duplication (suggestive of unbalanced translocation)[c]	54	1.3%	0.7%
Sex chromosome abnormality	27	0.7%	0.36%
Uniparental isodisomy (whole-chromosome or segmental; nine cases with a trisomy)	18	0.45%	0.24%
Multiple regions of homozygosity (two cases with a trisomy)	6	0.15%	0.08%
Variants of uncertain significance	149		2%

[a]Excludes 149 cases with variants of uncertain significance. [b]Causative of pregnancy loss. [c]Uncertain whether causative of pregnancy loss (105 of these 181 cases with involved segment >10 Mb were potentially causative).

SOURCE: T. Sahoo, et al. Genetics in Medicine (2016) doi:10.1038/gim.2016.69

FINANCIAL MODEL

CombiMatrix Corporation

	2015 A	Q1A	Q2E	Q3E	Q4E	2016 E	2017 E	2018 E	2019 E
Diagnostic Svcs	$9,941.0	$2,930.0	$2,884.7	$3,028.3	$3,148.2	$11,991.2	$14,349.2	$16,772.0	$19,800.9
YOY Growth	*25.95%*	*28.12%*	*14.3%*	*22.1%*	*18.8%*	*20.62%*	*19.66%*	*16.88%*	*18.06%*
Royalties	$147.0	$42.0	$42.0	$42.0	$42.0	$168.0	$170.0	$172.0	$176.0
YOY Growth	*-1.34%*	*0.00%*	*68.0%*	*-6.7%*	*20.0%*	*14.3%*	*1.2%*	*1.2%*	*2.3%*
Total Revenues	$10,088.0	$2,972.0	$2,926.7	$3,070.3	$3,190.2	$12,159.2	$14,519.2	$16,944.0	$19,976.9
YOY Growth	*25.4%*	*27.6%*	*14.8%*	*21.5%*	*18.9%*	*20.5%*	*19.4%*	*16.7%*	*17.9%*
Cost of Services	$5,444.0	$1,419.0	$1,543.3	$1,592.9	$1,646.5	$6,201.7	$6,988.1	$7,949.9	$8,969.8
Gross Income	$4,644.0	$1,553.0	$1,383.4	$1,477.4	$1,543.7	$5,957.5	$7,531.1	$8,994.1	$11,007.1
Services Margin	*46.0%*	*51.6%*	*46.5%*	*47.4%*	*47.7%*	*49.0%*	*51.3%*	*52.6%*	*54.7%*
R&D	$466.0	$143.0	$122.0	$140.0	$125.0	$530.0	$628.0	$667.0	$738.0
% R&D	*4.6%*	*4.8%*	*4.2%*	*4.6%*	*3.9%*	*4.4%*	*4.3%*	*3.9%*	*3.7%*
SG&A	$10,519.0	$2,862.0	$2,874.3	$2,927.0	$2,995.6	$11,658.8	$12,299.6	$13,016.2	$14,383.4
% SG&A	*104.3%*	*96.3%*	*98.2%*	*95.3%*	*93.9%*	*95.9%*	*84.7%*	*76.8%*	*72.0%*
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)	($1,477.0)	($1,637.9)	($1,614.6)	($1,601.9)	($6,331.4)	($5,506.5)	($4,799.1)	($4,114.3)
Operating Margin	*-63.8%*	*-49.7%*	*-56.0%*	*-52.6%*	*-50.2%*	*-52.1%*	*-37.9%*	*-28.3%*	*-20.6%*
Total Other income	($63.0)	($14.0)	($15.0)	($15.0)	($15.0)	($59.0)	($125.0)	($150.0)	($150.0)
Pre-Tax Income	($6,601.0)	($1,491.0)	($1,652.9)	($1,629.6)	($1,616.9)	($6,390.4)	($5,631.5)	($4,949.1)	($4,264.3)
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	$890	$1,643	$0	$0	$0	$0	$0	$0	$0
Net Income	($7,491.0)	($3,134.0)	($1,652.9)	($1,629.6)	($1,616.9)	($6,390.4)	($5,631.5)	($4,949.1)	($4,264.3)
YOY Growth	*-14.0%*	*18.0%*	*2.5%*	*-3.4%*	*5.2%*	*-14.7%*	*-11.9%*	*-12.1%*	*-13.8%*
Net Margin	*-74.3%*	*-105.5%*	*-56.5%*	*-53.1%*	*-50.7%*	*-52.6%*	*-38.8%*	*-29.2%*	*-21.3%*
EPS	($9.02)	($3.63)	($1.39)	($1.21)	($1.15)	($5.33)	($2.05)	($1.52)	($1.24)
YOY Growth	*-23.8%*	*7.5%*	*-26.8%*	*-39.5%*	*-36.5%*	*-40.9%*	*-61.6%*	*-25.6%*	*-18.8%*
Diluted Shares O/S	831	864	1,185	1,350	1,400	1,200	2,750	3,250	3,450

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