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Zacks Small-Cap Research

Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

CombiMatrix Cp (CBMX-NASDAQ)

CBMX: Overhyped Risks Provide Attractive Entry Point

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	07/07/2014
Current Price (01/21/15)	$1.53
Target Price	**$3.50**

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, entering into key partnerships and leveraging competitive advantages. Early indications are that this plan is already bearing fruit.

SUMMARY DATA

52-Week High	**$3.65**
52-Week Low	**$1.09**
One-Year Return (%)	**-44.84**
Beta	**0.14**
Average Daily Volume (sh)	**113,089**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$17**
Short Interest Ratio (days)	**4.54**
Institutional Ownership (%)	**4**
Insider Ownership (%)	**2**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**12.8**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2014 Estimate	**N/A**
P/E using 2015 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Blend**
Industry	**Instru-Scientfc**

ZACKS ESTIMATES

Revenue
(in 000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	1,611 A	1,500 A	1,503 A	1,753 A	6,367 A
2014	1,822 A	1,941 A	2,062 A	2,148 E	7,972 E
2015					11,104 E
2016					16,379 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.59 A	-$0.37 A	-$0.30 A	-$1.50 A	-$3.11 A
2014	-$0.18 A	-$0.23 A	-$0.23 A	-$0.21 E	-$0.85 E
2015					-$0.61 E
2016					-$0.34 E

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

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WHAT'S NEW….

Risks Overhyped…

We think CBMX has been dogged by circumstances that we think have been more exaggerated than warranted and which have had the effect of keeping the shares from appreciating beyond what we think is an undeservedly undervalued level. We continue to think fair value is approximately $3.50/share yet the stock has traded well below this level since early 2014 despite significant and consistent improvement in financial results. The recent hyper-risk scare has provided an attractive entry point for investors, although we would expect the share price to appreciate towards our target price as specifics of these recent events and their potential impact (or non-impact) on CBMX becomes more clear and investors begin to again focus on the ever-improving fundamentals of the company.

The most glaring of these overhyped risks, in our opinion, have been an ongoing lawsuit and, more recently, FDA's recent decision to begin oversight of laboratory developed tests. It is clear that the most significant overhang on the stock has been the long outstanding lawsuit first filed by Michael Strathman, a former employee of CombiMatrix, against CombiMatrix (and two other defendants) in early 2011 in the state of California. The suit claimed that the company filed false insurance claims related to a prior lawsuit. While specifics in terms of potential damages/awards are not clear, court documents suggest this could be as much $75 million.

Lawsuit risk greatly diminished with 2nd ruling in CBMX's favor…

The lawsuit was dismissed by the court later in 2011. An appeals court reversed this decision in late 2012 and the case was remanded to the Superior Court of California. Strathman filed an amended complaint and, following an unsuccessful motion by CBMX for the court to rule in their favor without a trial, on January 6, 2015 the Superior Court issued a tentative ruling in favor of CombiMatrix and against all claims of Michael Strathman. The court specifically determined that the defendants had no fraudulent intent.

Mr. Strathman has fifteen business days following the ruling (i.e.- Jan 27th) to file any objections. The court then has about 60 days to consider any objections or to hear any additional arguments before issuing its final ruling. So while it is possible the court may consider any objections that Mr. Strathman may file, we think, given that Mr. Strathman has now lost twice, that any potential adverse outcomes from this lawsuit have now significantly diminished.

LDT oversight more bark than bite…

Another potential overhang on the stock has been FDA's recent guidance on additional regulation of laboratory developed tests (LDTs). FDA has historically had discretion regarding regulation of these tests. But in the summer 2014 FDA issued a guidance document to Congress notifying them that the agency intends to propose risk-based oversight framework for LDTs which are designed, manufactured and used within a single lab. A draft guidance document was issued in October detailing more specifics. This oversight is expected to include premarket review for what the agency will classify as higher-risk tests that compete against already FDA-approved companion diagnostics and a potential phase-in over time of premarket review for other high risk and moderate risk LDTs.

The only requirement so far is for LDT manufacturers to notify FDA that they are currently making and using these tests and to provide information about the tests. The guidance recommends that premarket review begin 12 months after the guidance is finalized for the highest risk LDTs, for it to phase in over four years for the remaining high risk devices and for premarket review to begin five years after the guidance is finalized for moderate risk devices.

Exactly what might be involved in the premarket review still isn't clear. What is clear, however, is that FDA believes many of the LDTs already on the market have been validated by clinical studies and literature and that the agency will use this as part of its review. Per the draft guidance, "FDA emphasizes that it is the Agency's practice to leverage such information from the literature in lieu of requiring additional studies to demonstrate clinical validity. In these cases FDA may still require studies demonstrating device performance (e.g., analytical evaluations) but generally intends to rely on the scientific literature to support clinical validity if appropriate. FDA intends to work with the laboratory community, the healthcare professional community and other stakeholders to determine whether an LDT's clinical validity has already been established in the literature."

And while this premarket review (i.e. – FDA clearance) requirement will likely apply to most LDTs, including CBMX's, we think the financial and operational risk to CBMX is minimal. For one, the premarket review phase-in period could be as long as five years. And secondly, and most important, is that as we have highlighted in our coverage of CBMX, there is significant clinical evidence and published studies demonstrating the performance of the company's tests. We also note that there are over 11,000 LDTs currently commercialized by more than 2,000

labs and we think it is unlikely that FDA will implement an approval process that is so stringent and costly that it could have the effect of potentially decimating this hugely important cog in the medical diagnostics space.

Q3 Financial Results In-Line…

CBMX announced financial results for the third quarter ending September 30th on November 4th. Revenue was in-line with our estimate (which we upwardly revised following the company's 10/7/14 preannouncement) while operating expenses came in slightly better than our numbers. The beat on operating expense is despite this continuing to be artificially high due to significant litigation expense, which was almost $750k in Q3 (although down from almost $900k in Q2).

Importantly the fundamentals of the company remain very strong, with prenatal microarray testing, total microarray testing and non-microarray testing volumes posting 71%, 24% and 84% yoy growth, respectively. In aggregate, the number of total billable tests increased 36% from the same period in 2012 to 1,959. The 925 prenatal microarray tests, 539 non-microarray tests and 1,959 total tests billed in Q3 were all-time records (as was testing revenue).

The impressive performance was not confined just to testing volumes and revenue, however, as CBMX also realized relatively strong pricing in Q3 with price per microarray test coming in at $1,294, up from an average of $1,278 in 2013 and $1,252 through the first six months of 2014. Indications are that pricing may be firming up, from both out-of-pocket payers and third-party reimbursement. This would be a meaningful and positive development as pricing had experienced some moderate softening over the recent past.

Total revenue was $2.06M including $2.01M from diagnostic testing services, compared to our $2.00M and $1.96M respective estimates. Q3 marked the fifth consecutive quarter where testing services revenue set a new all-time record. Testing services revenue increased 37% yoy and 6% sequentially.

	Q3 E	Q3 A
Non-Prenatal Microarray growth rate	-18.0%	-18.0%
Non-Prenatal $ per test	$0.940	$1.059
Non-Prenatal Microarray Revenue	$466	$524
Number of Non-Prenatal tests	495	495
Number of tests		
Total Prenatal Microarray tests	925	925
prenatal as % of total microarray tests	65%	65%
YOY Growth	*71.0%*	*71.0%*
Total Microarray tests	1,420	1,420
microarray % of total tests	80%	72%
YOY Growth	*24.1%*	*24.0%*
Non-microarray tests	363	539
non-microarray % of total tests	20%	28%
YOY Growth	*23.9%*	*84.0%*
Total Billable tests	**1,783**	**1,959**
YOY Growth	*24.0%*	*36.2%*
Revenue per test		
Prenatal nicroarrays	$1.522	$1.419
All microarrays	$1.319	$1.294
Non-microarrays	$0.250	$0.323
Total	**$1.101**	**$1.027**
Total revenue per test		
Prenatal microarrays	$1,408	$1,313
YOY Growth	*66.2%*	*55.0%*
All microarrays	$1,874	$1,837
YOY Growth	*35.7%*	*33.0%*
Non-microarrays	$91	$174
YOY Growth	*3.9%*	*99.2%*
Total	**$1,964**	**$2,011**
YOY Growth	*33.8%*	*37.0%*
Diagnostic Svcs	$1,964.3	$2,011.0
YOY Growth	*33.8%*	*37.0%*
Royalties	$40.0	$51.0
YOY Growth	*14.3%*	*45.7%*
Total Revenues	$2,004.3	$2,062.0
YOY Growth	*33.4%*	*37.2%*

Gross margin continues to benefit from improved test processing efficiencies. Service margin at 43.9% was well-improved from 41.1% in the year-earlier period and up from 43.1% for the full year 2013. Service margin benefitted from lower test processing costs from the company's recent switch to an Illumina platform as well as much higher total revenue per test ($1,027 vs. $1,021 in Q3 2013 and $1,009 in 2013).

Operating expenses were $3.4M, meaningfully better than our $3.8M estimate. Included in operating expense was $746k in litigation-related expense. Excluding litigation-related expenses, operating expense was about $2.7M, flat from Q2. Relative to the year-earlier period, while opex excluding litigation expense was up on an absolute basis (opex was $2.0M in Q3 2013), it fell as a percentage of revenue (129% vs 133%). The latter highlights improvement in operating leverage despite the additional expense related to growth of the sales force and investments made in the company's billing and reimbursement departments over the last few quarters.

As we noted in a prior update, these investments are paying significant dividends via revenue growth, increasing operating leverage, record cash collections, increasing reimbursement and a growing list of managed care contracts. In addition, these investments have facilitated the company's strategic focus on ramping growth of their prenatal microarray platform, which commands the highest revenue per test among the company's offerings and also holds the most potential for outsized long-term growth. Prenatal microarray testing now accounts for 47% of all billable tests (and 65% of total testing revenue), up from 38% (58% of total testing revenue) in Q3 2013 and 36% (57% of total testing revenue) for all of 2013.

Net loss and EPS were $2.5M and ($0.23), compared to our $2.9M and ($0.26) estimates. We have made no meaningful changes to our model following Q3 results. We are maintaining our Outperform rating and $3.50/share price target.

Add'l Study Data Supports CMA's Superiority Over Standard Genetic Testing…

CBMX presented new study data at the American Society of Human Genetics Annual Meeting in October which provides additional support of the superiority of CMA as compared to standard prenatal genetic testing. The study included 3,408 samples from both fresh tissue (n = 2,712) and tissue preserved (n = 564) with formalin and embedded paraffin (FFPE) which were analyzed by three CMA platforms; BAC-aCGH, oglio-aCGH and SNP array. SNP, one of the platforms that CBMX utilizes, demonstrated the highest abnormality detection rate at 53.8%.

CMA analysis provided a successful result in 86.5% (2,345/2,712) of the fresh samples and 87.2% (492/564) of the preserved samples. This relatively high success rate is similar to other studies which have shown CMA provides a successful result between 87% and 98% of the time while karyotyping, the standard products of conception testing method, produces a successful result only about 60% - 70% of the time.

The lower success rate of karyotyping is largely due to the need to culture the cells (which is not required with CMA) for a period prior to analysis, during which time the cells may die. This "culture failure" can occur in as many as 20% - 55% of cases, making karyotyping much less reliable than CMA given that the latter can analyze non-living tissue.

SNAPSHOT

CombiMatrix Corporation (CBMX), founded in 1995 and currently headquartered in Irvine, CA, is involved in the field of molecular diagnostics with a primary focus on prenatal and postnatal genetic testing, miscarriage/stillbirth management and the diagnosis of developmental disorders (and to a lesser extent hematology/oncology genetic testing). The company performs a variety of methods of genetic testing out of its CLIA and CAP-certified lab including chromosomal microarray analysis (CMA).

While the company also offers other types of genetic tests for areas outside of prenatal disorders, including fluorescence in situ hybridization (FISH) for genetic abnormalities associated with cancer and hematological diseases, and traditional karyotyping, CBMX has recently shifted the majority of its focus for growth on CMA in the prenatal setting and simultaneously de-emphasized their oncology/hematology platform. The strategy appears to be paying off, with prenatal microarray testing volumes growing 126% in 2013 and 65% through the first nine months of 2014 and accounting for almost the entire 19% and 26% revenue growth in those respective periods.

CMA looks to have several key advantages to karyotyping, the current standard genetic testing method for prenatal disorders. These include that CMA can identify extremely small chromosomal abnormalities, can be used on non-living tissue (while karyotyping can not), it produces a successful test result more often than karyotyping and also has a faster sampling-to-results turnaround time. CMA has recently gained attention as a result of National Institute of Health (NIH) studies published in late 2012 in the New England Journal of Medicine and a December 2013 recommendation from the American College of Obstetricians, both of which support use of CMA in addition to or in lieu of karyotyping for miscarriage management and prenatal testing of at-risk pregnancies. Anecdotal evidence indicates that, since the publications and positive opinion from ACOG, that there has been an ongoing shift from use of karyotyping to CMA by maternity specialists for miscarriage management.

The recent endorsements for the use of CMA along with rapid growth of the overall molecular diagnostics market should provide a tailwind to CombiMatrix's recently implemented and ongoing efforts to expand awareness of the technology, ramp sales and further their quest to become the preeminent diagnostic services laboratory for prenatal microarray testing. Their strategy to do so includes direct sales to OB/GYNs, pathologists (i.e. - the hospital/clinic-level decision-makers in terms of which lab/test to utilize) and maternal-fetal medicine (MFM) specialists with a recently beefed up sales force, cultivation of relationships with pathology partners including other lab service providers, broadening reimbursement and entering into complementary industry alliances, all of which are aimed at expanding distribution and growing revenue.

Recent headway in implementation of this strategy has already borne fruit, evidenced in part by consummation of an alliance with Sequenom, Inc. in late 2013, recently entered partnerships with certain pathology labs, a doubling of the sales force, an increase in the number of third-party payers that reimburse for the company's services, a rapid increase in prenatal microarray testing volumes and consistent double-digit sales growth.

We view the low-hanging fruit for CBMX as the market for miscarriage/stillbirth testing, also known as products of conception (POC) - the U.S. market for which the company estimates at approximately $250M and only ~10% penetrated and which we think may be ripe for a relatively rapid transition from karyotyping to CMA. Prenatal testing for developmental disorders is another attractive market, although penetration of CMA in this segment may be much more measured as CMA can provide results with uncertain clinical significance - potentially offering a challenge to clinicians in counseling patients and causing patient anxiety. As more clinical data becomes available and more is known about certain copy number variants with currently unknown clinical significance, we think use of CMA in prenatal testing could become much more widespread.

CBMX believes that it differentiates itself from competing and larger laboratories that also offer CMA by offering a higher level of genetic counseling services and providing an overall superior customer relations experience. As CMA is a relatively new and highly complex technology that requires specific expertise in interpreting and relaying results, the company's on-staff genetic counselors offer clinicians and patients a readily available and knowledgeable source of information on testing results. Finally, in terms of competitive positioning, while the prenatal microarray testing markets are relatively large and attractive for a company of CBMX's small size, the opportunity may not appear nearly as enticing for much larger competitors. This is because to exploit these prenatal microarray markets (which are relatively small for large labs) requires a relatively high volume of hand-holding of doctors and patients which may not fit well with the more automated oriented functioning of larger labs.

BACKGROUND

Rapid Growth of Molecular Diagnostics

Molecular diagnostics (i.e. - genetic testing) refers to analysis of a person's individual DNA. Genetic testing is used for a variety of purposes including the determination of biological heritage, for criminal forensics, to predict an individual's response to a particular drug, to establish potential vulnerability to inherited diseases and in prenatal diagnosis to determine risk of a baby being born with a chromosomal or genetic disorder.

Molecular diagnostics has been around since the 1970s and in the early years made up a relatively miniscule portion of the overall diagnostics market. Initially it was mostly focused on prenatal testing to determine, for example, whether an unborn fetus is carrying gene mutations associated with certain diseases. Since then the field of molecular diagnostics has rapidly expanded, interest in and growth of which was particularly fueled by the completion of the Human Genome Project in 2003 which sequenced the entire human genome.

Molecular diagnostics now makes up approximately 11% of the total worldwide in-vitro diagnostics market and, per Frost and Sullivan, is expected to grow at about 12% over the next five years, about 70% faster than the 7% growth predicted for the entire diagnostics market. While much of the recent and near-term anticipated growth in molecular diagnostics is being driven by applications in infectious diseases and oncology, the recent emergence and increasing adoption of newer DNA testing methods and overall improved accuracy and utility of molecular analysis has spurred growth across a spectrum of applications, including prenatal testing.

Traditional Prenatal and POC Testing Done by Karyotyping…

Prenatal diagnosis is done in order to determine the health and condition (as well as sex) of the fetus prior to being born. Initially this is typically done with relatively non-invasive screening techniques such as ultrasound and maternal blood tests. Maternal blood tests, called non-invasive prenatal testing (NIPT), examine fetal DNA that is circulating in the mother's blood stream. NIPT is generally used to determine if the baby is at risk of Down Syndrome (i.e. - trisomy 21), although it can also identify risk of certain other abnormalities and conditions including Edwards syndrome (trisomy 18) and Patau syndrome (trisomy 13). For other conditions, however, a more invasive test must be used.

CombiMatrix recently entered into a marketing and distribution agreement with Sequenom, Inc., a manufacturer of an NIPT test, whereby Sequenom will market CBMX's CMA prenatal testing services. Sequenom's MateriT21 PLUS is one of the largest selling NIPT tests on the market.

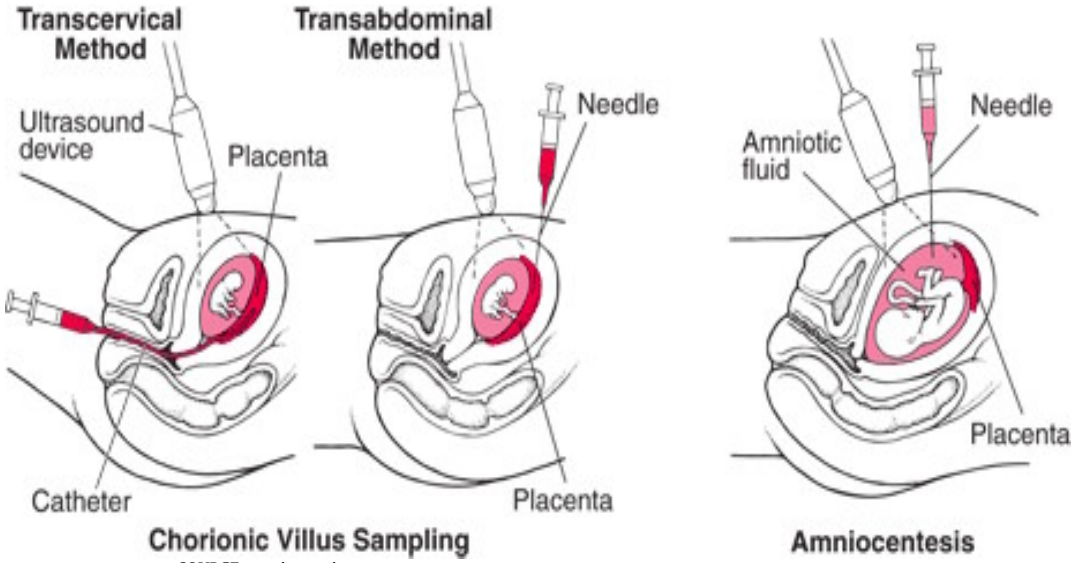
Ultrasound Image of Fetus Suspected of Having Down Syndrome



SOURCE: asianetindia.com

If an abnormality is detected with a non-invasive screen or the pregnancy is otherwise at higher risk (such as the mother being of older age), typical protocol often calls for a more invasive procedure, such as amniocentesis ("amnio) or chorionic villus sampling (CVS), to be performed to provide a more definitive

diagnosis. Amniocentesis and chorionic villus 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. The traditional prenatal chromosomal analysis methods have been karyotyping and/or fluorescent in situ hybridization (FISH), although a portion of this now appears to be shifting towards CMA. This shift has most recently been facilitated by a November 2013 Committee Opinion by The American College of Obstetricians and Gynecologists (ACOG) advocating for the use of CMA as a first tier option.



SOURCE: merckmanuals.com

FISH analysis only provides the number of copies of a particular chromosome but unlike karyotyping, does not provide any other information such as structure or physical characteristics of the chromosomes. FISH uses fluorescent probes which are made of DNA specific to certain chromosomes and these probes bind to the matching DNA in the sample. FISH therefore can determine the number of copies present of a particular chromosome - probes for chromosomes 13, 18 and 21 are typically used in FISH. So if, for example, FISH finds three 21 chromosomes, that indicates the baby has Down Syndrome. The advantage of FISH is that the sample does not require culturing and analysis can be done relatively quickly. The disadvantages are that FISH provides only the number of chromosomes of interest but will not provide any other information on the chromosomes of interest or any information on any other chromosomes.

Karyotyping, which has been considered the gold-standard for both prenatal testing and POC, involves a 7 to 10-day culturing (i.e. - growing) of the cells from the sample, staining the cells and then viewing the chromosomes under a microscope. Abnormalities can be identified by missing chromosomes, unusual banding patterns or certain physical characteristics. The advantage of karyotyping is that it can provide comprehensive information of the chromosomes which can be useful in diagnosing potentially hundreds of abnormalities. It can also identify balanced translocations, a relatively rare and often asymptomatic chromosomal abnormality, while CMA can not. The disadvantages are that diagnosis time is typically one to two weeks, requires culturing of the cells (which is problematic if the tissue dies, in which case the test will be unsuccessful) and has been found to be less sensitive than microarray analysis.

Specific to culturing, studies have shown that culture failure (i.e. - tissue dies) occurs in as many as 20% - 55% of POCs, 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.

Chromosomal Microarray Analysis May Be The Future of Prenatal Testing and POC

Microarray testing is a relatively new chromosomal analysis technique. Unlike karyotyping and FISH, microarray testing allows for analysis of all 46 chromosomes in the human body at once by analyzing copy number variations. It accomplishes this by comparing a patient's entire DNA to a reference (or control) DNA source, labeling the patient's and reference DNA with different fluorescent molecule.

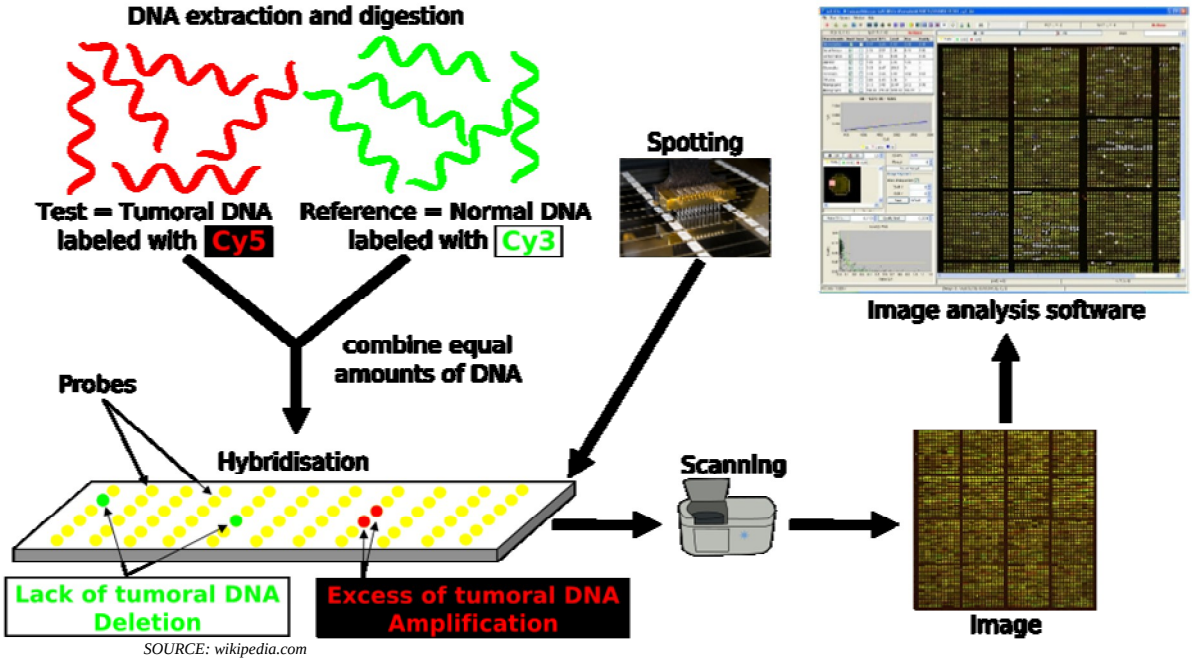
CBMX employs two complementary microarray platforms, array comparative genomic hybridization (aCGH) using 180k oligonucleotide probes and single nucleotide polymorphisms (SNP) using 850k oligonucleotide probes. Probes are specific DNA sequences that are attached to the microarray chip to which the DNA of the

patient sample and reference DNA binds (i.e. - hybridizes). The oligo probes used by CBMX are relatively small (25-75 base pairs in length) and spaced closely together, affording relatively high resolution.

aCGH analyzes DNA copy number variation (CNV), which is the variation (normal or abnormal) in the number of copies of sections of the DNA. Some abnormal CNV, where sections of the genome have been either deleted or duplicated, have been associated with causing genetic disorders. The aCGH process involves labeling a patient's and reference DNA of equal quantities with different fluorophores and hybridizing these to probes on a microarray chip. Digital imaging instruments are then used to analyze the difference in fluorescence (i.e. – difference in intensity of the two colors) of the probes to determine copy number variation. Additions or deletions in copy number are determined by greater or less intensity of the sample versus the control.

While many copy number variants are known to be associated with certain disorders, this is not the case for all variants. While databases are constantly updated with new genomic information and are used as a source to help determine the significance of yet-to-be characterized copy number variants, the clinical significance of some variants remains uncertain.

Schematic Example of Array Comparative Genomic Hybridization



SOURCE: wikipedia.com

While the process for performing SNP arrays is similar to that of aCGH, unlike aCGH, SNP arrays hybridize only the patient sample DNA to the array chip and analyze variation at single sites in the DNA, which is the most common type of variation in the genome. SNP arrays provide information on the specific SNP location and associated chromosomal disorders and abnormalities.

CBMX can use the aCGH and SNP platforms either separately or in combination. While aCGH has the advantage of looking at the entire genome, it can not detect triploidy, a very rare chromosomal disorder which SNPs can detect. And as noted earlier, chromosomal microarray analysis can also not detect balanced translocations, a common cause of recurrent miscarriages.

Balanced Translocations

In rare cases, a section of a chromosome of one pair switches places with a section of another pair of chromosomes. As there is no gain or loss of DNA, chromosomal microarray analysis can not detect balanced translocations.



On the left are two pairs of normal chromosomes. The ends of two chromosomes change places. On the right, a balanced translocation. This is called a reciprocal translocation.

SOURCE: Unique, Maj Hulten, University of Warwick

Clinical Studies, ACOG Supports Use of Chromosomal Microarray in Prenatal & POC Testing

Two studies were done by the National Institute of Health and published in December 2012 in the New England Journal of Medicine. One study, *Karyotype versus Microarray Testing for Genetic Abnormalities after Stillbirth* (Reddy et al.), compared CMA to karyotyping in the analysis of stillbirths for genetic abnormalities, while the other, *Chromosomal Microarray versus Karyotyping for Prenatal Diagnosis* (Wapner et al.), compared CMA to karyotyping in prenatal diagnosis. Based on certain benefits that the authors cite of CMA as compared to karyotyping, both studies indicated that CMA should be used in lieu of or in combination with karyotyping for their respective study populations.

Approximately one-year (i.e. - December 2013) following publication of the studies, The American College of Obstetricians and Gynecologists, the organization with perhaps the most influence in proposing changes to OB/GYN and MFM clinical protocol, issued a Committee Opinion which recommended the use of CMA for many cases of prenatal diagnosis as well as for stillbirth analysis and in some instances, in lieu of karyotyping.

♦ ***Reddy Study Supports CMA in Stillbirths…***

The Reddy study[1], conducted from March 2006 to September 2008, analyzed a sample of 532 stillbirths from 59 hospitals with both karyotyping and CMA. Investigators conducting CMA were blinded to the karyotype results. Stillbirth, defined as fetal death $\geq$ 20 weeks, happens in less than 1% of births (~26k) in the U.S. but, according to several sources, the cause of the stillbirth is unknown in approximately 40% of cases.

Karyotyping was used in both fetal and placental tissue in 158 of 532 stillbirths (29.7%), only fetal tissue in 309 stillbirths (58.1%), only placental tissue in 64 stillbirths (12.0%) and tissue of unknown type in 1 stillbirth. 375 of the 532 (70.5%) karyotypes yielded a results while 157 (29.5%) did not yield a result.

Microarray analysis used placental DNA (426 cases or 80.0%) unless it was not available - in that case cord blood, fetal muscle or fetal liver was used (106 cases or 20.0%). Microarray analysis yielded a result in 465 of 532 stillbirths, or 87.4% of cases - significantly ($p<0.001$) higher than the 70.5% yield with karyotyping. This resulted in 90 more (24.0%) viable samples with the use of CMA.

Of the karyotypes that yielded a result, 8.3% (31 of 375) were classified as abnormal (aneuploidy or pathogenic copy number variants), compared to 9.5% (44 of 465) CMAs that yielded a result. Even more telling of CMAs improved detection over karyotyping, however, is that when considering the entire sample populations, 8.3% of CMAs (44 of 532) were considered abnormal versus just 5.8% (31 of 532) of karyotypes. The difference, a 41.9% increase in detection in favor of CMA, is statistically significant ($p=0.007$). Additionally, when variants of unknown significance were included (25 of 532 for CMA, 0 of 532 for karyotype), the difference between CMA abnormalities and karyotyping abnormalities (13.0% vs. 5.8%, $p<0.001$) was even greater - a 122.6% increase in favor of CMA. The table below from the NEJM article provides more detail of the comparison of results.

[1] Reddy UM, et al. *Karyotype versus Microarray Testing for Genetic Abnormalities after Stillbirth.* NEJM 367;23 Dec 2012

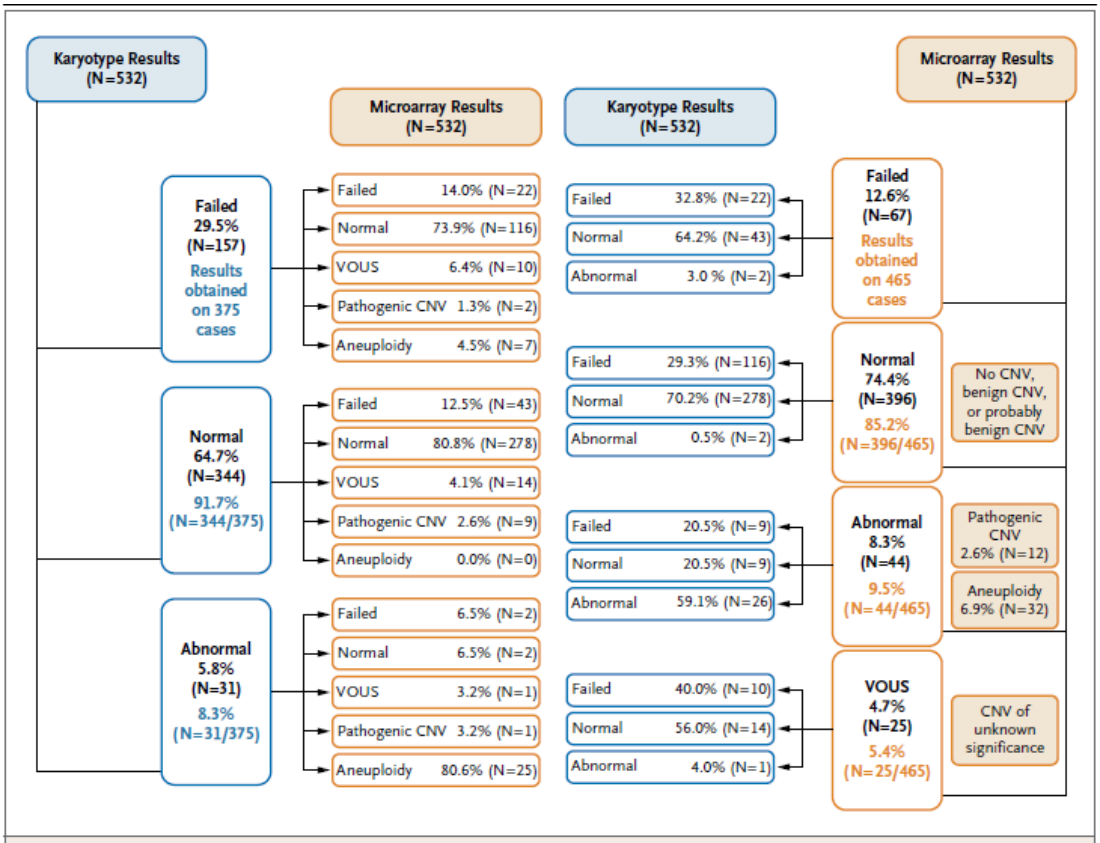


Figure 1. Performance of Karyotype and Microarray Analyses in Samples Obtained after Delivery in 532 Stillbirths.

On the left, karyotype results (blue) are categorized as failed, normal, or abnormal, as compared with findings from the same cases on microarray analysis (orange). On the right, the microarray results are categorized as failed, normal, abnormal, or variants of unknown significance (VOUS), with the corresponding karyotype results in the same cases. CNV denotes copy-number variant.

SOURCE: footnote 1

The study also looked at CMA's ability to detect abnormalities that were identified by karyotype. Of the 31 stillbirths with abnormal karyotype, 29 had abnormal results with CMA - 25 of which were consistent with the karyotype results. Two samples with 10% or less abnormal cells on karyotype showed as normal on CMA and two samples with abnormal karyotypes had a different abnormality on CMA. In addition two more abnormal karyotypes did not yield a CMA result due to degradation of the DNA.

The authors made several points about the comparison between karyotyping and CMA in the analysis of stillbirths. While the article did not state that the higher yield of CMA was specifically a result of culture failure, the authors did note that, "The primary benefit of using microarray analysis over karyotype analysis is the greater likelihood of obtaining a result because of the ability to analyze nonviable tissue." The study also showed that CMA provided better detection of genetic abnormalities (aneuploidy or pathogenic copy number variants), identified significantly more (8.8% vs 6.5%, p=0.02) antepartum stillbirths (the most common cause of stillbirths), and identified more stillbirths with congenital anomalies (29.9% vs 19.4%, p=0.008). And while CMA can not detect balanced translocations, the authors imply that this is not a significant limitation of CMA as balanced translocations are not likely to cause stillbirths.

The authors concluded that due to CMAs higher chance of obtaining a result and higher detection rates that it "is especially valuable in analyses of stillbirths with congenital anomalies or in cases in which karyotype results can not be obtained." We note that approximately 10% of stillbirths are the result of congenital anomalies and that, according to this study, approximately 30% karyotypes do not yield a result. As such, we interpret the study results to indicate the chromosomal microarray has real utility in stillbirth analysis.

♦ ***Wapner Study Supports CMA in Prenatal Testing…***

The Wapner study[2], conducted from October 2008 to July 2011 was designed to compare the accuracy, efficacy and yield of CMA to karyotyping in samples of women from 21 sites who underwent prenatal testing. 4,406 women were enrolled and indicated for prenatal testing due to advanced maternal age (46.6%),

[2] Wapner RJ., et al. *Chromosomal Microarray versus Karyotyping for Prenatal Diagnosis.* NEJM Dec 2012, 367(23):2175-2184

abnormal results on Down Syndrome screening (18.8%), structural anomalies found on ultrasound (25.2%) and other indications (9.4%). 2,275 women underwent chorionic villus sampling and 2,131 underwent amniocentesis.

Karyotyping and CMA were performed on each sample. Microarray analysis was successful in 98.8% (4340 of 4391) of cases with 78.5% (3408 of 4340) of the successful microarray study results coming from uncultured samples and 21.5% (932 of 4340) of the successful microarrays study results coming from cultured samples.

Results showed that microarray analysis found clinically significant chromosomal abnormalities that were not detected by karyotyping. Microarray analysis found 96 of the 3,822 (2.5%) samples that karyotype determined to be normal, had a copy number variant (deletion or duplication) that was of clinical significance (see table below).

In addition, in an analysis of subgroups of women with normal karyotypes and (see table below);

- with fetuses with suspected growth or structural anomalies found on ultrasound, 45 of 755 (6.0%) had clinically relevant findings which were not detected on karyotyping
- which underwent an ultrasound because of advanced maternal age, 34 of the 1,966 women (1.7%) who showed no anomalies on ultrasound had a normal karyotype but were found to have clinically relevant findings on microarray
- had a positive result on Down Syndrome screening, 12 of the 729 women who had a positive result on Down Syndrome screening had a normal karyotype but were found to have clinically relevant findings on microarray
- had copy number variants from microarray analysis associated with autism and neurocognitive alterations - this was the case in 51 of 3822 (1.3%) of pregnancies that karyotype classified as normal, 27 of 755 (3.6%) with structural anomalies and 24 of 3,067 (0.8%) without structural anomalies

Frequency and Clinical Interpretation of Microdeletions and Duplications on Chromosomal Microarray in the 3822 Samples with a Normal Karyotype, According to Indication for Prenatal Testing

Indication for Prenatal Diagnosis	Normal Karyotype	Common Benign	Pathogenic	Uncertain Clinical Significance (N = 130)		Total Known Pathogenic and Potential for Clinical Significance *
				Likely to Be Benign	Potential for Clinical Significance	
	no.			no. (%)		no. (%) [95% CI] *
Any	3822	1234 (32.3)	35 (0.9)	69 (1.8) ‡	61 (1.6)	96 (2.5) [2.1–3.1]
Advanced maternal age	1966	628 (31.9)	9 (0.5)	37 (1.9)	25 (1.3)	34 (1.7) [1.2–2.4]
Positive on Down's syndrome screening	729	247 (33.9)	3 (0.4)	13 (1.8)	9 (1.2)	12 (1.6) [0.9–2.9]
Anomaly on ultrasonography	755	247 (32.7)	21 (2.8)	16 (2.1)	24 (3.2)	45 (6.0) [4.5–7.9]
Other §	372	112 (30.1)	2 (0.5)	3 (0.8)	3 (0.8)	5 (1.3) [0.6–3.1]

* Total includes those predetermined as known to be pathogenic and those classified by the clinical advisory committee as clinically relevant.

† CI denotes confidence interval.

‡ Includes 36 samples determined likely to be benign by the study geneticist and 33 determined by the independent clinical advisory committee on the basis of size, gene content, inheritance, the literature, and ultrasonography findings.

§ Other indications include family history, previous pregnancy with chromosomal abnormalities, and elective decision.

SOURCE: footnote 2

Overall, the results showed that microarray was equivalent to karyotyping for the most common prenatal abnormalities but provided additionally clinically relevant information that karyotyping did not identify in 1.7%

of cases and in 6% of cases which ultrasound did not identify. The authors concluded that this study data shows that microarray analysis provides beneficial and clinically relevant information for prenatal testing. They do note, however, that both karyotyping and microarray analysis can detect variants of uncertain significance, and as we noted earlier, this has the potential to present challenges for counseling and cause patient anxiety. In this study 3.4% (130 of 3822) of all karyotype normal cases returned variants of uncertain significance under microarray analysis – although the authors indicate that as additional information on the pathogenicity of variants with previously unknown significance comes to light through ongoing research, that the number of variants with unknown significance will fall.

And while microarray analysis did not identify any balanced translocations or fetal triploidy, that was not unexpected as this is a known limitation of microarray analysis. Caveats are, however, that both of these are relatively rare occurrences (17 or 0.4% of samples were triploid) and fetal triploidy can be detected with SNP, a capability that CBMX has. Triploid was detected in 17 (0.4%) of samples on karyotype, 14 of which were detected on ultrasound. Balanced translocations occur in only about 0.08% to 0.09% of prenatal samples.

Results of Karyotype and Microarray Analysis in 4282 Samples with a Nonmosaic Karyotype, According to Cytogenetic Abnormality

Abnormality	Detected on Karyotyping	Detected on Microarray*		
		Total	Full Complement	Mosaic Complement
	no. (%)	*no. (%)*	*no.*	*no.*
Any autosomal or sex-chromosome abnormality	374 (8.7)	374 (100)	366	8
Any common autosomal trisomy	317 (7.4)	317 (100)	312	5
Trisomy 21	188	188 (100)	185	3
Trisomy 18	93	93 (100)	91	2
Trisomy 13	36	36 (100)	36	0
Other autosomal trisomy	4 (0.1)	4 (100)	4	0
Any sex-chromosome aneuploidy	57 (1.3)	57 (100)	54	3
45,X	39	39 (100)	36	3
47,XXX; 47,XXY; 47,XYY	18	18 (100)	18	0
Structural rearrangement	65 (1.5)			
Balanced	40	0	0	0
Unbalanced	22	22 (100)	21	1
Marker	3	2 (66.7)	2†	0
Triploidy	17 (0.4)	0‡	0	0

*All results are reported from uncultured samples where available, and otherwise from cultured samples.

†No euchromatin was identified on fluorescence in situ hybridization in the marker with a normal result on chromosomal microarray.

‡A total of 15 of the 17 triploidy cases (88.2%) were identified in maternal-cell contamination studies. One other was recorded as mosaic 47,XXY on microarray

SOURCE: footnote 2

♦ ***ACOG / SMFM Recommend Use of Microarray Analysis for Prenatal and Stillbirth Testing…***

One year following the publication of the two NEJM-published studies exploring the utility of microarray analysis jn stillbirth and prenatal testing, the American College of Obstetricians (ACOG) and Gynecologists and the Society for Maternal Fetal Medicine (SMFM) issued recommendations regarding the use of microarray analysis in both prenatal and stillbirth testing. The organizations advocate for use of CMA in both

the prenatal and stillbirth setting and in certain cases, recommend that CMA should be used instead of karyotyping. Their recommendations were based on results of the Wapner study as well as other (non-cited) studies.

The authors pointed to several advantages of microarray analysis as compared to karyotyping including;

- CMA yields more genetic information (which they characterized as the "primary" relative advantage) due to higher resolution
- Results are typically available more quickly as CMA usually does not require culturing
- CMA may be more useful in stillbirths due to the high culture-failure rate of karyotyping for those types of samples
- As CMA analysis is done with computers it may be less prone to human error compared to karyotyping, which relies on subjective assessment via a microscope

However, the authors also reiterated others' concerns relative to potential for substantial patient anxiety in the event microarray returns results of variants with unknown significance – but also acknowledging that over time interpretation of results has and should continue to improve as more is learned about the human genome. The paper also noted that there is a current need for patient pre- and post-test counseling from qualified personnel to deal with the potential issue of uncertain microarray results – which is a focus for CBMX in an effort to help drive adoption of CMA as well as to differentiate themselves from competing CMA providers.

The specific recommendations by ACOG / SMFM for use of microarray analysis, published in December 2013 were;

- Chromosomal microarray should be used in lieu of karyotyping in cases where ultrasound identified one of more major structural abnormalities
- Either chromosomal microarray or karyotyping is appropriate in cases where ultrasound did not find any structural abnormalities
- Chromosomal microarray should not be restricted just to women aged 35 years and older as most genetic mutations identified by CMA are not associated with increasing age
- For analysis of stillbirths, chromosomal microarray on fetal tissue is recommended because of its increased likelihood of obtaining results and better detection capabilities [as compared to karyotyping]
- Chromosomal microarray analysis is not recommended at this time for miscarriages (first and second trimester losses) as there is currently only limited data available on its clinical utility in this setting
- A qualified counselor should provide patient pre- and post-test counseling on the benefits, limitations and results of CMA and chromosomal microarray should not be done without documented patient consent

As ASCO and SMFM wield influence in directing changes to clinical protocol in the prenatal and POC segments, we view these recommendations as potentially significant in terms of driving greater adoption of chromosomal microarray analysis for prenatal testing and stillbirth analysis. And while the organizations' current recommendations do not specifically support use of CMA in miscarriage analysis, they cite 'not enough clinical data yet' as the reason – implying that future clinical studies demonstrating utility of CMA for miscarriage analysis could compel an update to their recommendation to a positive opinion for CMA in this indication.

Chromosomal Microarray vs Karyotyping: Strengths and Weakness

We think it is clear that both chromosomal microarray and karyotyping have their respective strengths and weaknesses in terms of clinical utility, some of which may be more pronounced for certain indications. The data borne out of the two NEJM-published studies as well as analysis conducted by ACOG/SMFM in terms of respective clinical advantages and disadvantages of each method largely mirror that of earlier, smaller studies. We discuss below what we believe are the major points a clinician or pathologist would consider when choosing CMA or karyotyping for prenatal testing, stillbirth and miscarriage analysis.

- Sample Viability: culture failure has been widely cited as a significant drawback of karyotyping in stillbirth and miscarriage analysis with failure rates as high as 20% - 55%. As CMA analyzes DNA extracted directly from the tissue/fluid and can be performed on non-living tissue, lack of sample viability is much less of a concern. CMA can also be used, and has high success rates with, tissue that has been preserved with formalin and embedded paraffin (FFPE), which karyotyping can not. As

miscarriage/stillbirth tissue samples may often be fixed in FFPE, this precludes use of karyotyping in these instances. CMA successfully returns a result in 90%+ of cases. We think, because of this, CMA would have a clear advantage for stillbirth analysis and this would also add credence to CMA for miscarriage analysis. In prenatal analysis, culture failure is a relative non-issue

- Test Turnaround time: turnaround time, or the amount of time from sampling to test result, is approximately 5-7 days with CMA, but about 12-15 days with karyotyping due to culturing of fetal samples with stillbirth and miscarriage analysis. In addition, before a culture is declared a failure, it must be grown for 21 days. As parents that just experienced a miscarriage or stillbirth may experience significant anxiety as they wait for the test results, test turnaround time can be of the essence. The combination of high failure rates and relatively long turnaround times with karyotyping, clearly favors CMA
- Breadth of data: CMA provides greater breadth of data as it has the ability to detect very small chromosomal abnormalities that can not be detected with karyotyping. The ACOG opinion pointed to this as the primary advantage over karyotyping
- Interpretation of Results: while interpretation of results from both methods requires a high level of expertise, CMA analysis may be less prone to error as it is accomplished with digital imaging systems while karyotyping analysis is done by a technician looking through a microscope, the latter more subjective and prone to human error
- Variants of Unknown Significance: this is clearly a much bigger issue with CMA due to its ability to provide more genetic information than karyotyping. Some of this risk may be mitigated with implementation of stringent counseling protocol, although we expect this will remain a headwind to CMA for some period of time. Over time as more is learned about the human genome, the number of variants with unknown significance should decline and may result in an even greater rate of adoption of CMA in place of karyotyping
- Triploidy and Balanced Translocations: CMA can not detect either triploidy or balanced translocations, while karyotyping can. However, we do not necessarily see this as a significant impediment to adoption of CMA for prenatal testing or for stillbirth analysis because of 1) CMA's advantages in providing more genetic information, much lower rate of test failure and faster turnaround time 2) triploidy can be detected with an SNP array (for which CBMX has the capability and ~99% of CBMX's POC volume uses SNP) and 3) as Reddy et al. note, balanced translocations are unlikely to be a cause of stillbirth
- Miscarriage Analysis: despite about two-thirds of miscarriages being linked to chromosomal abnormalities of the fetus, physicians will often initially focus on the parents and not the fetus (which is consistent with ACOG's current view) when miscarriage analysis is requested. The rationale being that since most fetal chromosomal abnormalities are not inherited by the parents, a negative result on a parental chromosome test should indicate that a future pregnancy will not be affected. Typically this is done with karyotyping and as balanced translocations (which CMA can not detect) are the most common condition in couples with a chromosomal abnormality that have had a miscarriage, this is something that is of interest in testing for. For this testing protocol, karyotyping is almost always the testing method of choice.

In summary, in terms of utility of the two methods, we think it is reasonable to assume that clinicians and pathologists may favor chromosomal microarray analysis over karyotyping for both stillbirth and prenatal analysis due to its significantly higher success rate, ability to successfully test all sample types including those preserved with FFPE, faster turnaround time and ability to provide more genetic information as compared to karyotyping. The drawbacks of CMA, most notably its inability to detect triploidy (triploidy is a non-issue for CBMX given their ability to detect it with SNP) and balanced translocations, we believe are sufficiently manageable for prenatal and stillbirth testing. However, the risk of results of variants of unknown significance will likely remain a headwind to adoption of CMA, which may be more significant in the prenatal space.

Relative to miscarriage analysis, while we expect interest in genomic testing to continue to evolve and result in greater adoption of CMA (potentially fairly rapidly over the next few years), as typical protocol for miscarriage analysis is focused mostly on the parents, CMA's penetration of this market may be somewhat more elongated than with the stillbirth segment until more outcomes data provides additional support for the modality in this indication. However, despite parental testing being the norm in miscarriage analysis, CBMX's chromosomal microarray miscarriage analysis tests have been their fastest growing test in terms of volumes. We think this has been a result of the company's relationship building and high level servicing of customers (i.e. - hospitals, OB/GYNs, MFMs) as well as their active participation in communicating the benefits of chromosomal microarray analysis on prenatal tissue for miscarriages and a resultant increasing adoption of CMA by clinicians for this indication. The rate of further adoption of CMA in this segment will be something to keep an eye on as this is where we see another potential significant inflection point for CBMX.

INVESTMENT CONSIDERATIONS

> Focus is Prenatal / POC

While CBMX has historically generated the majority of revenue from microarray analysis of postnatal genetic disorders and for certain hematological and oncological applications, these are now being treated as more legacy segments as management focuses on the prenatal / POC segments to drive future growth of the company.

This shift is already well underway. In 2012 prenatal microarray tests accounted for 27% of microarray volume and 37% of microarray revenue, in 2013 prenatal microarray tests accounted for 49% of microarray volume and 61% of microarray revenue. Through the first nine months of 2014, prenatal microarray tests have accounted for 60% of microarray volume and 68% of microarray revenue.

> Niche Markets: *Attractive for CBMX, Maybe Not So Much for Larger Labs - We See CBMX as Very Competitive*

CBMX estimates the prenatal and miscarriage markets at approximately 100k and 140k patients annually. With 26k stillbirths each year, this would put CBMX's total potential annual market at about 260k patients. However, we note that this 260k patient number may actually be somewhat conservative as, depending on the source, there are between 200k and 400k invasive (i.e. - amnio and CVS) procedures done every year. And while demand for NIPT is increasing at the expense of invasive procedures, a 200k patient potential prenatal market size (360k patient potential total market size) would not be an unreasonable estimate in our opinion.

The company received $1.6k on average per prenatal test in all of 2013 - this fell to slightly lower than $1.5k through the first nine months of 2014. If we assume $1.5k per test going forward and a 260k patient market size, the company's potential prenatal and POC markets aggregate to roughly $150M and $250M, respectively.

Total markets worth about $400M are significant for a company of CBMX's relatively small size, even if the company captures just low double-digit market share. However, for the other chromosomal microarray providers targeting the prenatal and POC spaces, which mostly consists of relatively large diagnostic testing companies with various different lines of products and services, several thousands of employees and billions of dollars in annual revenue, $400M market size is not likely to be considered high priority. We think this is particularly true given that this niche segment requires a relatively high level of support and counseling services which do not lend itself well to a more automated-oriented functioning and perhaps rigid structure of large diagnostic companies. CBMX expects to differentiate themselves from competing providers via providing superior customer relations with a particular focus on counseling services.

Competitors in Microarray Analysis Market

Company	2013 Revenue (M)	Market Cap (M)	Employees
Quest Diagnostics	$7,146	$8,550	41,000
PerkinElmer Inc	$2,166	$5,320	7,600
LabCorp	$5,808	$8,700	34,000

And while CBMX does still offer other types of tests and for applications in postnatal and oncology indications, the company has transitioned to largely being a pure-play provider of chromosomal microarray analysis tests for the prenatal and POC segments. Management estimates that the POC market alone is only approximately 10% penetrated, leaving the vast majority up for grabs among just a small handful of participants. If CBMX can prove more competitive in terms of service and sales model, we think it is reasonable to expect that the company can capture meaningful share of the ~$400M markets that they are focused on exploiting.

> Reimbursement: *Reimbursement In Place, Expanding In-Network Status With Managed Care Contracts*

Third party commercial payers account for the majority of reimbursement for CBMX's diagnostic testing services, although a meaningful portion of the company's revenue does come from direct payers. The proportion of revenue in 2012 and 2013 that came from direct billing and commercial insurance companies was 38% / 31% and 55% / 67%. Medicare/Medicaid accounted for the remaining 7% / 2%.

Relative to Medicare/Medicaid, two CPT codes have been established (81228 and 81229) and can be used to bill for chromosomal microarray analysis. The codes became effective beginning in calendar 2013 on the Clinical Laboratory Fee Schedule although no reimbursement amount was included - that remains the case for calendar 2014. While CBMX does receive reimbursement from Medicare/Medicaid, this patient population represents a very small percentage of the company's customer base and prenatal and POC testing in general.

CPT Code	Description
81228	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (e.g., Bacterial Artificial Chromosome
81229	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP)

Commercial insurers typically adopt coverage decisions made by Medicaid/Medicare, although reimbursement amounts are often higher with private payers. In general, CBMX is considered an out-of-network provider by most private insurers, although they have (and expect to continue to) entered into managed care contracts with some third-party reimbursers which gives them in-network provider status. Reimbursement amounts from carriers where CBMX is considered out-of-network can be variable, while the contractual arrangements with in-network payers provides the company with a set rate.

Recently Executed Managed Care Contracts

Date	Payor Group	Covered Lives
2013: Q4	• FedMed National Provider Network • America's Choice Provider Network • Blue Cross and Blue Shield of Kansas City • Three Rivers Provider Network	• 40 million • 14 million • 800,000 • 15 million
2013: Q3	• Blue Shield of California	• 3 million
2012	• Multiplan	• 57 million

SOURCE: Combimatrix

In addition to the list of contracts above, CBMX has entered into additional contracts over the last several months. This includes a managed care contract signed in July 2014 with Stratose Networks, one of the largest directly managed PPO networks in the country with more than 850k members. The most recent contract, with BC/BS of Illinois, was signed in early September which adds an approximate 7 million more members that have reimbursed access to CBMX's tests.

In some circumstances CBMX bills the hospital/clinic directly. The company notes that while they have been successful in receiving payment from commercial insurers and through direct billing, that they recently beefed up their billing and collections departments to further improve upon this. Also, collection times can be somewhat payer-specific and can be drawn out - the investment in billing and collections infrastructure is also expected to reduce average collection times.

CBMX's average revenue per test in 2012, 2013 and in the first nine months of 2014 was $860, $1,009 and $1,044. CBMX's microarray tests have been reimbursed on average at approximately $1.3k (average reimbursement for microarrays for prenatal/POC have been paid at ~$1.5k), while non-microarray tests have been paid at between $200 - $250. This coupled with microarray tests having grown to account for 74% and 77% of total tests in 2013 and the first nine months of 2014, respectively, from just 63% in 2012, has resulted in the significant increase in average revenue per test since 2012.

Our view relative to CBMX's reimbursement picture is that while there is always risk of adverse changes to policies of third party payers and collectability of accounts, we would expect that as genetic testing continues to gain favor and adoption grows that future modifications to reimbursement policy may include broader coverage. There has recently been some downward pressure on reimbursement pricing, although this could also potentially improve with more widespread adoption of CMA (our model assumes little change in average reimbursement going forward). As CBMX enters into additional managed care contracts, risk of both collectability and variation in reimbursement amounts should decrease and further improve confidence in projecting per-test revenue.

> Commercialization Strategy: *3-Pronged Approach Focused on Expanding Distribution, Sales*

CBMX is employing a multi-pronged commercialization strategy aimed at expanding distribution and growing revenue, earnings and cash flow. This strategy includes direct sales to OB/GYNs, pathologists and maternal-fetal medicine (MFM) specialists with a recently beefed up sales force, cultivation of relationships with pathology groups and establishing strategic partnerships with other companies targeting the prenatal diagnostic space.

Since late 2013 the company has more than doubled the size of its direct sales force from six to fourteen reps and may continue to selectively add headcount in specific geographical territories. Ramping of the sales force comes on the heels of the December 2013 ACOG Committee Opinion and about one year following publishing of the two NEJM articles. The company expects that the combination of support for chromosomal microarray in lieu of karyotyping and expansion of the sales force will result in steepening of the sales curve.

The **direct sales** force, armed with the recent NIH studies and ACOG endorsement, will target three specific physician groups; OB/GYNs, MFMs and pathologists. By focusing on these three groups, CBMX believes it will cover all the critical decision-makers in the testing and patient-facing process; the OB/GYNs and MFMs which are responsible for the procedure and consult with the patient, and the pathologists who decides which lab to send the sample to for testing. CBMX also expects this sales approach will differentiate themselves from their competitors, which they believe largely leaves out the pathologist focus.

CBMX management estimates a runway of at least 6 - 9 months for each new rep to reach moderate productivity - which is fairly typical of the diagnostics and med-tech space. On the Q1 2014 conference call management noted that their goal is to have their best performing reps generating $1 million in sales within 18 months of hire. As such, we expect revenue growth may show a more substantial inflection in the second half of this year.

Direct sales will be supplemented by **partnerships with pathology groups** in geographical areas outside of the company's direct footprint, allowing for immediate expanded distribution in territories that may otherwise go untapped. The company recently entered into two pathology group partnerships. In January of this year the company announced a partnership with ProPath, a Dallas-based pathology group to supply their patients with CMA miscarriage analysis testing. Then in mid-March CBMX announced similar arrangement with American Pathology Partners (AP2). AP2 has pathology labs in Denver, Colorado, Eastern North Carolina and West Palm Beach, FL.

The final piece of CBMX's sales/distribution plan includes **alliances with strategic industry partners**. In August 2013 the company announced a collaboration with Sequenom Inc. (SQNM) whereby the companies will jointly market CBMX's CMA testing services. We view this collaboration as not only beneficial in terms of expanding CBMX's distribution but, perhaps just as important, as validation of the company's CMA testing services as SQNM is a leader in NIPT testing with MaterniT21 PLUS being one of the largest selling NIPT tests on the market. The collaboration appears to be a good fit for both parties; providing CBMX with significantly expanded distribution and SQNM a low-cost ancillary revenue source as CMA can be offered as an adjunct to their MaterniT21 PLUS test.

> Expect Expanded Distribution To Make Meaningful Impact in Near-Term

CBMX's recent shift to de-emphasize their oncology/hematology platform and turn their majority focus on prenatal and POC chromosomal microarray analysis already appears to be paying off. This is evidenced by prenatal microarray testing volumes growing 126% in 2013 and 64% in the first nine months of 2014 and accounting for almost the entire 19% and 26% revenue growth in those respective periods. The company expects to pursue this strategy with even greater vigor as it continues the implementation of its more aggressive distribution plan.

As noted, with recent doubling of the sales force and an expected 6 - 9 month breaking-in period, we think direct sales-related revenue may show a more pronounced rate of acceleration over the next several quarters. The pathology partnerships, while providing incremental distribution, are unlikely to result in significant volume in our opinion, particularly over the near-term.

We believe the alliance with Sequenom is more significant given that SQNM's MaterniT21 PLUS test is one of the largest selling NIPT tests (at ~150k annually) which instantly and meaningfully expands CBMX's footprint. Sequenom's endorsement of CBMX's services also, in our opinion adds validation to the CMA technology as well as CBMX's abilities to service SQNM's customer base. As such, we think this partnership, as well as potential future similar alliances, has the potential to provide revenue contribution beginning in the near-term as well as helping to broaden awareness of prenatal chromosomal microarray analysis and CBMX's position as the only pure-play prenatal-focused CMA provider.

> Prenatal Analysis / POC Continues to Evolve - Presents Potential Opportunities and Challenges

We expect increased awareness, including that generated by the recent NEJM articles and ACOG Committee Opinion, to help drive adoption of CMA in prenatal and POC analysis. Chromosomal microarray analysis remains a relatively new technology, however, and certain challenges including how to sufficiently address genetic variants of unknown significance may hamper uptake, particularly for certain indications.

We view the stillbirths market, while much smaller than the miscarriage or overall prenatal markets, as likely the most receptive in the near term for rapid adoption of CMA and a potential low-hanging-fruit opportunity for CBMX. The miscarriage segment is where the bulk of CBMX's recent volume growth has come from, however - this may indicate that while physicians often initially focus on the parents and not the fetus in miscarriage analysis, that the tide may be starting to shift, or at least starting to include a greater focus on testing of the fetus for analysis of copy number variants. We see this as both a challenge and an opportunity - a challenge to build greater awareness of the benefits of CMA miscarriage analysis and an opportunity in terms of penetrating the relatively sizable $250M market, which remains largely untapped. We view the MFMs as the most well-informed physician group in terms of the benefits of CMA and as a result, the most influential in terms of driving more widespread adoption of the technology. As such, we think CBMX will have an especially targeted focus on detailing at the MFM level.

The prenatal market for chromosomal microarray analysis is estimated at about $150M annually and, again, is barely penetrated and ripe for the picking. While we think the recent clinical evidence demonstrates high utility of CMA (either in concert with or in lieu of karyotyping) in this segment, there are challenges. In addition to the issue of variants of unknown significance, the use of NIPT tests in lieu of amniocentesis or CVS has been on the rise. The first NIPT test (Sequenom's) launched in late 2011 and since then three other manufacturers (Verinata, Ariosa and Natera) have brought an NIPT test to the market. While an amnio or CVS is still often recommended following a positive NIPT result, these non-invasive tests have clearly slowed the market specific to karyotyping and CMA. However, the opportunity for CBMX, specific to this challenge, is their partnership with Sequenom where a patient with a positive result on a MaterniT21 PLUS test can be referred to testing with CBMX's CMA services.

> Additional Growth Could Come From Expanding Test Menu: *Initial Focus May Be IVF*

CBMX first noted in their Q1 2014 earnings release and on the subsequent earnings call that they are in early R&D stage with two new "complementary products" with potential launch in Q4 of this year. This timeline guidance was reiterated on the Q3 call in early November. Further discussion with management indicated that at least one of these products could be a microarray-based in-vitro fertilization (IVF) test. An IVF test could presumably fit directly within the company's distribution footprint, calling on OG/GYNs and MFMs and provide a seamless complement to their miscarriage and stillbirth tests. CBMX noted that they expect to be able to provide additional information about these pipeline tests in the second half of this year.

> Financial Condition

During Q4 2013 CBMX raised $10.7M (net) via the issuance of convertible preferred stock. This followed raises totaling $3.9M (net) from the issuance of convertible preferred earlier in 2013. All of the issued preferred stock has since been converted into common shares.

As of the most recent reporting period (ending 9/30/2014) the company had $7.4M in cash and short-term investments and no long-term debt or preferred stock outstanding. Basic share count stood at 11.1M, in

addition there were 8.5M common equivalent (anti-dilutive) shares outstanding representing options, warrants and restricted stock units.

Cash burn was approximately $5.9M in 2013 and $4.0M through the first six months of 2014. At the most recent quarterly burn rate, the current (as of 9/30/2014) cash balance represents almost 12 months worth of operating funds. With recent stabilization in opex as a percentage of revenue and continued expectations that revenue will accelerate, we think it is reasonable that current cash balance and cash from operations will be sufficient to fund the company for about the next 12 - 15 months (or potentially longer, depending on the level of sales).

OUTLOOK / VALUATION

OUTLOOK

CombiMatrix's prenatal microarray testing volumes increased 126% (983 to 2,222) from 2012 to 2013 while their non-prenatal microarray testing volumes fell 12% (2,641 to 2,318) over the same period, reflecting the company's deliberate strategic shift to focus on the area that holds the most potential for long-term growth. While 2013 benefitted from the company allocating the bulk of sales efforts towards the prenatal microarray market, as well as potentially from the NEJM articles, the addition of other catalysts along with what we believe are important competitive advantages of CBMX have the potential to extend this growth momentum of prenatal microarray testing over the long-term. And as prenatal microarray per-test revenue and margins are the highest among the company's testing segments, this is also where the bulk of the opportunity for profitability lies.

The ACOG Committee Opinion was published in December 2013 and we also expect this, along with the supporting December 2012 NEJM articles, to help build awareness of the benefits of prenatal chromosomal microarray testing - although we view the benefit of these as more longer-term catalysts in helping to shape changes in clinical practice away from the use of karyotyping and towards the use of chromosomal microarray. We also assign real value to CBMX's competitive strengths including; 1) their sales strategy, whereby they will detail to several decision-makers, including the pathologist, in order to increase the number of shots on goal, 2) high-level, high-expertise, on-staff counseling services and 3) test turnaround times that are as fast or faster than their competitors'.

We estimate the market size directly related to CBMX's prenatal / POC microarray offerings at approximately $400M or more. As a placeholder for now, we assume this market expands at approximately 5% per year. The company has already made some headway in penetrating this market - particularly in miscarriage analysis, although we think 90%+ of this market remains virtually untapped. Almost all of our anticipated revenue growth for every modeled period is coming from prenatal microarray while we model flat growth of non-prenatal microarray and non-microarray testing.

Our 2014 revenue growth, including +45% from prenatal microarray testing, is driven mostly from expansion of the sales force. Through the first nine months of 2014 prenatal microarray testing volumes increased 64% while non-prenatal microarray testing volumes fell 3% over that same period. We model a somewhat similar theme throughout the remainder of the current year. CBMX just recently more than doubled the size of its sales force from six to fourteen - we expect the new reps will need a several month learning curve and believe the next several months may show a higher rate of revenue growth.

Beyond 2014 we think contribution from the additional, aforementioned catalysts begin to make a more substantial impact. We also think it is not unreasonable to believe that additional future studies and publications will provide further insight into the human genome, soften certain current headwinds to adoption of CMA (i.e. - provide more knowledge related to variants of unknown significance) and provide support for the utility of chromosomal microarray analysis in the prenatal space. These catalysts should result in steepening of the rate of adoption of chromosomal microarray analysis. This, coupled with the company's competitive positioning and our assumption that CBMX continues to grow their distribution footprint via incremental expansion of their sales force and, possibly, additional partnerships, provide what we believe will be a position of strength for CBMX in terms of being able to increase penetration of their target prenatal markets and grow revenue over the long-term.

We currently model CBMX achieving just over 1% penetration of the targeted prenatal microarray markets in 2014 and this growing to ~mid-single digit penetration by 2018 and approximately 10% by 2022. Any new product launches, including products that are currently under development, could prompt an upward revision to our forecast, particularly as it relates to our out-years. We look for incremental widening of gross margin as prenatal microarray, the highest priced of the company's tests, grows to account for an ever larger proportion of total revenue. We model decreasing leverage in operating expenses during the current year, reflecting the additional headcount and sales infrastructure but for this improve in 2015 and beyond as the newer reps achieve a higher level of productivity and with additional growth in revenue.

VALUATION

We use a 10-year DCF model to value CBMX. We model revenue to grow from $7.8M in 2014 to $22.3M in 2017 and to $85.0M in 2024, representing a 10-year CAGR of 27%. We believe our revenue estimates are reasonable, particularly as out our out-year number assumes just less than 13% penetration of the estimated prenatal chromosomal microarray analysis market at that time. And, as noted, we model relatively flat growth of all other testing segments, which is also arguably conservative. We also do not incorporate contribution from any new products that CBMX may potentially bring to market through the term of DCF - new product launches and/or a higher rate of revenue growth (relative to our assumptions) from existing tests could provide some upside to our numbers and associated calculated valuation.

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 $3.50/share. We are maintaining our Outperform rating and $3.50/share price target.

FINANCIAL MODEL

CombiMatrix Corporation

	2013 A	Q1A	Q2A	Q3A	Q4E	2014 E	2015 E	2016 E	2017 E
Prenatal microarrays	$3,551	$1,122	$1,221	$1,313	$1,480	$5,136	$8,484	$13,759	$19,541
YOY Growth	*112.1%*	*34.2%*	*46.1%*	*55.0%*	*43.4%*	*44.6%*	*65.20%*	*62.18%*	*42.02%*
All microarrays	$5,802	$1,714	$1,790	$1,837	$2,033	$7,374	$10,644	$15,919	$21,724
YOY Growth	*27.8%*	*19.5%*	*33.4%*	*33.0%*	*23.5%*	*27.1%*	*44.36%*	*49.56%*	*36.46%*
Non-microarrays	$403	$76	$116	$174	$75	$441	$300	$300	$300
YOY Growth	*-6.6%*	*-49.9%*	*12.3%*	*99.2%*	*23.7%*	*9.4%*	*-31.99%*	*0.00%*	*0.00%*
Total	**$6,205**	**$1,790**	**$1,906**	**$2,011**	**$2,108**	**$7,815**	**$10,944**	**$16,219**	**$22,024**
YOY Growth	*24.8%*	*12.9%*	*31.9%*	*37.0%*	*23.5%*	*25.9%*	*40.05%*	*48.20%*	*35.79%*
Diagnostic Svcs	$6,204.0	$1,790.0	$1,906.0	$2,011.0	$2,107.6	$7,814.6	$10,944.2	$16,219.4	$22,023.7
YOY Growth	*24.7%*	*12.9%*	*31.9%*	*37.0%*	*23.6%*	*26.0%*	*40.05%*	*48.20%*	*35.79%*
Royalties	$163.0	$32.0	$35.0	$51.0	$40.0	$158.0	$160.0	$160.0	$160.0
YOY Growth	*-9.4%*	*28.0%*	*-36.4%*	*45.7%*	*-16.7%*	*-3.1%*	*1.27%*	*0.0%*	*0.0%*
Total Revenues	$6,367.0	$1,822.0	$1,941.0	$2,062.0	$2,147.6	$7,972.6	$11,104.2	$16,379.4	$22,183.7
YOY Growth	*19.0%*	*13.1%*	*29.4%*	*37.2%*	*22.5%*	*25.2%*	*39.3%*	*47.5%*	*35.4%*
Cost of Services	$3,527.0	$998.0	$1,053.0	$1,129.0	$1,180.3	$4,360.3	$5,734.8	$7,980.0	$10,439.2
Gross Income	$2,840.0	$824.0	$888.0	$933.0	$967.4	$3,612.4	$5,369.5	$8,399.5	$11,744.5
Services Margin	*43.1%*	*44.2%*	*44.8%*	*43.9%*	*44.0%*	*44.2%*	*47.6%*	*50.8%*	*52.6%*
R&D	$1,011.0	$134.0	$224.0	$228.0	$314.0	$900.0	$1,216.0	$1,341.0	$1,386.0
% R&D	*15.9%*	*7.4%*	*11.5%*	*11.1%*	*14.6%*	*11.3%*	*11.0%*	*8.2%*	*6.2%*
SG&A	$7,970.0	$2,643.0	$3,325.0	$3,174.0	$2,929.0	$12,071.0	$11,392.9	$13,152.7	$14,530.3
% SG&A	*125.2%*	*145.1%*	*171.3%*	*153.9%*	*136.4%*	*151.4%*	*102.6%*	*80.3%*	*65.5%*
Patent amort. & royalties	$254.0	$32.0	$28.0	$28.0	$28.0	$116.0	$125.0	$120.0	$110.0
Goodwill impairment	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($6,395.0)	($1,985.0)	($2,689.0)	($2,497.0)	($2,303.6)	($9,474.6)	($7,364.5)	($6,214.2)	($4,281.9)
Operating Margin	*-100.4%*	*-108.9%*	*-138.5%*	*-121.1%*	*-107.3%*	*-118.8%*	*-66.3%*	*-37.9%*	*-19.3%*
Total Other income	$2,453.0	($11.0)	$110.0	($18.0)	($20.0)	$61.0	($180.0)	($200.0)	($225.0)
Pre-Tax Income	($3,942.0)	($1,996.0)	($2,579.0)	($2,515.0)	($2,323.6)	($9,413.6)	($7,544.5)	($6,414.2)	($4,506.9)
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	$8,271	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	($12,213.0)	($1,996.0)	($2,579.0)	($2,515.0)	($2,323.6)	($9,413.6)	($7,544.5)	($6,414.2)	($4,506.9)
YOY Growth	*19.0%*	*48.0%*	*91.7%*	*83.7%*	*-71.5%*	*-22.9%*	*-19.9%*	*-15.0%*	*-29.7%*
Net Margin	*-191.8%*	*-109.5%*	*-132.9%*	*-122.0%*	*-108.2%*	*-118.1%*	*-67.9%*	*-39.2%*	*-20.3%*
EPS	($3.10)	($0.18)	($0.23)	($0.23)	($0.21)	($0.85)	($0.61)	($0.34)	($0.16)
YOY Growth	*-67.1%*	*-68.7%*	*-38.5%*	*-25.9%*	*-86.2%*	*-72.6%*	*-28.7%*	*-43.5%*	*-52.0%*
Diluted Shares O/S	3,941	10,927	11,063	11,063	11,250	11,076	12,452	18,742	27,446

Brian Marckx, CFA

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MANAGEMENT

Mark McDonough
President & CEO

Mr. McDonough brings over 16 years of experience in diagnostic healthcare and life sciences to CombiMatrix. Led by his passion for patient care, he has spent his career growing early stage and emerging Cancer Diagnostics, Molecular Diagnostics and Commercial Laboratory organizations. In August 2012, Mr. McDonough joined CombiMatrix as Chief Commercial Officer. His efforts to optimize the commercial aspects of CombiMatrix and his focus on prenatal testing had an immediate impact on the company's long-term strategy and financial success. Mr. McDonough came to CombiMatrix from Pathwork Diagnostics where he was Vice President of Sales and Service. His business acumen was instrumental in driving all phases of the commercial efforts at Pathwork Diagnostics; including sales, reimbursement strategies, and market creation of novel diagnostics that fulfilled a critical, yet unmet need for patients with metastatic disease. Preceding his time at Pathwork Diagnostics, Mr. McDonough held positions of increasing responsibility at US LABS, ultimately assuming the role of Vice President of Sales. He also served in an executive capacity at Dianon and Laboratory Corporation of America (post acquisition). His contributions as a field sales resource and sales leader from 2002-2004 were instrumental in the growth of US LABS from $17M to $75M, resulting in its successful acquisition by Laboratory Corporation of America in early 2005. Prior to US LABS, Mr. McDonough was with EMC Corporation and Ventana Medical Systems. Before to joining the healthcare industry, Mr. McDonough was a ranking officer in the United States Navy for six years, where he served as Navigator of the USS FLETCHER (DD 992).
Mr. McDonough received his Bachelor's Degree in Finance from Miami University-Ohio.

Scott Burell
Chief Financial Officer

Scott Burell was promoted to Chief Financial Officer of CombiMatrix in November 2006. He has successfully led the split-off of the Company in 2007 from its former parent, has led several successful public and private debt and equity financing transactions and successfully executed the Company's reorganization and relocation in 2010. Prior to this, Mr. Burell had served as our Vice President of Finance since November 2001 and as our Controller from February 2001 to November 2001. From May 1999 to first joining CombiMatrix in February 2001, Mr. Burell was the Controller for Network Commerce, Inc., a publicly traded technology and information infrastructure company located in Seattle. Prior to this, Mr. Burell spent 9 years with Arthur Andersen's Audit and Business Advisory practice in Seattle. During his tenure in public accounting, Mr. Burell worked with many clients, both public and private, in the high-tech and healthcare markets, and was involved in numerous public offerings, spin-offs, mergers and acquisitions.
Mr. Burell obtained his Washington state CPA license in 1992 and is a certified public accountant (currently inactive). He holds Bachelor of Science degrees in Accounting and Business Finance from Central Washington University.

R. Weslie Tyson, M.D., F.A.C.M.G
Chief Medical Officer

R. Weslie Tyson (Wes) has been a practicing pediatric and perinatal pathologist for 24 years. He attended medical school at the University of Colorado where he also undertook his residency in Anatomic Pathology. A 4th year was spent in Clinical Genetics followed by a 2-year fellowship in Pediatric and Perinatal Pathology at the University of British Columbia Women and Children's Hospitals. He began his clinical practice at the Kosair Children's Hospital and the University of Louisville (1990-1993). He has practiced perinatal and pediatric pathology in the Denver committee for the previous 20 years (The Children's Hospital 1993-1998) and comes to CombiMatrix from UniPath, a multispecialty pathology group that staffs 8 metro hospitals and a large central laboratory.
Dr. Tyson has directed the pediatric and perinatal service for UniPath since 1999. He has published multiple articles, given extensive presentations and has been recognized by families and peers for his work and expertise in the area of perinatal pathology and poor pregnancy outcome.

Kim Leroux
Vice President of Billing & Reimbursement

Kim Leroux offers over 12 years of experience in laboratory experience, specifically focused on Billing and Support Services. Ms. Leroux serves as CombiMatrix's Vice President of Billing & Reimbursement.
Prior to joining CombiMatrix, Ms. Leroux worked at US LABS, a division of Laboratory Corporation of America for 10 years. There, she served as National Director of Client Services, and was instrumental in standardizing Client Service process at affiliated facilities, developing call-back programs to increase revenue and days sales outstanding (DSO), and developing Management Programs to monitor top revenue accounts.
Ms. Leroux earned her Bachelor Degree in Public Relations from California State University of Fullerton.

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Andy Moye

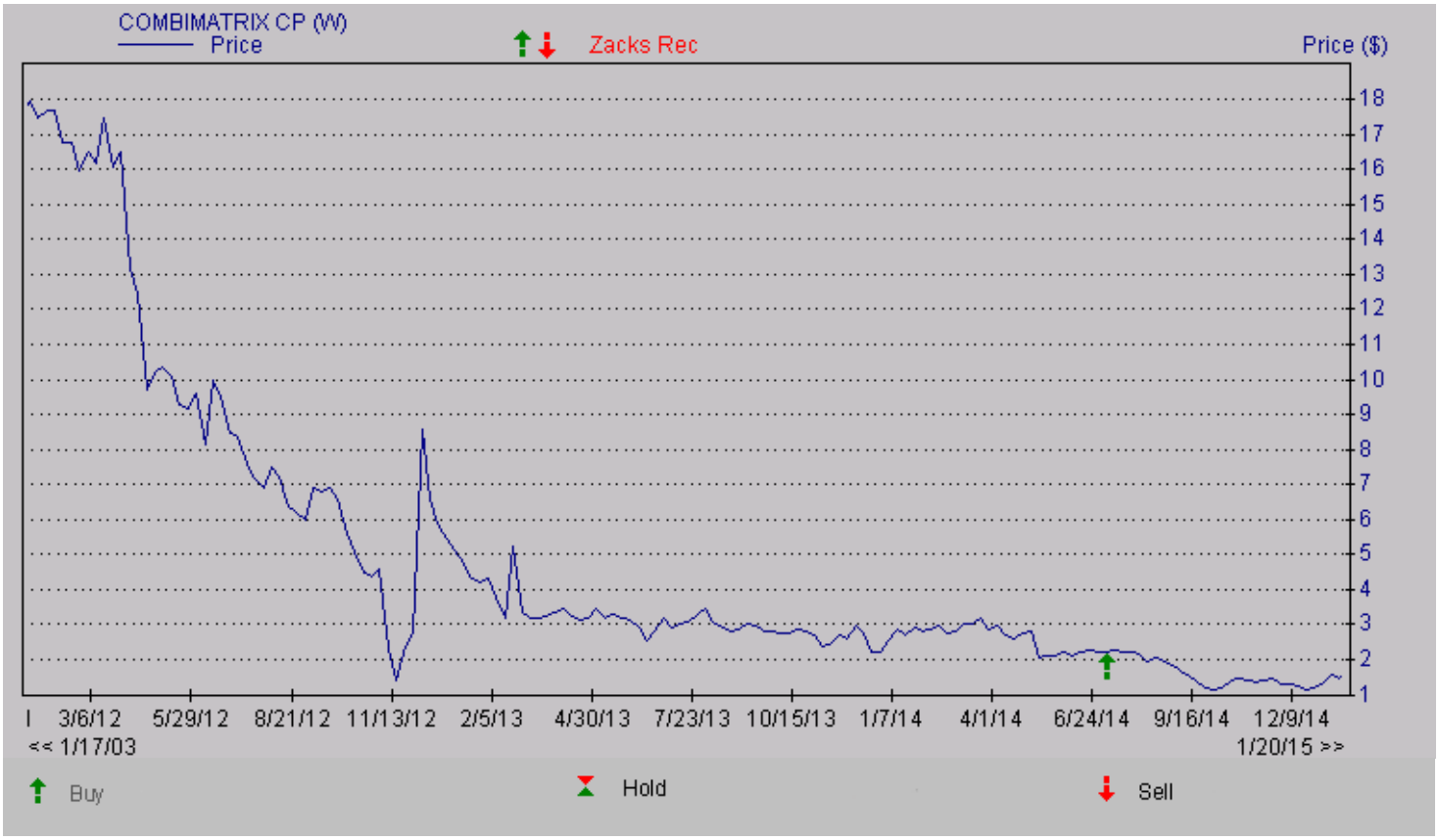
Vice President of Sales & Business Development

Andy Moye has over 8 years of healthcare experience, specifically in sales and business development for diagnostics and life sciences companies. In August 2013, Mr. Moye joined CombiMatrix and has led multiple successful business development partnerships. Currently Mr. Moye serves as the VP for sales and business development, focusing on the commercial aspects of CombiMatrix through direct sales, business development, and product development.

Mr. Moye came to CombiMatrix from Riveron Consulting where he served as Principal for healthcare mergers and acquisitions. Prior to Riveron, Mr. Moye served as VP, Product and Business Development, and VP of Hematology for Caris Life Sciences, which was acquired by Miraca Holdings in 2011. Before joining the healthcare industry, Mr. Moye spent eight years as a Naval Officer flying on P-3C Orion aircraft during Operations Enduring Freedom and Iraqi Freedom.

Mr. Moye received his Bachelor's Degree in Physiology from the University of Arizona and his MBA from the University of Florida.

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