Zacks Small-Cap Research

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CombiMatrix Corporation (CBMX-NASDAQ)

CBMX: Q3 Sets Across-The-Board Records. CF Break-Even Looks Attainable

We use a 10-year DCF model to value CBMX. We model revenue to grow from $10.1M in 2015 to $21M 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 $12/share.

Current Price (11/04/16)	$2.67
Valuation	**$12.00**

OUTLOOK

Positive coverage decisions by have helped push up average reimbursement in the miscarriage segment by 25% in just the last 12 months. This, along with growing demand for miscarriage analysis testing, success of the recently launched PGS (IVF) test, laboratory and operating efficiencies, and concentrating sales efforts in reimbursement-friendly areas is pushing up revenues, margins and cash flow to new records. Fundamentals point to this trend continuing. Our 2016 revenue growth, including +35% from reproductive health services testing, is driven from the recent expansion and increasing productivity of the sales force, new payor contracts, more insurers starting to cover recurrent pregnancy loss testing, increasing number of billable customers, greater awareness of the benefits of CMA analysis, improved pricing and some incremental growth from new products. Shares trade well below what we calculate as fair value.

SUMMARY DATA

52-Week High	**$16.94**
52-Week Low	**$2.20**
One-Year Return (%)	**-82.17**
Beta	**0.70**
Average Daily Volume (sh)	**99,531**
Shares Outstanding (mil)	**2**
Market Capitalization ($mil)	**$6**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**8**
Insider Ownership (%)	**3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**22.7**
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	**Above Avg.,**
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	3107 A	3248 A	3343 E	12671 E
2017					15361 E
2018					18100 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	-$0.89 A	-$0.38 A	-$0.41 E	-$2.64 E
2017					-$1.23 E
2018					-$0.75 E

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

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Q3: New Records In Revenue, Customers, Pricing, Margins, Cash Collections, Profitability

Déjà vu, except even better. CBMX reported financial results for the third quarter ending September 30th. Not only was this the sixth straight quarter of improving profitability but sequential operating loss fell by an impressive 31%, from $1.2M in Q2 2016 to just $846k in Q3, marking the first time that operating loss fell below the $1M mark.

Management has done a noteworthy job of growing the top line through a combination of test volume growth, expansion of the customer base (to a current record of 257), improved cash collections and higher average test pricing (or reimbursement). But, in our opinion, what is even more impressive is that they've done so while also shedding expenses and improving margins. The result has been revenue growing 26% yoy through the first nine months of 2016 (including 29% in Q3) and average gross margin and operating loss improving from 45.6% and $4.9M to 53.6% and $3.5M over the same period.

The company is getting ever-closer to reaching profitability. In the Q2 earnings release management announced their expectations of reaching cash flow positive by Q4 2017 – they reiterated that goal with the Q3 earnings release.

And, importantly, we characterize the improved profitability as 'high quality' and what reasonably could be expected to be replicable given that these are the products of CombiMatrix's direct efforts and/or favorable changes in industry fundamentals. CBMX has been actively engaged in their fate by targeting geographic areas with favorable reimbursement, sponsoring or otherwise supporting evidence-based studies, communicating with payers and optimizing their product portfolio to include cash-pay products. The company's recent implementation of a new compensation model and other efficiency initiatives has resulted in a rapid and substantial shedding of expenses. And favorable changes in payers' coverage decisions, CBMX's investments in billing and collections resources and their deft updates to their product portfolio have contributed to margin expansion and greatly improved cash collections.

As a reminder, following CBMX's announced Q1 results we noted in our May 6th update that "results were what we would characterize as very good in general and even more compelling on the reimbursement side, particularly in miscarriage testing. Q1 could prove to be an inflection point of sorts on the reimbursement and insurance coverage fronts." We doubled-down on that supposition when CBMX reported strong Q2 results. We are tripling down on that with the even stronger results in Q3.

Average pricing in each of the six itemized testing categories continues to be very strong and particularly so in the reproductive health microarray segment (i.e. prenatal, miscarriage analysis and CombyPGS), which is expected to continue generate outsized growth for the company. Average reimbursement in CBMX's reproductive health segment increased by 20% through the first nine months of 2016 as compared to the same period in 2015.

Miscarriage analysis, which accounts for approximately 70% of the reproductive health microarray portfolio's revenue, and just over 50% of CBMX's total diagnostic services revenue, is the main driving force behind the significant increase in average reimbursement as well as the company's total revenue growth. Positive coverage decisions by payers (already 22 have revised in 2016) as a result of more clinical evidence supporting the use of CMA in miscarriage testing along with CBMX's direct efforts in facilitating the customer billing and reimbursement process have helped push up average reimbursement in this segment (i.e. miscarriage testing) by 25% in just the last 12 months. This, along with growing demand for miscarriage analysis testing, success of the recently launched PGS (IVF) test, laboratory and operating efficiencies, and concentrating sales efforts in reimbursement-friendly areas is pushing up revenues, margins and cash flow to new records.

Miscarriage analysis…

We noted in our recent updates that while it appeared recent coverage decisions were making a positive impact to average per test miscarriage pricing, we felt there needed to be more history before we could make a more determined commitment in upwardly revising our forecasted miscarriage reimbursement. But, now with three consecutive quarters of very strong pricing, continued action by more insurers including CMA as 'medically necessary' for the evaluation of pregnancy loss, growing database of evidence supporting the use of CMA and management's industry insight indicating this positive shift will continue, have all contributed to us meaningfully upwardly revising our forecasted miscarriage pricing.

And while miscarriage analysis volumes came in slightly lower than our estimates over the last two quarters, at least a portion of this was due to a certain customer bringing testing in-house. Importantly, CBMX noted on the Q3 call that they added "several large accounts" over the last six months and we fully expect miscarriage testing volumes to accelerate going forward. And despite this miss to our number in Q3, miscarriage volumes and revenue both exhibited strong growth on both yoy and sequential basis.

Miscarriage analysis generated $1.6M in revenue in Q3 on 990 tests sold – this compares to $1.2M (+42%) and 866 (+14%) tests in Q3 2015 and $1.4M (+11%) and 901 (+10%) tests in Q2 2016. Average pricing in Q3 was $1,638 – while not a record, it remained very strong and largely consistent with 1H 2016 ($1,624). Average pricing through the first nine months of 2016 was $1,629, 25% higher than the same period in 2015 ($1,302).

While miscarriage testing had already been a major catalyst to the company's growth, with it now accounting for 50%+ of total revenue, volumes growing in the double digits (save for the non-fundamental slide in Q2) and already carrying one of the highest average payment rates, the recent supporting industry fundamentals and CBMX's plan to dedicate an even greater focus on this area could result in an ever-steepening revenue curve. The recent jump in average pricing is not only benefitting revenue it is also having a dramatic positive effect on margins and profitability. In addition to certain lab efficiencies, the 25% yoy growth in average miscarriage pricing helped push gross margins up by an average of 800 basis points (45.6% vs 53.6%) over the same period. This includes a 1,040 b.p. difference in the most recent quarter (43.6% vs. 54.0%).

IVF (CombiPGS, Multi-PGS, PGD)…

While CombiPGS (IVF test) volumes were largely flat on a sequential basis in Q3, they continue to show strong yoy growth. PGS volume was 199 in Q3, up 57% from 127 in Q3 2015. And while volume was approximately flat from 200 in Q2 2016, importantly average pricing per test continues to demonstrate strong growth both yoy and sequentially. Average pricing in Q3 was $1,437, up 23% from $1,173 in Q3 2015 and 14% higher than Q2 of this year. In fact the relatively strong pricing in the most recent period pushed PGS total revenue up to $286k, which is a new record and 13% higher than the previous best ($252k in Q2 2016). Management noted that PGS pricing is benefitting in part from testing a greater average number of embryos per patient.

CBMX recently launched PGS on a Next Gene Sequencing (NGS) platform which provides benefits of even greater accuracy and greater throughput should further benefit demand and testing volume. CBMX's IVF business could also see incremental benefit from their recently launched multi-cycle PGS offering as well as the more recently introduced PGD test. PGD tests an embryo for specific genetic disorders or genetic abnormalities based on the genetic status of the parents (which may be carriers of certain genetic abnormalities). Similar to PGS, PGD is offered on a per-embryo or multicycle basis. If PGD adoption is as swift as PGS has been, it will be needle-mover for CBMX – this, along with the newly launched PGS-NGS test will be something to keep on eye on. And with all of these tests being cash pay, CBMX avoids being at the mercy of insurers' coverage decisions, making cash flow and collections more predictable.

Prenatal…

Prenatal had slipped fairly consistently over the course of 2015 – going from 324 tests sold in Q1 to just 228 in Q4. Sequential volume has ticked back up to 264 in Q1 and 294 in Q3 of this year, although on a yoy basis volumes are down 8% through the first nine months of the year. We suspect an issue since early 2015 may have been CBMX's distribution partner, Sequenom (SQNM), driving a push of their NIPT tests. And LabCorp's (LH) recent acquisition of Sequenom may shake things up even more. But, on the positive side, management noted that they have been able to pick up some of Sequenom's accounts to which they can now sell direct. As such, we think prenatal could return to consistent sequential growth.

And there are other reasons to be optimistic about the prenatal business. This includes the recent improvement in average reimbursement (up 7% through the first nine months of 2016), recent updated recommendations from ACOG and SMFM (discussed below) supporting the use of CMA for prenatal diagnosis and additional recent clinical evidence highlighting the significant accuracy issues (i.e. susceptibility to high rates of false-positive and false-negative results) of NIPS. And while NIPS demand remains robust, and could benefit further from a recent update by the American College of Medical Genetics and Genomics (ACMGG) recommending use of it for screening of Patau, Edwards and Down Syndrome in place of conventional screening, its accuracy issues mean that CMA will continue to be used as a confirmatory diagnosis. In fact ACMG's recent recommendation notes that*, "For some patients the goal in prenatal screening may be to maximize the detection of fetal genetic diagnoses. In this scenario, fetal diagnostic testing (e.g., chorionic villous sampling or amniocentesis) followed by chromosomal microarray (CMA) using fetal DNA should be offered, and NIPS may not be the best choice."*

Pediatric…

Pediatric volume growth was flattish in 2015. Through the first nine months of 2016 volume fell to 1,454 from 1,557 (-6%) in the same period 2015. But due to a favorable move up in pricing, on a revenue measure pediatric performed slightly better, falling just 2% ($1,687 to $1,647). Despite the recent softness, we continue to think pediatric has some room for incremental volume growth going into 2017.

Non-array…

While not considered CMBX's bread-and-butter focus, non-array has and continues to be an important contributor. Non-array volume and revenue grew 51% and 69%, respectively, in 2015 accounting for almost 10% of total revenue. The first nine months of 2016 saw sequential and yoy volume growth of non-array of 16% and 18%, respectively. But, despite the strong growth of the segment, non-array pricing, while fairly stable, remains at roughly 25% of CBMX's average microarray tests. As such, while still meaningful contributor to revenue, we don't expect this segment to be much of a driver of the top-line or of margins.

Totals…

- Billable tests:
    - Volume: Q3 set a new record in total billable tests at 2,835 – up 14% yoy and 2% sequentially
    - Diagnostic Revenue: Q3 also set a new record in revenue at $3,211 - up 29% yoy and 5% sequentially

- Reproductive Health: this is CBMX's major area of focus.
    - Volume: Q3 set a new record in total billable Reproductive Health tests at 1,483 - up 17% yoy and 6% sequentially
    - Revenue: Q3 set a new record in reproductive health revenue at $2,316 is up 39% yoy and 6% sequentially

	Q3 '15	Q2 '16	Q3 '16
Number of tests			
Prenatal yoy growth	*2.6%*	*-11.2%*	*8.1%*
Prenatal tests	272	302	294
Miscarriage yoy growth	*31.2%*	*-1.6%*	*14.3%*
Miscarriage analysis tests	866	901	990
CombiPGS yoy growth	*#DIV/0!*	*566.7%*	*56.7%*
CombiPGS	127	200	199
Total Reproductive Hlth	**1,265**	**1,403**	**1,483**
prenatal as %of total microarray tests	71%	74%	75%
YOY Growth	*36.8%*	*9.1%*	*17.2%*
Pediatric Microarray	509	497	505
pediatric as %of total microarray tests	29%	26%	25%
YOY Growth	*6.5%*	*-14.5%*	*-0.8%*
Total Microarray tests	1,774	1,900	1,988
microarray %of total tests	71%	68%	70%
YOY Growth	*24.9%*	*1.8%*	*12.1%*
Non-microarray tests	721	880	847
non-microarray %of total tests	29%	32%	30%
YOY Growth	*33.8%*	*20.2%*	*17.5%*
Total Billable tests	**2,495**	**2,780**	**2,835**
YOY Growth	*27.4%*	*7.0%*	*13.6%*
Pricing per test			
Prenatal microrray	$1.353	$1.563	$1.388
Miscarriage analysis	$1.322	$1.617	$1.638
CombiPGS	$1.173	$1.260	$1.437
Total Reproductive Hlth	**$1.314**	**$1.555**	**$1.562**
Pediatric	$1.096	$1.123	$1.166
All microarays	$1.251	$1.442	$1.461
Non-microarays	$0.362	$0.352	$0.361
Total	**$0.994**	**$1.097**	**$1.133**
Total revenue per test			
Prenatal microrray	$368	$472	$408
Miscarriage analysis	$1,145	$1,457	$1,622
CombiPGS	$149	$252	$286
Total Reproductive Hlth	**$1,662**	**$2,181**	**$2,316**
YOY Growth	*26.6%*	*31.9%*	*39.4%*
Pediatric Microarray	$558	$558	$589
YOY Growth	*11.4%*	*-11.4%*	*5.6%*
All microarays	$2,220	$2,739	$2,905
YOY Growth	*20.8%*	*19.8%*	*30.9%*
Non-microarays	$261	$310	$306
YOY Growth	*50.0%*	*30.3%*	*17.2%*
Total	**$2,481**	**$3,049**	**$3,211**
YOY Growth	*23.4%*	*20.8%*	*29.4%*
Diagnostic Svcs	$2,481.0	$3,049.0	$3,211.0
YOY Growth	*23.4%*	*20.8%*	*29.4%*
Royalties	$45.0	$58.0	$37.0
YOY Growth	*-11.8%*	*132.0%*	*-17.8%*
Total Revenues	$2,526.0	$3,107.0	$3,248.0
YOY Growth	*22.5%*	*21.9%*	*28.6%*
Cost of Services	$1,400.0	$1,432.0	$1,476.0
Gross Income	$1,126.0	$1,675.0	$1,772.0
Services Margin	*43.6%*	*53.0%*	*54.0%*

Relative strength in pricing particularly in miscarriage and prenatal, coupled with CBMX's direct efforts in facilitating the customer billing and reimbursement process, pushed service margin up to 54% which is a new record and ahead of our 52% estimate. Service margin in the comparable periods were 43.6% in Q3 2015 and 53% in Q2 2016. The recent big jump in margin, coupled with strong pricing on miscarriage, positive industry fundamentals, recent favorable coverage decisions and CBMX's own successful efforts in facilitating collections have prompted us to make another upward revision to our service margin estimates. In fact management noted that they believe 50%+ GM is sustainable going forward.

Q3 OpEx was $2.6M, significantly better than our $3.2M estimate. CBMX continues to see greater leverage in OpEx with ramping revenue, productivity gains from the sales force and efficiency efforts. Management also noted on the Q3 call that they have implemented a compensation policy for new hires which places greater emphasis on production and which has also had a significant positive benefit to OpEx. Noteworthy is that Q3 witnessed the greatest leverage in operating expenses that CMBX has experienced on not only a percentage of sales basis, but

due to the very strong service margin, even more so on a percentage of gross income basis. Operating expenses were 1.46x gross income in Q3 2016 – this compares to 2.37x in all of 2015, 2.76x in 2014 and 3.16x in 2013. It is also significantly better than the 1.72x in Q2 2016 - the prior best. This highlights how the growth in test volume and improvement in pricing and margins is moving CBMX closer to profitability.

The $3.1M in cash collections also were a new record. CBMX used $813k in cash for operations in Q3 and exited the quarter with $4.3M in cash. Management believes the current cash balance is sufficient to fund operations for at least the next 12 months. Based on the current burn rate and expectations that revenue and profitability continue to improve, it's possible the current cash balance could be sufficient to fund operations until Q4 2017 - which is when management is forecasting being to the point of cash flow break even.

Several Recent Events Could Catalyze Additional Revenue Growth Including; Updated Prenatal Testing Guidelines, Additional Evidence of Superiority of CMA vs. Karyotyping and Beneficial Revisions to Insurers' Coverage Policies…

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

ACOG / SMFM Updated Recommendations Provide Further Support for Use of CMA

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

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

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

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

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

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

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

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

Insurers Revise Policies to Define CMA as 'Medically Necessary' for Recurrent Pregnancy Loss

Since the beginning of this year at least 22 insurers have revised their policies to include coverage of recurrent pregnancy testing. This includes major and mid-tier payers. CBMX recently cited Cigna Health Services, BC/BS of North Carolina, Premera BC/BS and Life Wise of Oregon as revising their medical policies to include CMA as 'medically necessary' for the evaluation of pregnancy loss. 'Medically necessary' essentially means that there is no ambiguity in terms of whether the procedure will be covered. If this trend continues with other insurers revising

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

policies for specific coverage of CMA for pregnancy loss, it would almost certainly be a meaningful benefit to CBMX and demand for their miscarriage analysis tests. The company's strong results in 2016, including setting record sales volume of miscarriage tests, suggests that these recent favorable policy decisions may already be making an impact.

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

OUTLOOK / VALUATION

OUTLOOK

Our 2016 revenue growth, including +35% from reproductive health services testing, is driven from the recent expansion and increasing productivity of the sales force, new payor contracts, more insurers starting to cover recurrent pregnancy loss testing, increasing number of billable customers, greater awareness of the benefits of CMA analysis, improved pricing and some incremental growth from new products. Relative to the sale force, management has noted increased productivity per rep, which they think will continue to help drive revenue higher – we think as additional add-to-the-bag products come online there will be even more room for productivity gains.

Average pricing is one variable that could be particularly influential to updates to our model. As noted, 2016 has seen very strong pricing in miscarriage and gains in IVF and prenatal as well. Beyond 2016 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, 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. Additional new product launches could prompt an upward revision to our forecast, particularly as it relates to our out-years.

VALUATION

We use a 10-year DCF model to value CBMX. We model revenue to grow from $10.1M in 2015 to $21M in 2019. 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. We also do not incorporate contribution from any other new products that CBMX may potentially bring to market through the term of DCF - new product launches, higher rates of revenue growth, markedly better pricing and lower operating expenses (relative to our assumptions) are all potential items that 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 $12/share.

FINANCIAL MODEL

CombiMatrix Corporation

	2015 A	Q1A	Q2A	Q3A	Q4E	2016 E	2017 E	2018 E
Diagnostic Svcs	$9,941.0	$2,930.0	$3,049.0	$3,211.0	$3,302.4	$12,492.4	$15,180.5	$17,900.4
YOY Growth	*25.95%*	*28.12%*	*20.8%*	*29.4%*	*24.7%*	*25.67%*	*21.52%*	*17.92%*
Royalties	$147.0	$42.0	$58.0	$37.0	$42.0	$179.0	$180.0	$200.0
YOY Growth	*-1.34%*	*0.00%*	*132.0%*	*-17.8%*	*20.0%*	*21.8%*	*0.6%*	*11.1%*
Total Revenues	$10,088.0	$2,972.0	$3,107.0	$3,248.0	$3,344.4	$12,671.4	$15,360.5	$18,100.4
YOY Growth	*25.4%*	*27.6%*	*21.9%*	*28.6%*	*24.6%*	*25.6%*	*21.2%*	*17.8%*
Cost of Services	$5,444.0	$1,419.0	$1,432.0	$1,476.0	$1,519.1	$5,846.1	$6,831.2	$7,876.2
Gross Income	$4,644.0	$1,553.0	$1,675.0	$1,772.0	$1,825.3	$6,825.3	$8,529.3	$10,224.2
Services Margin	*46.0%*	*51.6%*	*53.0%*	*54.0%*	*54.0%*	*53.9%*	*55.0%*	*56.0%*
R&D	$466.0	$143.0	$149.0	$88.0	$115.0	$495.0	$555.0	$600.0
% R&D	*4.6%*	*4.8%*	*4.8%*	*2.7%*	*3.4%*	*3.9%*	*3.6%*	*3.3%*
SG&A	$10,519.0	$2,862.0	$2,727.0	$2,505.0	$2,662.4	$10,756.4	$11,229.6	$11,889.3
% SG&A	*104.3%*	*96.3%*	*87.8%*	*77.1%*	*79.6%*	*84.9%*	*73.1%*	*65.7%*
Patent amort. & royalties	$100.0	$25.0	$25.0	$25.0	$25.0	$100.0	$110.0	$110.0
Operating Income	($6,441.0)	($1,477.0)	($1,226.0)	($846.0)	($977.1)	($4,526.1)	($3,365.3)	($2,375.1)
Operating Margin	*-63.8%*	*-49.7%*	*-39.5%*	*-26.0%*	*-29.2%*	*-35.7%*	*-21.9%*	*-13.1%*
Total Other income	($63.0)	($14.0)	($9.0)	($10.0)	($12.0)	($45.0)	($75.0)	($100.0)
Pre-Tax Income	($6,601.0)	($1,491.0)	($1,235.0)	($856.0)	($989.1)	($4,571.1)	($3,440.3)	($2,475.1)
Taxes	$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%*
Preferred Dividends	$890	$1,643	$0	$0	$0	$0	$0	$0
Net Income	($7,491.0)	($3,134.0)	($1,235.0)	($856.0)	($989.1)	($4,571.1)	($3,440.3)	($2,475.1)
YOY Growth	*-14.0%*	*18.0%*	*-23.4%*	*-49.3%*	*-35.6%*	*-39.0%*	*-24.7%*	*-28.1%*
Net Margin	*-74.3%*	*-105.5%*	*-39.7%*	*-26.4%*	*-29.6%*	*-36.1%*	*-22.4%*	*-13.7%*
EPS	($9.02)	($3.63)	($0.89)	($0.38)	($0.41)	($2.64)	($1.23)	($0.75)
YOY Growth	*-23.8%*	*7.5%*	*-53.1%*	*-81.0%*	*-77.5%*	*-70.7%*	*-53.5%*	*-39.0%*
Diluted Shares O/S	831	864	1,382	2,254	2,420	1,730	2,800	3,300

Brian Marckx, CFA

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