Zacks Small-Cap Research

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CombiMatrix Corporation (CBMX-NASDAQ)

CBMX: Q1 Record Results Shows Momentum Continues. CF Positive In Sight

We use a 10-year DCF model to value CBMX. We model revenue to grow from $12.9M in 2016 to $22.0M 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 (05/11/17)	$5.86
Valuation	**$12.00**

OUTLOOK

2016 was somewhat of a transformative year for CBMX in that initiatives that had been put in place to return the company to sustainable growth and improved financial performance became much more obvious as measured by financial and operating metrics. Specifically, 2016 set new records on revenue, gross margin, operating loss and cash collections as well as on test pricing and test volumes – the latter including (the important) miscarriage analysis and overall reproductive health segment. Clearly that momentum has not slowed. Management reiterated expectations of reaching a point of positive operational cash flow by Q4 of this year. We think likelihood of that happening improved even more given the performance in Q1, which further extended records on revenue, gross margin, profitability and cash flow. Revenue jumped 27% yoy and was up 17% from Q4 '16 – which was the prior record. Gross margin surprised fairly substantially on the upside – widening 150 basis points from Q4 (also the prior best) to 59.9% and benefitting from a combination of strong pricing and efficiency initiatives.

SUMMARY DATA

52-Week High	**$6.63**
52-Week Low	**$2.15**
One-Year Return (%)	**87.31**
Beta	**0.99**
Average Daily Volume (sh)	**168,001**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$17**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**12**
Insider Ownership (%)	**3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**24.4**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Blend**
Industry	**Med Diagnostics**

ZACKS ESTIMATES

Revenue
(in 000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	2970 A	3107 A	3248 A	3542 A	12869 A
2017	3787 A	3889 E	4067 E	4158 E	15900 E
2018					18861 E
2019					21994 E

EPS

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$3.63 A	-$0.89 A	-$0.38 A	-$0.22 A	-$2.35 A
2017	-$0.19 A	-$0.17 E	-$0.14 E	-$0.11 E	-$0.62 E
2018					-$0.15 E
2019					$0.06 E

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

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Q1 2017: No Slowing Down, Records Across The Board. CF Positive By Q4 In Sight…

2016 was somewhat of a transformative year for CBMX in that initiatives that had been put in place to return the company to sustainable growth and improve performance became much more obvious as measured by financial and operating metrics. Specifically, 2016 set new records on revenue, gross margin, operating loss and cash collections as well as on test pricing and test volumes – the latter including (the important) miscarriage analysis and overall reproductive health segment.

Clearly that momentum has not slowed. On the Q1 call (which we missed due to a timing conflict) management reiterated their expectations of reaching a point of positive operational cash flow by Q4 of this year. We think likelihood of that happening improved even more given the performance in Q1, which further extended records on revenue, gross margin, profitability and cash flow. Revenue jumped 27% yoy and was up 17% from Q4 '16 – which was the prior record. Gross margin surprised fairly substantially on the upside – widening 150 basis points from Q4 (also the prior best) to 59.9% and benefitting from a combination of strong pricing and efficiency initiatives.

	FY		FY'16		Q1		Q1 '17	
	2015	2016	record?	Change	2016	2017	record?	Change
Revenue (k)	$10,088	$12,869	Y	27.6%	$2,972	$3,787	Y	27.4%
Gross Margin	46.0%	55.0%	Y	900 bp	51.6%	59.9%	Y	830 bp
Oper. Loss (k)	-$6,441	-$4,093	Y	-36.5%	-$1,477	-$517	Y	-65.0%
Cash Collect. (k)	$9,300	$11,800	Y	26.9%	$2,500	$3,400	Y	36.0%
Cash Coll/Rev	92.2%	91.7%	NA	NA	84.1%	89.8%	NA	NA
Avg test price	$994	$1,151	Y	15.8%	$1,106	$1,279	Y	15.6%
Avg Miscarr price	$1,341	$1,677	Y	25.1%	$1,630	$1,843	Y	13.1%
Avg Reprod price	$1,316	$1,587	Y	20.6%	$1,518	$1,739	Y	14.6%
Test volumes	10,002	11,033	Y	10.3%	2,648	2,938	Y	11.0%
Miscarr volumes	3,603	3,915	Y	8.7%	995	1,105	Y	11.1%
Reprod volumes	5,126	5,824	Y	13.6%	1,426	1,642	Y	15.1%

Growth was particularly broad-based in the most recent quarter with volumes of every itemized test category increasing on a yoy basis through Q1 and all but one growing on a sequential basis – and the one product (pediatric) that didn't grow from Q4, fell by just 1%. In fact miscarriage analysis, PGS and the reproductive health segment in general, which represents much of the margin and the bulk of the near-term growth opportunity, all turned in record volumes. Pricing was similarly robust with miscarriage analysis and prenatal microarray, as well as average pricing of all tests combined, setting new record highs in the quarter.

Both revenue and gross margin have now increased on a sequential basis for six straight quarters and operating loss has improved for eight straight quarters. Cash collections are at a record high and cash burn at a record low. Meanwhile, operating expenses as a percent of revenue again reached an all-time low and, we think, will likely trend even lower through the rest of 2017.

The step-wise fashion in which these metrics have improved is telling of management's direct efforts - which has included adding new cash-pay products (such as PGS), sponsoring or otherwise supporting evidence-based studies aimed at expanding reimbursement coverage and adoption of their tests (most notably their bread-and-butter miscarriage analysis tests), investing in billing and collections resources, selective hiring and training of their sales force and closely watching expenses. Much of these efforts have helped to significantly increase both the number of tests sold and the average revenue per test – particularly in their reproductive health segment, which saw testing volumes and average revenue per test increase by 36% and 35%, respectively, over the last two years (i.e. from Q1 '15 to Q1 '17). The combination of growth in both volumes and average pricing has been dramatic as total testing revenue increased 64% over that same period.

And there remain near-term catalysts to extend this record financial performance. This includes the potential that additional payors favorably revise their coverage policies as it relates to recurrent pregnancy loss (at least 25 have done so since January 2016). CBMX is also adding three new reps to their sales force as of mid-May – growing the total to 13. Productivity gains from the sales force have also contributed to sales growth while keeping operating expenses relatively flat – there may be more opportunity in that regard. Additionally, uptake of the PGS test rebounded in Q1 – management indicated that adoption of PGS-NGS (next-gen sequencing) was a contributor –

and we think this may have more room to grow, particularly given that the company recently put a greater emphasis on increasing sales of the test, which has also had a favorable reception from physicians and patients. Prenatal has also shown recent strength which could continue given that CBMX has had some success in picking up some of Sequenom's (i.e. their previous distributor) legacy accounts. And as it relates to pricing, while average revenue per test is at an all-time high, further positive changes in insurers' coverage decisions, incremental improvement in cash collections and outsized growth of cash-pay tests (such as PGS) could all push average pricing even higher. And, finally, bolt-on growth – potentially in the form of acquiring add-to-the-bag products, partnerships or licensing remain on the table of near-term possibilities. In the meantime, expect management to remain very diligent on watching costs and cash flow as there is little doubt about their determination to reach cash flow positive by Q4 2017.

Q1 Totals…

- Billable tests:
  - Volume: 2,938 total billable tests – up 11% yoy, up 6% sequentially
  - Diagnostic Revenue: Q1 set a new record at $3,758 - up 28% yoy and 7% sequentially

- Reproductive Health: this is CBMX's major area of focus.
  - Volume: Q1 set a new record at 1,642 - up 15% yoy and 9% sequentially
  - Revenue: Q1 set a new record at $2,856 is up 32% yoy and 11% sequentially

	Q1 '16	Q4 '16	Q1 '17
Number of tests			
Prenatal yoy growth	*-18.5%*	*28.5%*	*16.3%*
Prenatal tests	264	293	307
Miscarriage yoy growth	*12.8%*	*9.6%*	*11.1%*
Miscarriage analysis tests	995	1029	1105
CombiPGS yoy growth	*#DIV/0!*	*-5.9%*	*37.7%*
CombiPGS	167	190	230
Total Reproductive Hlth	**1426**	**1,512**	**1,642**
prenatal as %of total microarray tests	76%	74%	76%
YOY Growth	*18.24%*	*10.4%*	*15.1%*
Pediatric Microarray	452	520	513
pediatric as %of total microarray tests	24%	26%	24%
YOY Growth	*-3.21%*	*5.5%*	*13.5%*
Total Microarray tests	$1,878	2,032	2,155
microarray %of total tests	71%	73%	73%
YOY Growth	*12.25%*	*9.1%*	*14.7%*
Non-microarray tests	770	738	783
non-microarray %of total tests	29%	27%	27%
YOY Growth	*14.58%*	*5.3%*	*1.7%*
Total Billable tests	**2,648**	**2,770**	**2,938**
YOY Growth	*12.92%*	*8.1%*	*11.0%*
Pricing per test			
Prenatal microrray	$1.216	$1.495	$1.661
Miscarriage analysis	$1.630	$1.810	$1.843
CombiPGS	$1.329	$1.463	$1.343
Total Reproductive Hlth	**$1.518**	**$1.706**	**$1.739**
Pediatric	$1.106	$1.242	$1.181
All microarrays	$1.419	$1.587	$1.606
Non-microarrays	$0.34	$0.381	$0.378
Total	**$ 1.106**	**$ 1.266**	**$ 1.279**
Total revenue per test			
Prenatal microrray	$321	$438	$510
Miscarriage analysis	$1,622	$1,863	$2,037
CombiPGS	$222	$278	$309
Total Reproductive Hlth	**$2,165**	**$2,579**	**$2,856**
YOY Growth	*39.32%*	*37.3%*	*31.9%*
Pediatric Microarray	$500	$646	$606
YOY Growth	*0.20%*	*20.7%*	*21.2%*
All microarrays	$2,665	$3,225	$3,462
YOY Growth	*29.94%*	*33.7%*	*29.9%*
Non-microarrays	$265	$281	$296
YOY Growth	*12.29%*	*19.1%*	*11.7%*
Total	**$ 2,930**	**$ 3,506**	**$ 3,758**
YOY Growth	*28.12%*	*32.4%*	*28.3%*
Diagnostic Svcs	$2,930.0	$3,506.0	$3,758.0
YOY Growth	*28.12%*	*32.4%*	*28.3%*
Royalties	$42.0	$36.0	$29.0
Total Revenues	$2,972.0	$3,542.0	$3,787.0
YOY Growth	*27.6%*	*32.0%*	*27.4%*
Cost of Services	$1,419.0	$1,460.0	$1,508.0
Gross Income	$1,553.0	$2,082.0	$2,279.0
Services Margin	*51.6%*	*58.4%*	*59.9%*

The widening of gross margin has also been a major impetus for the consistent improvement in operating loss. As noted, increase in test pricing – particularly in the reproductive health segment, coupled with lab efficiencies, favorable changes in insurers' coverage policy and CBMX's direct efforts in facilitating the customer billing and reimbursement process have all contributed. While we expect service margin in 2017 to increase relative to 2016, we are not modeling any incremental growth from the Q1 '17 level given that changes in product and payer mix can have some influence and likely favorably affected margin in the most recent quarter. Nonetheless, we think further growth in average reimbursement would likely benefit margins.

Q1 OpEx was $2.8M, while slightly higher than our $2.7M estimate it was about 8% lower than the comparable prior-year period. OpEx has been relatively flattish over the last 9 quarters – over the same period revenue has increased by 62% (Q1 '15 vs Q1 '17). This has resulted in substantial improvement in operating leverage as measured by OpEx as a percentage of revenue – which has gone from 152% in 2014, 108% in 2015, 86% in 2016 and to a record low of 73.2% in Q1 2017. That improvement has also been reflected in the greatly decreased cash burn.

The $3.4M in cash collections in Q1 also was a new record. CBMX used $495k in cash for operations in Q1, down from $539k in Q4 '16 and from $1.7M in Q1 '16. Cash balance at quarter-end was $3.2M, compared to $3.7M at the close of 2016. 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, we think the current cash balance should be more than sufficient to fund operations until Q4 2017 - which is when management is forecasting being to the point of cash flow break even.

Operational Update:

Miscarriage analysis…

Over five consecutive quarters we have seen very strong pricing of miscarriage analysis testing, continued action by more insurers including CMA as 'medically necessary' for the evaluation of pregnancy loss and a growing database of evidence supporting the use of CMA. Since January 2016 at least 25 payors have updated their coverage policies relative to miscarriage testing. Management, using their industry insight, has indicated that they believe this positive shift will continue.

Another reason for the rapid miscarriage revenue growth has been retraining of the company's sales force – management noted on a recent earnings call that at around mid-2016 they had their sales reps focus almost entirely on building their miscarriage franchise. This appears to have paid dividends as CBMX recently noted that they added several large accounts. We expect, based on the industry fundamentals and CBMX's direct efforts to capitalize on them, to result in continued growth of their miscarriage testing products.

Miscarriage analysis generated $2.0M in revenue in Q1 on 1,105 tests sold – this compares to $1.6M (+26%) and 995 (+11%) tests in Q1 2016 and $1.9M (+9%) and 1,029 (+7%) tests in Q4 2016. Average pricing per test in Q1 was $1,843, a new record and up from $1,630 (+13%) in Q1 2016 and $1,810 (+2%) in Q4 2016.

While miscarriage testing had already been a major catalyst to the company's growth, with it now accounting for about 54% of total revenue, growing volumes and a rapid increase in average pricing, coupled with recent supporting industry fundamentals and CBMX's continued dedicated focus on this area, there is no sign that revenue will slow. The recent jump in average pricing is not only benefitting revenue, it is also having a dramatically positive effect on margins and profitability.

IVF (CombiPGS, Multi-PGS, PGD)…

CombiPGS (IVF test) volumes grew 37% yoy and were up 21% from Q4 2016 to 230 in Q1. Volumes had effectively stalled around the 190 – 200 tests per quarter range throughout 2016 as CBMX had shifted more of its focus towards growing their miscarriage analysis tests. But a renewed focus on growing PGS volumes through sales force retraining (included as part of their national sales meeting in January 2017), similar to what helped grow miscarriage analysis in 2016, as well as installing one of their lead IVF reps to head the IVF sales effort, seems to be bearing fruit. Additionally, management noted on the Q1 call that PGS-NGS demand has picked up and contributed to growth in the quarter.

PGS pricing dipped about 8% sequentially but was just slightly better than flat from the comparable prior-year period. The significant jump in volume helped to push PGS revenue to $309k in Q1 – a record high and representing yoy and sequential growth of 39% and 11%, respectively.

Prenatal…
Prenatal volumes were generally flat in 2016 compared to the prior year and averaged approximately 290 tests per quarter. As we noted in the recent past, we think one issue since around early 2015 has been CBMX's distribution partner, Sequenom, driving a push of their NIPT tests. And LabCorp's (LH) recent acquisition of Sequenom likely shook things up even more. On the positive side, management recently noted that they were able to pick up some of Sequenom's accounts to which they can now sell direct. This appears to be now showing up in the numbers as prenatal volume and revenue grew 16% and 59% from Q1 2016 – the big jump in revenue also reflects a 37% increase in average pricing. In fact at $1,661 per test, pricing looks like be at a record high – management attributed the strength in pricing to favorable payor mix.

In addition to onboarding of additional accounts and recent increase in pricing, we continue to think there are other reasons to be optimistic about the prenatal business. This includes 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 and fell about 4% in 2016, although volume in the second half of '16 was up about 2% yoy. Q1 2017 volume was 513, up 14% yoy but down 1% from Q4 2016. Despite the recent softness in volumes, we continue to think pediatric has some room for incremental volume growth through the remainder of 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 15% and 20%, respectively, in 2016 accounting for approximately 9% of total diagnostic services revenue. Q1 2017 saw non-array volume increase 2% yoy and 6% sequentially. But, despite pricing of non-array continuing to grow, it 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.

Several Potential Catalysts to Additional Revenue Growth Include; Updated Prenatal Testing Guidelines, Additional Evidence of Superiority of CMA vs. Karyotyping, Beneficial Revisions to Insurers' Coverage Policies, Possible New Products…

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

[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

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 2016 at least 25 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 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 and through Q1 2017, including setting record sales volume and average pricing of miscarriage tests, suggests that these recent favorable policy decisions have been making a positive 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.

Expect Any New Products Will Be 'Add-to-the-Bag' and Accretive..

We also expect CBMX will remain diligent in seeking additional products to add to their portfolio – but are also confident that they are looking for only products that offer a seamless fit into their existing infrastructure and footprint. Our expectation is that any product acquisitions would be in the 'add-to-the-bag' category – that is, only products that can be detailed at existing call points with existing sales and marketing infrastructure and that can be immediately accretive to cash flow.

Management has done an impressive job in controlling costs and improving productivity of the sales force – operating expenses have remained roughly flat over the last 9 quarters while revenue increased by 62% over the same period. That was not by accident. Management runs a tight ship and as such, we expect any new product that comes aboard will carry its own weight.

OUTLOOK / VALUATION

OUTLOOK

Our 2017 revenue growth, including 28% from reproductive health services testing, is driven from continued productivity gains 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 sales force, management noted that they expect to bring on three additional reps in mid-May, bringing the total to 13. Management's goal is for each of the field reps to be generating between $1M and $2M in annual sales. The company believes there are more productivity gains to be made in 2017, particularly with newer reps who should have an opportunity to make relatively significant near-term strides. As management further indicated that they do not expect to add additional sales personnel in the near-term, although will consider incremental additions if conditions warrant, this further implies that we should continue to see consistent improvement in operating loss and cash burn.

In terms of pricing – this is one variable that could be particularly influential to updates to our model. As noted, 2016 saw very strong pricing gains in all of the reproductive health tests; miscarriage, PGS and prenatal – the trend was similar in Q1 2017. 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. CBMX recently brought on Dr. James Wheless, a renowned expert in pediatric neurology, to their Scientific Advisory Board. Management has talked about a desire to expand their product portfolio and the addition of Dr. Wheless may provide additional impetus in that direction.

VALUATION

We use a 10-year DCF model to value CBMX. We model revenue to grow from $12.9M in 2016 to $22.0M in 2019. We believe our revenue estimates are reasonable, particularly as out our out-year number assumes less than 15% 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

	2016 A	Q1A	Q2E	Q3E	Q4E	2017 E	2018 E	2019 E
Diagnostic Svcs	$12,696.0	$3,758.0	$3,852.6	$4,030.7	$4,122.1	$15,763.4	$18,661.0	$21,817.8
YOY Growth	*27.71%*	*28.3%*	*26.4%*	*25.5%*	*17.6%*	*24.16%*	*18.38%*	*16.92%*
Royalties	$173.0	$29.0	$36.0	$36.0	$36.0	$137.0	$200.0	$176.0
YOY Growth	*17.7%*	*-31.0%*	*-37.9%*	*-2.7%*	*0.0%*	*-20.8%*	*46.0%*	*-12.0%*
Total Revenues	$12,869.0	$3,787.0	$3,888.6	$4,066.7	$4,158.1	$15,900.4	$18,861.0	$21,993.8
YOY Growth	*27.6%*	*27.4%*	*25.2%*	*25.2%*	*17.4%*	*23.6%*	*18.6%*	*16.6%*
Cost of Services	$5,787.0	$1,508.0	$1,637.4	$1,713.1	$1,731.3	$6,589.7	$7,744.3	$9,054.4
Gross Income	$7,082.0	$2,279.0	$2,251.3	$2,353.7	$2,426.8	$9,310.7	$11,116.7	$12,939.4
Services Margin	*55.0%*	*59.9%*	*57.5%*	*57.5%*	*58.0%*	*58.6%*	*58.5%*	*58.5%*
R&D	$493.0	$85.0	$114.0	$111.0	$108.0	$418.0	$530.0	$595.0
% R&D	*3.8%*	*2.2%*	*2.9%*	*2.7%*	*2.6%*	*2.6%*	*2.8%*	*2.7%*
SG&A	$10,582.0	$2,686.0	$2,600.9	$2,620.4	$2,605.0	$10,512.3	$10,951.3	$11,986.6
% SG&A	*82.2%*	*70.9%*	*66.9%*	*64.4%*	*62.6%*	*66.1%*	*58.1%*	*54.5%*
Patent amort. & royalties	$100.0	$25.0	$25.0	$25.0	$25.0	$100.0	$100.0	$100.0
Operating Income	($4,093.0)	($517.0)	($488.7)	($402.7)	($311.2)	($1,719.5)	($464.6)	$257.8
Operating Margin	*-31.8%*	*-13.7%*	*-12.6%*	*-9.9%*	*-7.5%*	*-10.8%*	*-2.5%*	*1.2%*
Total Other income	($47.0)	($1.0)	($16.0)	($17.0)	($18.0)	($52.0)	($22.0)	($36.0)
Pre-Tax Income	($4,140.0)	($518.0)	($504.7)	($419.7)	($329.2)	($1,771.5)	($486.6)	$221.8
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	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	($4,140.0)	($518.0)	($504.7)	($419.7)	($329.2)	($1,771.5)	($486.6)	$221.8
YOY Growth	*-44.7%*	*-83.5%*	*-59.1%*	*-51.0%*	*-41.0%*	*-57.2%*	*-72.5%*	*-145.6%*
Net Margin	*-32.2%*	*-13.7%*	*-13.0%*	*-10.3%*	*-7.9%*	*-11.1%*	*-2.6%*	*1.0%*
EPS	($2.35)	($0.19)	($0.17)	($0.14)	($0.11)	($0.62)	($0.15)	$0.06
YOY Growth	*-74.0%*	*-94.8%*	*-80.6%*	*-62.2%*	*-48.4%*	*-73.8%*	*-76.0%*	*-143.6%*
Diluted Shares O/S	1,765	2,761	2,915	2,920	2,925	2,880	3,300	3,450

Brian Marckx, CFA

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