Zacks Small-Cap Research

February 27, 2017

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

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

CombiMatrix Corporation (CBMX-NASDAQ)

CBMX: Q4 New Records On Almost Every Measure. Still Guiding CF B/E in Q4 '17

We use a 10-year DCF model to value CBMX. We model revenue to grow from $12.9M in 2016 to $21.7M 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 (02/27/17)	$4.70
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 2017 revenue growth, including 25% 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.

SUMMARY DATA

52-Week High	**$7.96**
52-Week Low	**$2.15**
One-Year Return (%)	**4.07**
Beta	**0.90**
Average Daily Volume (sh)	**313,676**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$12**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**14**
Insider Ownership (%)	**3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**23.5**
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-Value**
Industry	**Instru-Scientfc**

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	3587 E	3884 E	4067 E	4158 E	15695 E
2018					18581 E
2019					21722 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	-$0.28 E	-$0.26 E	-$0.19 E	-$0.16 E	-$0.89 E
2018					-$0.30 E
2019					-$0.04 E

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

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

Q4: New Records On Almost Every Measure. Mgmt Still Guiding CF Positive Q4 '17

Some things only change for the better. That continues to be the story with CBMX's operational and financial results. The company reported Q4 earnings last week which set new records on revenue, gross margin, profitability and cash collections. The strong financial performance was largely the product of their bread-and-butter reproductive health microarray portfolio (i.e. prenatal, miscarriage and CombiPGS/IVF) – which turned in not only a record number of tests in the quarter, but did so at a record average revenue per test. The most significant driving force in the reproductive health portfolio has been miscarriage analysis testing – which also set new records on both volume and average price per test.

As we have noted in the past, the company's financial performance is a direct result of execution of management's strategy. 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, sales force training and their deft updates to their product portfolio have contributed to margin expansion and greatly improved cash collections.

Additionally, as financial performance has been the product of a diversified array of improvements related to the industry, market, reimbursement, customer base and the company, this in our opinion minimizes any 'three-legged stool' risk. We also think it being a diversified basket of fundamentals which have contributed to CBMX's recent financial successes is one of the reasons why management remains confident that growth in revenue, profitability and cash flow will continue to grow.

The full year numbers attest to the progress and significant success that management has made. FY2016 revenue increased 28%, GM expanded 900 b.p. and operating loss fell by $2.3M (or 37%) compared to 2015. Over the same period test volumes increased 10%, with reproductive health test volumes growing almost 14%. Meanwhile, average revenue per test increased 16%, with revenue per test in the reproductive health segment increasing almost 21% (see table below).

As we explained in a recent investor note, while increasing test volumes have been an important catalyst to the company's financial performance, an increase in average test pricing has been an even more significant component. Average pricing of all tests ($1,266 in Q4 '16, $1,151 in FY '16) and of the reproductive health segment ($1,706 in Q4 '16, $1,587 in FY '16) set a new quarterly and annual record in Q4 and FY2016.

We think perhaps the most remarkable part of the improved financial performance has been management's ability to actually shed operating expenses throughout 2016 while delivering what amounted to average sequential quarterly revenue growth of about 7.2%. This highlights the significant operating efficiencies and improved productivity of the company's sales force. And on top of that, gross margins also showed consistent improvement throughout the year, growing from 46.5% in Q4 2015 to 58.4% in Q4 2016. Gross margin improvement is coming from a combination of lower test-processing costs and higher average per test pricing.

We note that oftentimes rapid revenue growth comes with an even greater increase in operating expenses – an outcome that often proves more pyrrhic than shareholder friendly. While this seems to be particularly prevalent in the microcap space, it has not been the case with CBMX as a result of management's stringent focus on cost-control and wringing out laboratory and other operating efficiencies. This is evidenced by their operating loss which has also shown consistent narrowing throughout the course of 2016 and came in at just $544k in Q4, the slimmest in history and down from $1.5M in the comparable prior-year period. Management again reiterated their expectation of reaching a point of positive cash flow generation by Q4 2017.

The compilation of financial and test-related metrics in the table below, almost all of which set new quarterly and annual records through 12/31/2016, illustrates the broad-based improvement over the last 12 months. And while test volumes in Q4 '16 were not a new record, the reason was a 109 test sequential drop in (lower priority and lower margin) non-microarray volumes from Q3 '16 – the period with the greatest volume of tests (2,835). Meanwhile, reproductive health test volumes, at 1,512 in Q4 '16 was a new record as was the 1,029 miscarriage tests.

	Q4				FY			
	2015	2016	Q4 '16 record?	Change	2015	2016	FY'16 record?	Change
Revenue (k)	$2,684	$3,542	Y	32.0%	$10,088	$12,869	Y	27.6%
Gross Margin	46.5%	58.4%	Y	1,190 bp	46.0%	55.0%	Y	800 bp
Oper. Loss (k)	-$1,520	-$544	Y	-64.2%	-$6,441	-$4,093	Y	-36.5%
Cash Collect. (k)	$2,300	$3,300	Y	43.5%	$9,300	$11,800	Y	26.9%
Cash Coll/Rev	87%	94%	NA	7.0%	NA	NA	NA	NA
Avg test price	$1,034	$1,266	Y	22.4%	$994	$1,151	Y	15.8%
Avg Miscarr price	$1,452	$1,810	Y	24.7%	$1,341	$1,677	Y	25.1%
Avg Reprod price	$1,372	$1,706	Y	24.3%	$1,316	$1,587	Y	20.6%
Test volumes	2,563	2,770	N	8.1%	10,002	11,033	Y	10.3%
Miscarr volumes	939	1,029	Y	9.6%	3,603	3,915	Y	8.7%
Reprod volumes	1,369	1,512	Y	10.4%	5,126	5,824	Y	13.6%

Miscarriage analysis, which accounts for approximately 72% 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 (at least 23 have revised since beginning of 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…

Over four 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. 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 the Q4 call that at around mid-2016 they had their sales reps focus almost entirely on building their miscarriage franchise.

And while miscarriage analysis volumes came in slightly lower than our estimates over the last three quarters, at least a portion of this was due to a certain customer bringing testing in-house. Importantly, CBMX recently noted that they added "several large accounts" and we fully expect miscarriage testing volumes to accelerate going forward. And despite this miss to our volume estimate in Q4, miscarriage testing volumes continue to grow on both a sequential and yoy basis and revenue actually beat our number in the most recent quarter as a result of better than expected pricing.

Miscarriage analysis generated $1.9M in revenue in Q4 on 1,029 tests sold – this compares to $1.4M (+37%) and 939 (+10%) tests in Q4 2015 and $1.6M (+15%) and 990 (+4%) tests in Q3 2016. Average pricing in Q4 was $1,810, a new record and up 25% from $1,452 in Q4 2015. Average pricing through the full year 2016 was $1,677, 25% higher than in 2015 ($1,341).

While miscarriage testing had already been a major catalyst to the company's growth, with it now accounting for just over 50% of total revenue, growing volumes and a rapid increase in average pricing, coupled with 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 dramatically 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 1,190 basis points (46.5% vs 58.4%) in Q4 and by 900 basis points for the full year 2016 (46.0% vs 55.0%).

IVF (CombiPGS, Multi-PGS, PGD)…
CombiPGS (IVF test) volumes were down 5% on a sequential basis and down 6% yoy in Q4. Volumes seemed to stall around the 190 – 200 tests per quarter range throughout 2016. Management addressed as much on the Q4 call, noting that they attribute the lack of growth to their recent hyper-focus on miscarriage analysis. But with 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, management expects PGS volumes to return to growth.

And while PGS volume growth has recently fallen flat, average pricing has shown considerable growth. Average PGS pricing per test was $1,463 in Q4, up 2% sequentially and 33% yoy. For the full year 2016, average pricing was $1,373 per test, up 20% from $1,145 in 2015. Management attributes at least a portion of the improved pricing to an increase in the average number of embryos per case (~3.5 in Q4 '15 to ~5 in Q4 '16).

So despite the mid-single digit contraction in volumes, the increase in pricing resulted in Q4 '16 PGS revenue falling just 3% sequentially and actually growing 25% from the same period in 2015.

CBMX recently launched PGS on a Next Generation 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 was after launch, it will be needle-mover for CBMX – this, along with the newly launched PGS-NGS test and the fruits from the retrained sales force will be something to keep an 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 volumes were generally flat in 2016 compared to the prior year and averaged approximately 290 tests per quarter. Q4 '16 volume was 293 tests, while up almost 29% yoy, this was flat from the 294 tests in Q3 '16. For the full year 2016 prenatal volume was 1,153, roughly even with the 1,164 tests in 2015.

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.

We see the prenatal business as somewhat more difficult to model than some other of CBMX's products given that some industry dynamics and company fundamentals should benefit growth while others are likely to have the opposite effect.

But we continue to think there are reasons to be optimistic about the prenatal business. This includes the recent improvement in average reimbursement (up 10% in 2016 vs 2015), 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. And despite the slip in volume for the full year, pediatric revenue actually ticked up 3% ($2,222 2015 vs. $2,293 2016) from 2015 due to a favorable 7% move up in pricing. Despite the recent softness in volumes, we continue to think pediatric has some room for incremental volume growth going in 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. Q4 '16 saw non-array volume increase 5% yoy but fall 13% 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.

Q4 Totals…

- Billable tests:
  - Volume: 2,770 total billable tests – up 8% yoy, down 2% sequentially (due to decrease in non-array)
  - Diagnostic Revenue: Q4 set a new record at $3,506 - up 32% yoy and 9% sequentially

- Reproductive Health: this is CBMX's major area of focus.
  - Volume: Q4 set a new record in total billable Reproductive Health tests at 1,512 - up 10% yoy and 2% sequentially
  - Revenue: Q4 set a new record in reproductive health revenue at $2,579 is up 37% yoy and 11% sequentially

	Q4 '15	Q3 '16	Q4 '16
Number of tests			
Prenatal yoy growth	*-17.7%*	*8.1%*	*28.5%*
Prenatal tests	228	294	293
Miscarriage yoy growth	*10.6%*	*14.3%*	*9.6%*
Miscarriage analysis tests	939	990	1029
CombiPGS yoy growth	*#DIV/0!*	*56.7%*	*-5.9%*
CombiPGS	202	199	190
Total Reproductive Hlth	**1,369**	**1,483**	**1,512**
prenatal as %of total microarray tests	74%	75%	74%
YOY Growth	*21.6%*	*17.2%*	*10.4%*
Pediatric Microarray	493	505	520
pediatric as %of total microarray tests	26%	25%	26%
YOY Growth	*-8.0%*	*-0.8%*	*5.5%*
Total Microarray tests	1,862	1,988	2,032
microarray %of total tests	73%	70%	73%
YOY Growth	*12.0%*	*12.1%*	*9.1%*
Non-microarray tests	701	847	738
non-microarray %of total tests	27%	30%	27%
YOY Growth	*12.0%*	*17.5%*	*5.3%*
Total Billable tests	**2,563**	**2,835**	**2,770**
YOY Growth	*12.0%*	*13.6%*	*8.1%*
Pricing per test			
Prenatal microrray	$1.285	$1.388	$1.495
Miscarriage analysis	$1.452	$1.638	$1.810
CombiPGS	$1.099	$1.437	$1.463
Total Reproductive Hlth	**$1.372**	**$1.562**	**$1.706**
Pediatric	$1.085	$1.166	$1.242
All microarrays	$1.296	$1.461	$1.587
Non-microarrays	$0.337	$0.361	$0.381
Total	**$ 1.034**	**$ 1.133**	**$ 1.266**
Total revenue per test			
Prenatal microrray	$293	$408	$438
Miscarriage analysis	$1,363	$1,622	$1,863
CombiPGS	$222	$286	$278
Total Reproductive Hlth	**$1,878**	**$2,316**	**$2,579**
YOY Growth	*32.6%*	*39.4%*	*37.3%*
Pediatric Microarray	$535	$589	$646
YOY Growth	*-4.3%*	*5.6%*	*20.7%*
All microarrays	$2,413	$2,905	$3,225
YOY Growth	*22.1%*	*30.9%*	*33.7%*
Non-microarrays	$236	$306	$281
YOY Growth	*12.9%*	*17.2%*	*19.1%*
Total	**$ 2,649**	**$ 3,211**	**$ 3,506**
YOY Growth	*21.2%*	*29.4%*	*32.4%*
Diagnostic Svcs	$2,649.0	$3,211.0	$3,506.0
YOY Growth	*21.2%*	*29.4%*	*32.4%*
Royalties	$35.0	$37.0	$36.0
YOY Growth	*12.9%*	*-17.8%*	*2.9%*
Clinical Trial Supt Svcs	$0.0	$0.0	$0.0
YOY Growth	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*
Total Revenues	$2,684.0	$3,248.0	$3,542.0
YOY Growth	*21.1%*	*28.6%*	*32.0%*
Cost of Services	$1,416.0	$1,476.0	$1,460.0
Gross Income	$1,268.0	$1,772.0	$2,082.0
Services Margin	*46.5%*	*54.0%*	*58.4%*

Relative strength in pricing particularly in the reproductive health segment, lab efficiencies and CBMX's direct efforts in facilitating the customer billing and reimbursement process, pushed service margin up to 58.4% in Q4 which is not only a new record but ahead of the prior best by an impressive 440 basis points. Service margin in the comparable periods were 46.5% in Q4 2015 and 54% in Q3 2016 (the prior record). While we believe there may be some more room for service margin to grow in 2017, we do not expect any further improvement to mirror the 900 b.p. widening from 2015 to 2016. But, we think further growth in average reimbursement would likely benefit margins. Management continues to expect that 50%+ GM is sustainable going forward.

Q4 OpEx was $2.6M and better than our $2.8M 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 a recent call that they 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 operating leverage has shown a regular and consistent improvement with Q4 witnessing 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 1.25x gross income in Q4 2016 – this compares to 1.46x in Q3 ’16 (the prior best), 1.72x in Q2 ’16, 1.94x in Q1 ’16 and 2.37x in all of 2015. This highlights how the growth in test volume and improvement in pricing and margins is moving CBMX closer to profitability.

The $3.3M in cash collections in Q4 also was a new record. CBMX used $539k in cash for operations in Q4, down from $813k in Q3 ’16. Cash balance at year end was $3.7M. 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.

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 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"

[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

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 23 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, 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 remained roughly flat from 2015 to 2016 as revenue grew almost 28% 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 25% 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 currently have 12 people, including 10 field reps, a VP of Sales and a Director of IVF. 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. 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 $21.7M 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	Q1E	Q2E	Q3E	Q4E	2017 E	2018 E	2019 E
Diagnostic Svcs	$12,696.0	$3,550.5	$3,848.1	$4,030.7	$4,122.1	$15,551.4	$18,381.1	$21,546.3
YOY Growth	*27.71%*	*21.2%*	*26.2%*	*25.5%*	*17.6%*	*22.49%*	*18.20%*	*17.22%*
Royalties	$173.0	$36.0	$36.0	$36.0	$36.0	$144.0	$200.0	$176.0
YOY Growth	*17.7%*	*-14.3%*	*-37.9%*	*-2.7%*	*0.0%*	*-16.8%*	*38.9%*	*-12.0%*
Total Revenues	$12,869.0	$3,586.5	$3,884.1	$4,066.7	$4,158.1	$15,695.4	$18,581.1	$21,722.3
YOY Growth	*27.6%*	*20.7%*	*25.0%*	*25.2%*	*17.4%*	*22.0%*	*18.4%*	*16.9%*
Cost of Services	$5,787.0	$1,562.2	$1,693.2	$1,753.4	$1,772.5	$6,781.3	$7,903.9	$9,264.9
Gross Income	$7,082.0	$2,024.3	$2,191.0	$2,313.4	$2,385.6	$8,914.2	$10,677.2	$12,457.4
Services Margin	*55.0%*	*56.0%*	*56.0%*	*56.5%*	*57.0%*	*56.8%*	*57.0%*	*57.0%*
R&D	$493.0	$128.0	$144.0	$145.0	$137.0	$554.0	$580.0	$625.0
% R&D	*3.8%*	*3.6%*	*3.7%*	*3.6%*	*3.3%*	*3.5%*	*3.1%*	*2.9%*
SG&A	$10,582.0	$2,573.1	$2,685.2	$2,633.2	$2,649.0	$10,540.6	$10,974.2	$11,838.6
% SG&A	*82.2%*	*71.7%*	*69.1%*	*64.8%*	*63.7%*	*67.2%*	*59.1%*	*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)	($701.8)	($663.2)	($489.9)	($425.5)	($2,280.4)	($977.0)	($106.3)
Operating Margin	*-31.8%*	*-19.6%*	*-17.1%*	*-12.0%*	*-10.2%*	*-14.5%*	*-5.3%*	*-0.5%*
Total Other income	($47.0)	($15.0)	($16.0)	($17.0)	($18.0)	($66.0)	($22.0)	($36.0)
Pre-Tax Income	($4,140.0)	($716.8)	($679.2)	($506.9)	($443.5)	($2,346.4)	($999.0)	($142.3)
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)	($716.8)	($679.2)	($506.9)	($443.5)	($2,346.4)	($999.0)	($142.3)
YOY Growth	*-44.7%*	*-77.1%*	*-45.0%*	*-40.8%*	*-20.5%*	*-43.3%*	*-57.4%*	*-85.8%*
Net Margin	*-32.2%*	*-20.0%*	*-17.5%*	*-12.5%*	*-10.7%*	*-14.9%*	*-5.4%*	*-0.7%*
EPS	($2.35)	($0.28)	($0.26)	($0.19)	($0.16)	($0.89)	($0.30)	($0.04)
YOY Growth	*-74.0%*	*-92.4%*	*-71.0%*	*-49.6%*	*-24.7%*	*-62.2%*	*-65.9%*	*-86.4%*
Diluted Shares O/S	1,765	2,600	2,625	2,650	2,700	2,644	3,300	3,450

Brian Marckx, CFA

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



© Copyright 2017, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Brian Marckx, CFA, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.