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Zacks Small-Cap Research

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

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

CombiMatrix Corporation (CBMX-NASDAQ)

CBMX: Results Remain Very Strong, Despite Record Revenue Streak Ending

The value that CBMX shareholders will ultimately receive, assuming the transaction closes, will be influenced by NVTA share price as well as CBMX's net cash balance at time of consummation. Our proxy price is derived simply by multiplying NVTA's current share price ($8.95) by the midway point (0.88) of the implied range in exchange ratio (0.843 to 0.9115) of NVTA shares to be received per CBMX share based on management's (at the time of the merger announcement) estimated price per share ($8.00 to $8.65) that CBMX shareholders would receive at an assumed NVTA share price of $9.49.

Current Price (11/09/17)	$7.18
Valuation	**$7.90**

OUTLOOK

CBMX reported financial results for Q3. While financial results remained very strong, the streak of setting a new record on revenue ended with Q2 2017, which marked the seventh consecutive period. Gross margin was also slightly lower in Q3 than it was in Q2 of this year. But, as we detail in our report, there were several positives in the quarter.

And while miscarriage analysis revenue, which accounts for more than 50% of total testing revenue, did not set a new record, it was the second highest in history. The big sequential jump in CombiPGS volumes is particularly noteworthy given that CBMX had recently put a renewed focus on growing this product. PGS has been a tremendous success – Q3 2015 was the first full period for the product on the market and in just two years' time, it is generating an annual revenue run rate of $2M (~13% of total revenue). Clearly the miscarriage and reproductive health testing portfolio as a whole continues to perform extraordinarily well. Reimbursement across all of the products was also relatively strong in Q3.

SUMMARY DATA

52-Week High	**$8.20**
52-Week Low	**$2.20**
One-Year Return (%)	**206.25**
Beta	**0.86**
Average Daily Volume (sh)	**39,328**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$22**
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 (%)	**25.2**
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	**Above Avg.,**
Type of Stock	**Small-Growth**
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	4241 A	4012 A	4247 E	16287 E
2018					19065 E
2019					22283 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	-$0.13 A	-$0.21 A	-$0.17 E	-$0.69 E
2018					-$0.08 E
2019					$0.22 E

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

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Q3 2017: Results Remain Very Strong, Despite Record Revenue Streak Ending…

CBMX reported financial results for Q3. While financial results remained very strong, the streak of setting a new record on revenue ended with Q2 2017, which marked the seventh consecutive period. Gross margin was also slightly lower in Q3 than it was in Q2 of this year. But, there were several positives in the quarter including;

- record volumes of the company's bread-and-butter reproductive health segment
- record volumes and revenue of CombiPGS tests – volume was ahead of the prior best by almost 13%
- record volumes of miscarriage analysis tests
- 2nd highest volume of all tests combined
- record average reimbursement of prenatal microarray tests
- record average reimbursement of pediatric microarray tests
- while total revenue fell sequentially, it was the second highest on record
- excluding merger-related expenses, operating loss was also the second best on record
- cash collections, second highest on record
- cash collections as percentage of revenue set new record
- record low operating expenses as percentage of revenue

And while miscarriage analysis revenue, which accounts for more than 50% of total testing revenue, did not set a new record, it was the second highest in history. The big sequential jump in CombiPGS volumes is particularly noteworthy given that CBMX had recently put a renewed focus on growing this product. PGS has been a tremendous success – Q3 2015 was the first full period for the product on the market and in just two years' time, it is generating an annual revenue run rate of $2M (~13% of total revenue). Clearly the miscarriage and reproductive health testing portfolio as a whole continues to perform extraordinarily well. Reimbursement across all of the products was also relatively strong in Q3.

	1st 9 Months		YTD'17		Q-o-Q		Q3 '17	
	2016	2017	record?	Change	Q2 2017	Q3 2017	record?	Change
Revenue (k)	$9,327	$12,040	Y	29.1%	$4,241	$4,012	N	-5.4%
Gross Margin	53.6%	60.5%	Y	900 bp	61.3%	59.4%	N	140 bp
Oper. Loss (k)	-$3,549	-$1,118	Y	-68.5%	-$210	-$391	N	86.2%
Cash Collect. (k)	$8,500	$10,900	Y	28.2%	$3,100	$3,700	N	19.4%
Cash Coll/Rev	91.1%	90.5%	N	-0.7%	73.1%	92.2%	Y	26.2%
Avg test price	$1,112	$1,330	Y	19.6%	$1,365	$1,347	N	-1.3%
Avg Miscarr price	$1,629	$1,904	Y	16.9%	$2,017	$1,850	N	-8.3%
Avg Reprod price	$1,545	$1,748	Y	13.1%	$1,795	$1,709	N	-4.8%
Test volumes	8,263	8,977	Y	8.6%	3,087	2,952	N	-4.4%
Miscarr volumes	2,886	3,323	Y	15.1%	1,095	1,123	Y	2.6%
Reprod volumes	4,312	5,154	Y	19.5%	1,748	1,764	Y	0.9%

Despite not setting a new record high in every product category or on every operational or financial metric, growth remains fairly broad-based – particularly as compared to the prior year. Miscarriage and PGS volumes increased double digit percentages in Q3 as compared to 2016. And while prenatal and non-microarray volumes fell yoy by 14% and 18%, respectively, relatively strong average pricing of both resulted in prenatal revenue growing by 8% and non-microarray eking out 1% growth.

Q3 Totals…

- Billable tests:
  - Volume: 2,952 total billable tests. Second highest in history and up 4% yoy, down 4% sequentially
  - Diagnostic Revenue: $4,214k. Second highest in history and up 24% yoy but down 6% sequentially

- Reproductive Health: this is CBMX's major area of focus.
  - Volume: Q3 set a new record at 1,764 - up 19% yoy and 1% sequentially
  - Revenue: $3,015k. Second highest in history and up 30% yoy but down 4% sequentially

	Q3 '16	Q2 '17	Q3 '17
Number of tests			
Prenatal yoy growth	*8.1%*	*2.6%*	*-13.6%*
Prenatal tests	294	310	254
Miscarriage yoy growth	*14.3%*	*21.5%*	*13.4%*
Miscarriage analysis tests	990	1095	1123
CombiPGS yoy growth	*56.7%*	*71.5%*	*94.5%*
CombiPGS	199	343	387
Total Reproductive Hlth	**1,483**	**1,748**	**1,764**
prenatal as %of total microarray tests	75%	76%	78%
YOY Growth	*17.2%*	*24.6%*	*18.9%*
Pediatric Microarray	505	549	490
pediatric as %of total microarray tests	25%	24%	22%
YOY Growth	*-0.8%*	*10.5%*	*-3.0%*
Total Microarray tests	1,988	2,297	2,254
microarray %of total tests	70%	74%	76%
YOY Growth	*12.1%*	*20.9%*	*13.4%*
Non-microarray tests	847	790	698
non-microarray %of total tests	30%	26%	24%
YOY Growth	*17.5%*	*-10.2%*	*-17.6%*
Total Billable tests	**2,835**	**3,087**	**2,952**
YOY Growth	*13.6%*	*11.0%*	*4.1%*
Pricing per test			
Prenatal microrray	$1.388	$1.571	$1.732
Miscarriage analysis	$1.638	$2.017	$1.850
CombiPGS	$1.437	$1.289	$1.284
Total Reproductive Hlth	**$1.562**	**$1.795**	**$1.709**
Pediatric	$1.166	$1.321	$1.333
All microarrays	$1.461	$1.682	$1.627
Non-microarrays	$0.361	$0.444	$0.443
Total	**$ 1.133**	**$ 1.365**	**$ 1.347**
Total revenue per test			
Prenatal microrray	$408	$487	$440
Miscarriage analysis	$1,622	$2,209	$2,078
CombiPGS	$286	$442	$497
Total Reproductive Hlth	**$2,316**	**$3,138**	**$3,015**
YOY Growth	*39.4%*	*43.9%*	*30.2%*
Pediatric Microarray	$589	$725	$653
YOY Growth	*5.6%*	*29.9%*	*10.9%*
All microarrays	$2,905	$3,863	$3,668
YOY Growth	*30.9%*	*41.0%*	*26.3%*
Non-microarrays	$306	$351	$309
YOY Growth	*17.2%*	*13.2%*	*1.0%*
Total	**$ 3,211**	**$ 4,214**	**$ 3,977**
YOY Growth	*29.4%*	*38.2%*	*23.9%*
Diagnostic Svcs	$3,211.0	$4,214.0	$3,977.0
YOY Growth	*29.4%*	*38.2%*	*23.9%*
Royalties	$37.0	$27.0	$35.0
YOY Growth	*-17.8%*	*-53.4%*	*-5.4%*
Clinical Trial Supt Svcs	$0.0	$0.0	$0.0
YOY Growth	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*
Total Revenues	$3,248.0	$4,241.0	$4,012.0
YOY Growth	*28.6%*	*36.5%*	*23.5%*
Cost of Services	$1,476.0	$1,632.0	$1,614.0
Gross Income	$1,772.0	$2,609.0	$2,398.0
Services Margin	*54.0%*	*61.3%*	*59.4%*

Revenue was the second highest on record while gross margin was the third highest (behind only Q1 and Q2 2017). The widening of gross margin has been a major impetus for the consistent improvement in operating loss. An 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. We think further growth in average reimbursement would likely continue to benefit margins and we do have GM continuing to widen in the out-years in our model.

Excluding $391k of merger related expenses (captured in G&A), operating loss was $223k, which is significantly improved from every other historical quarter (including Q1 2017 of -$518k), save Q2 of this year – which, excluding $210k in merger related expenses, saw an operating loss of just $162k. Operating expenses as a percentage of

revenue (ex-merger related expenses) were 64.7% in Q3, an all-time low and just edging out Q2 (64.8%). As the merger is expected to close in Q4, our modeled operating expense includes additional allocation of merger expenses in that period.

In terms of cash, cash collections were $3.7M in Q3, slightly lower than the $3.8M generated in Q2 but better than every other prior period. Also noteworthy is that cash collections as a percentage of revenue, at 92.2%, were an all-time high. Through the first nine months of 2017 cash collections were $10.9M, also a record.

Excluding merger related expenses CBMX used $53k and $591k of cash for operations in the three and nine months ending 9/30/2017. Again, this looks to be the second lowest ever for the three-month period (only bested by Q2 of this year) and a record low for any consecutive nine-month period. Cash balance at Q3 quarter-end was $2.4M. While the company had been guiding to reach a point of cash-flow break-even by the close of 2017, a disclosure in the Q3 10-Q implies that they now expect that milestone (excluding merger related expenses) to be achieved in Q1 2018.

Operational Update:

Miscarriage analysis…
Over seven 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 recently 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 $2.1M in revenue in Q3 on 1,123 tests sold (record volume) – this compares to $1.6M (+28%) and 990 (+13%) tests in Q3 2016 and $2.2M (-6%) and 1,095 (+3%) tests in Q2 2017. Average pricing per test in Q3 was $1,850, higher than every other prior quarter save Q2 2017 ($2,017) and up 13% from Q3 2016 ($1,638).

While miscarriage testing had already been a major catalyst to the company's growth, with it now accounting for more than 50% 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 95% yoy and were up 13% from Q2 to 387 in Q3. 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 also recently noted that PGS-NGS demand was picking up.

PGS pricing was basically flat sequentially and contracted by about 11% from the comparable prior-year period. But, the significant jump in volume helped to push PGS revenue to $497k in Q3 – which is 12% higher than the prior best (set in Q2 2017) and up 74% from Q3 2016.

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. Volumes ticked up nicely through the first six months of

2017, posting yoy growth of 9% but then dipped in Q3 – falling 18% sequentially and 14% yoy. Through the first nine months of 2017 prenatal volumes are up 1%.

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 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. Through the first nine months of 2017 volumes are up about 7% yoy.

Non-array…
While not an area of focus for CMBX, 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. Volumes have softened in 2017, falling 17% in Q3 and 9% through the first nine months - although the lower volumes have been more than offset by continued increase in pricing resulting in non-array revenue increasing 1% in Q3 and 9% through the first nine months of 2017. 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 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 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 continue to catalyze growth of testing volumes and average pricing of CBMX's miscarriage analysis tests.

OUTLOOK / VALUATION

Invitae To Acquire CBMX In All-Stock Transaction…

On July 31st CBMX announced that they entered into an agreement with Invitae Corporation (NYSE: NVTA) whereby they will be acquired in an all-stock transaction. Based on the 10-day average of NVTA's stock price ($9.49) prior to the announcement and other considerations (including CBMX's cash balance at closing), the acquisition price approximates to $33M. The owners of CBMX common shares (2.92M shares o/s) as well as currently outstanding Series F preferred shares, restricted stock units and in-the-money options (equal to 126k shares in aggregate) will receive (in aggregate) approximately $27M worth of NVTA shares (again, based on a fixed price per share of NVTA stock of $9.49 and adjusted for forecasted net cash balance). Based on CBMX's forecasted at-closing net cash, they estimate that CBMX shareholders will receive between $8.00 and $8.65 per common share (equal to an estimated [NVTA shares/CBMX share] exchange ratio of between 0.843 and 0.9115). The value that CBMX common stockholders will receive will fluctuate based on the market price of NVTA shares.

Holders of CBMX Series F warrants (2.07M o/s) will receive (at least) $2.90 per warrant, or approximately $6M in aggregate of NVTA shares (based on NVTA share price of $9.49) - this value will similarly fluctuate based on NVTA's share price.

Closing of the transaction is subject to CBMX shareholder approval as well as at least 90% of Series F warrant holders tendering their securities. We note that while the minimum Series F warrant-holder participation is a gating factor, the merger agreement (exhibit 2.1 filed with July 31st 8-K) allows NVTA to offer more than $2.90 per warrant if needed as an enticement to hit the minimum threshold. The warrants have an exercise price of $5.17 per CBMX share - which at today's market price ($7.18) puts them in-the-money by $2.01 (i.e. the $2.90 offer is a premium to the in-the-money value).

Outlook

Our outlook is based on the scenario that CBMX remains an independent going concern, although we think it is likely that the proposed acquisition by Invitae will close in Q4 of this year.

Our 2017 forecasted revenue growth of 27%, which includes 32% growth in reproductive health revenue, is driven from continued productivity gains of the sales force, new payor contracts, more insurers starting to cover recurrent pregnancy loss testing (i.e. miscarriage analysis), increasing number of billable customers, greater awareness of the benefits of CMA analysis, improved pricing and some incremental growth from new products.

In terms of pricing – this is one variable that has been 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 continued in Q1 of this year and then has mostly stabilized over the last two quarters. 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 $22.3M 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.

But given the likely impending acquisition by Invitae, we think upside in the shares will be significantly limited which is reflected in our $7.90/share proxy acquisition price. The value that CBMX shareholders will ultimately receive, assuming the transaction closes, will be influenced by NVTA share price as well as CBMX's net cash balance at time of consummation. Our proxy price is derived simply by multiplying NVTA's current share price ($8.95) by the midway point (0.88) of the implied range in exchange ratio (0.843 to 0.9115) of NVTA shares to be received per CBMX share based on management's (at the time of the merger announcement) estimated price per share ($8.00 to $8.65) that CBMX shareholders would receive at an assumed NVTA share price of $9.49.

FINANCIAL MODEL

CombiMatrix Corporation

	2016 A	Q1A	Q2A	Q3A	Q4E	2017 E	2018 E	2019 E
Diagnostic Svcs	$12,696.0	$3,758.0	$4,214.0	$3,977.0	$4,211.3	$16,160.3	$18,865.0	$22,106.3
YOY Growth	27.71%	28.3%	38.2%	23.9%	20.1%	27.29%	16.74%	17.18%
Royalties	$173.0	$29.0	$27.0	$35.0	$36.0	$127.0	$200.0	$176.0
YOY Growth	17.7%	-31.0%	-53.4%	-5.4%	0.0%	-26.6%	57.5%	-12.0%
Total Revenues	$12,869.0	$3,787.0	$4,241.0	$4,012.0	$4,247.3	$16,287.3	$19,065.0	$22,282.3
YOY Growth	27.6%	27.4%	36.5%	23.5%	19.9%	26.6%	17.1%	16.9%
Cost of Services	$5,787.0	$1,508.0	$1,632.0	$1,614.0	$1,646.6	$6,400.6	$7,263.0	$8,444.6
Gross Income	$7,082.0	$2,279.0	$2,609.0	$2,398.0	$2,600.7	$9,886.7	$11,802.0	$13,837.7
Services Margin	55.0%	59.9%	61.3%	59.4%	60.9%	60.7%	61.5%	61.8%
R&D	$493.0	$85.0	$85.0	$90.0	$95.0	$355.0	$487.0	$555.0
% R&D	3.8%	2.2%	2.0%	2.2%	2.2%	2.2%	2.6%	2.5%
SG&A	$10,582.0	$2,686.0	$2,871.0	$2,897.0	$2,969.4	$11,423.4	$11,499.6	$12,366.7
% SG&A	82.2%	70.9%	67.7%	72.2%	69.9%	70.1%	60.3%	55.5%
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)	($372.0)	($614.0)	($488.7)	($1,991.7)	($284.6)	$816.0
Operating Margin	-31.8%	-13.7%	-8.8%	-15.3%	-11.5%	-12.2%	-1.5%	3.7%
Total Other income	($47.0)	($1.0)	$2.0	$4.0	$2.0	$7.0	$0.0	$0.0
Pre-Tax Income	($4,140.0)	($518.0)	($370.0)	($610.0)	($486.7)	($1,984.7)	($284.6)	$816.0
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)	($370.0)	($610.0)	($486.7)	($1,984.7)	($284.6)	$816.0
YOY Growth	-44.7%	-83.5%	-70.0%	-28.7%	-12.8%	-52.1%	-85.7%	-386.7%
Net Margin	-32.2%	-13.7%	-8.7%	-15.2%	-11.5%	-12.2%	-1.5%	3.7%
EPS	($2.35)	($0.19)	($0.13)	($0.21)	($0.17)	($0.69)	($0.08)	$0.22
YOY Growth	-74.0%	-94.8%	-85.8%	-45.1%	-24.2%	-70.7%	-88.2%	-371.2%
Diluted Shares O/S	1,765	2,761	2,915	2,926	2,944	2,886	3,500	3,700

Brian Marckx, CFA

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