CNH GLOBAL N V
Form 6-K
April 21, 2010
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SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 OR 15d-16 OF

THE SECURITIES EXCHANGE ACT OF 1934

For the month of April 2010

Commission File No. 333-05752

CNH GLOBAL N.V.

(Translation of Registrant s Name Into English)

World Trade Center

Tower B, 10th Floor

Amsterdam Airport

The Netherlands

(Address of Principal Executive Offices)

(Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.)

Form 20-F __X__ Form 40-F ______

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule101(b)(1): ¨

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule101(b)(7): ¨

(Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.)

Yes ______ No __X__

(If Yes is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-____ .)

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CNH GLOBAL N.V.

Form 6-K for the month of April 2010

List of Exhibits:

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CNH Global N.V.

By: /s/ RICHARD TOBIN
Richard Tobin
Chief Financial Officer

April 21, 2010

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FOR IMMEDIATE RELEASE

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CNH Agriculture and Construction Equipment Operations Post Improved Operating Profit

- **EPS of $.16 per share before restructuring and exceptional items from a loss of $.53 per share in the comparable period**
- **Reported net sales up 6% (-2% constant currency basis), as good market conditions in Latin America for construction equipment and rotary combines helped to offset weaker conditions in Europe.**
- **Operating Profit Margin up 310 basis points to 4.4%**
- **Positive equipment operating cash flow for the quarter, net cash position improves to $756 million**

BURR RIDGE, IL. (MARKET WIRE) CNH Global N.V. (NYSE: CNH - News) April 21, 2010: CNH Global today announced financial results for the first quarter of 2010. Net Sales rose 6.1% to $3,237 million for the first quarter. The Company reported an Operating Profit of $144 million from Equipment Operations for the quarter, up $105 million from the comparable period. Diluted Earnings Per Share Before Restructuring and Exceptional Items was $0.16 compared to a loss of $0.53 per share for first quarter 2009.

In a mixed agricultural capital goods trading environment, CNH was able to post improved profit performance over the prior year. Demand in North America was firm and Latin America strong on stable commodity pricing. The improving market conditions resulted in better than forecasted demand for agricultural equipment in the Americas, particularly tractors and combines, in a competitive pricing environment. Trading conditions in Western Europe and the CIS remained at reduced levels due to a continuing decline of overall economic conditions, while Asia and the Middle East demonstrated signs of improvement. The negative impact from reduced tractor unit sales and weaker demand in certain geographical markets was offset by improved mix of rotary combines in the Company s product portfolio, the benefits of prior period restructuring actions, and improved industrial economics lifting agricultural equipment gross margins 210 basis points from the comparable prior period.

The construction equipment sector displayed similar dynamics with unevenly distributed geographical demand mirroring overall differences in economic activity. For CNH, this resulted in good performance on the back of the Company s strong presence in Latin America and certain countries in Asia, combined with an improved industrial performance in North America which came off a low base. These served to offset a sluggish demand environment in Western Europe resulting in year-over-year top line growth of 27%. The sector s operating loss for the period narrowed as a result of cost alignment actions taken in 2009, reduced manufacturing input costs, and a favorable geographical mix despite the Company s sub-scale exposure to the high growth China market, and difficult pricing conditions in Western Europe and North America. For construction equipment, the Company continued to under produce retail sales during the quarter in an effort to work off finished goods inventory in low demand geographies and in preparation for new product launches of Tier IV equipment. Plans are in place for a step up of production in support of markets demonstrating improving demand conditions.

Equipment Operations generated $117 million in cash flow from operating activities. This was used to finance net capital expenditures of $32 million and to pay down debt. CNH Equipment Operations ended the quarter with a net cash position of $756 million, up 43% from the end of fiscal year 2009 and 185% from the same period last year.

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Our first quarter results highlight the impact of a more stable market and the results of our work to reduce costs. We have reduced structural costs and this is the main driver of our improved financial performance, said Harold Boyanovsky, CNH President and CEO. We are encouraged to see the market improvements, but we will continue to exercise tight controls over our operations.

CNH Capital successfully completed $1.3 billion in retail and wholesale financing transactions during the quarter as the ABS market conditions continued to improve.

Net Income Attributable to CNH was $16 million in the first quarter of 2010 compared with a net loss of $126 million in the same period of 2009. Diluted Earnings Per Share was $0.07 for the quarter, compared with a loss of $0.53 per share in the first quarter of 2009. For the first quarter of 2010, the Company incurred consolidated tax expense of $70 million, which included $26 million of tax charges due to the geographic mix of earnings and the $20 million impact of the new U.S. Patient Protection and Affordable Care Act.

2010 CNH Outlook

CNH will be discussing its market outlook and strategic business plan in a subsequent press release to be issued today which also discusses the Company s strategic business plan for 2010-2014.

First Quarter 2010 Highlights

(Unaudited, US$ in millions, except per share data and percentages)

	Quarter Ended		Percent
	3/31/2010	**3/31/2009**	**Change**
Net Sales of Equipment	**$ 3,237**	$ 3,052	6.1%
Equipment Operations Operating Profit	**$ 144**	$ 39	269.2%
Financial Services Net Income	**$ 51**	$ 1	n.a.
Net Income (Loss) Attributable to CNH	**$ 16**	$ (126)	n.a.
Restructuring and Exceptional Items	**$ 22**	$ 1	n.a.
Net Income (Loss) Before Restructuring and Exceptional Items	**$ 38**	$ (125)	n.a.
Diluted Earnings (Loss) Per Share (EPS)*	**$ 0.07**	$ (0.53)	n.a.
Diluted EPS Before Restructuring and Exceptional Items	**$ 0.16**	$ (0.53)	n.a.

* Attributable to CNH Global N.V. Common Shareholders

First Quarter Commercial Highlights

Worldwide agricultural industry retail unit sales increased 14% compared to the first quarter of 2009. Global retail tractor sales rose 14% and global retail combine sales fell 2% for the quarter. Tractor and combine sales rose slightly in North America while they declined sharply in Western Europe, where economic conditions continue to be challenging. Latin America saw significant increases in both tractor and combine markets on strong growth and commodity prices. Rest of World markets saw significantly stronger tractor sales, and weaker combine volumes.

CNH market share for tractors declined in North America, especially in the under 40 hp segment where the Company is reducing inventory in preparation for the introduction of new models later this year. European market share remained stable and Latin American market share declined due to heavy competitive pricing in the high volume, small and mid-sized categories. Share in Rest of World markets fell slightly.

CNH market share for combines was up in the first quarter. In North America, CNH increased market share by targeting key cash crop customers. In Western Europe, market share was stable, while Latin American market share rose significantly on strong demand for newly introduced CNH rotary combines. The Company picked up

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market share in Rest of World markets. CNH benefited from increased demand in Turkey where its brands are strongly positioned in the agricultural capital goods sector. In March 2010, the Company finalized an agreement to jointly manufacture agriculture and construction equipment with OJSC KAMAZ in Russia.

Global industry unit volume of construction equipment rose 31% in the first quarter compared to the prior year, with light equipment up 21% and heavy equipment up 40%. In both the North American and Western European markets, demand for the light and heavy segments continued to decline, albeit at reduced rates. In Latin America, the market rebounded compared to a weak first quarter last year on strong infrastructure and construction spending. Rest of World markets industry sales of construction equipment jumped more than 50 % for light and heavy equipment, dominated by demand in China on the back of infrastructure and commodity related spending.

In North America, CNH market share was in line for heavy and fell slightly in the light segments amid intense pricing competition. In Western Europe, CNH share was comparable with the prior year in the light equipment segment and increased in the heavy equipment segment. CNH share in Latin America was down for light equipment while market share increased in the heavy segment as our local manufacturing base was able to meet demand for key customers in a very tight market. In Rest of World markets, CNH saw no significant change in market share.

Market Outlook

CNH anticipates that global agriculture equipment markets will be flat to up 5% in 2010. The CNH outlook for the global construction equipment markets is for an increase of approximately 15-20 % in 2010.

First Quarter 2010 Net Sales Equipment Operations

Net Sales of Equipment	**Quarter Ended**		
(Unaudited, US$ in millions, except percents)	**3/31/2010**	**3/31/2009**	**Percent Change**
Agricultural Equipment	**$ 2,626**	$ 2,572	2.1%
Construction Equipment	**611**	480	27.3%
Total Net Sales of Equipment	**$ 3,237**	$ 3,052	6.1%

Agricultural Equipment s Net Sales were up 2.1% in the first quarter versus the comparable period in 2009 (-5.4 % on a constant currency basis). Construction equipment revenue rose 27.3% against first quarter last year (16.5% on a constant currency basis), as production significantly increased against 2009 with improved market conditions and reduction of finished goods inventory.

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Equipment Operations Gross & Operating Profit and Margin

Gross and Operating Profit and Margin	**Quarter Ended**		
(Unaudited, US$ in millions, except percents)	**3/31/2010**	**3/31/2009**	**Change**
Gross Profit and Margin:			
Agricultural Equipment	**$ 480**	$ 417	15.1%
Construction Equipment	**59**	8	637.5%
Total Gross Profit	**$ 539**	$ 425	26.8%
Agricultural Equipment	**18.3%**	16.2%	2.1pts
Construction Equipment	**9.7%**	1.7%	8.0pts
Total Gross Margin	**16.7%**	13.9%	2.8pts
Operating Profit and Margin:			
Agricultural Equipment	**$ 180**	$ 130	38.5%
Construction Equipment	**(36)**	(91)	n.a.
Total Operating Profit	**$ 144**	$ 39	269.2%
Agricultural Equipment	**6.9%**	5.1%	1.8pts
Construction Equipment	**(5.9)%**	(19.0)%	13.1pts
Total Operating Margin	**4.4%**	1.3%	3.1pts

Equipment Operations Gross Profit in the first quarter was $539 million, up 26.8% from the comparable period last year. The 280 basis point increase in gross margin was primarily driven by better fixed cost absorption in the construction equipment operations, more favorable net pricing, and the results of prior period restructuring actions to lower industrial costs.

Operating Margin was 4.4%, and operating profit improved $105 million over the comparable period last year. Agricultural Equipment Operating Margin increased 180 basis points for the quarter to 6.9%; Construction Equipment Operating Margin improved from (19.0%) in the first quarter last year to (5.9%).

First Quarter 2010 Operating Review Financial Services

Financial Services Highlights	**Quarter Ended**		
(Unaudited, US$ in millions, except percents)	**3/31/2010**	**3/31/2009**	**Percent Change**
Net Income Before Restructuring and Exceptional Items	**$ 51**	$ 2	2,450.0%
On-Book Asset Portfolio	**$ 16,446**	$ 9,131	80.1%
Managed Asset Portfolio	**$ 16,940**	$ 16,982	(0.2)%

For the first quarter, Financial Services Net Income Before Restructuring and Exceptional Items was $51 million, compared to $2 million in the respective period a year earlier. First quarter 2009 results included a $33 million ABS loss under that period s accounting standards. A higher level of on-book receivables, improved net interest margins, increased originations, and continued cost containment initiatives with respect to general and administrative expenses were positive factors in the profit improvement.

As of the beginning of 2010, Financial Services adopted new accounting guidance (FASB Statements No. 166, *Accounting for Transfers of Financial Assets*, and No. 167, *Amendments to FASB Interpretation No. 46(R)*) that required the Company to consolidate a significant portion of its securitization trusts. Certain transactions that historically had been accounted for off balance sheet, are now accounted for on the Financial Services balance sheet. The financial information presented prior to January 1, 2010 has not been adjusted for comparison purposes as CNH adopted this guidance prospectively.

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Equipment Operations Cash Flow and Net Debt (Cash)

Equipment Operations Cash Flow and Net Debt	**Quarter Ended**	
(Unaudited, U.S. GAAP, US$ in millions)	**3/31/2010**	**3/31/2009**
Net Income (loss)	**$ 9**	$ (133)
Depreciation & Amortization	**71**	62
Changes in Working Capital*	**(53)**	(470)
Other**	**90**	106
Net Cash Provided (Used) by Operating Activities	**117**	(435)
Net Cash Provided (Used) by Investing Activities***	**(51)**	(44)
All Other, Including FX Impact for the Period	**160**	14
(Increase)/Decrease in Net Debt (Cash)	**$ 226**	$ (465)
Net Debt (Cash)	**$ (756)**	$ 888

* Net change in receivables, inventories and payables including inter-segment receivables and payables, net of FX impact for the period.
** Changes in Other items such as marketing programs and tax accruals.
*** Excluding Net (Deposits In) / Withdrawals from Fiat Cash Pools, as they are a part of Net Debt (Cash).

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CNH Global N.V. is a world leader in the agricultural and construction equipment businesses. Supported by more than 11,600 dealers in approximately 170 countries, CNH brings together the knowledge and heritage of its Case and New Holland brand families with the strength and resources of its worldwide commercial, industrial, product support and finance organizations. CNH Global N.V., whose stock is listed at the New York Stock Exchange (NYSE:CNH), is a majority-owned subsidiary of Fiat S.p.A. (FIA.MI). More information about CNH and its Case and New Holland products can be found online at www.cnh.com.

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CNH management will hold a conference call later today, to review its first quarter 2010 results. The conference call Webcast will begin at approximately 1:00 p.m. U.S. Central Time; 2:00 p.m. U.S. Eastern Time. This call can be accessed through the investor information section of the company s Web site at www.cnh.com and is being carried by CCBN.

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Forward-looking statements. This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact contained in this press release, including statements regarding our competitive strengths, business strategy, future financial position, operating results, budgets, projected costs and plans and objectives of management, are forward-looking statements. These statements may include terminology such as may, will, expect, could, should, intend, estimate, anticipate, believe, outlook, continue, remain, on track, goal, or similar terminology.

Our outlook is predominantly based on our interpretation of what we consider key economic assumptions and involves risks and uncertainties that could cause actual results to differ. Crop production and commodity prices are strongly affected by weather and can fluctuate significantly. Housing starts and other construction activity are sensitive to the availability of credit and to interest rates and government spending. Some of the other significant factors which may affect our results include general economic and capital market conditions, the cyclical nature of our business, customer buying patterns and preferences, foreign currency exchange rate movements, our hedging practices, our customers access to credit, restrictive covenants in our debt agreements, actions by rating agencies concerning the ratings of our debt securities and asset backed securities, risks related to our relationship with Fiat S.p.A., political uncertainty and civil unrest or war in various areas of the world, pricing, product initiatives and other actions by competitors, disruptions in production capacity, excess inventory levels, the effect of changes in laws and regulations (including those related to tax, healthcare, retiree benefits, government subsidies and international trade), the results of legal proceedings, technological difficulties, results of our research and development activities, changes in environmental laws, employee and labor relations, pension and health care costs, relations with and the financial strength of dealers and critical suppliers, the cost and availability of supplies from our suppliers, raw material costs and availability, energy prices, real estate values, animal diseases, crop pests, harvest yields, government farm programs and consumer confidence, housing starts and construction activity, concerns related to modified organisms and fuel and fertilizer costs. Additionally, our achievement of the anticipated benefits of our margin improvement initiatives depends upon, among other things, industry volumes as well as our ability to effectively rationalize our operations and to execute our brand strategy. Further information concerning factors that could significantly affect expected results is included in our annual report on Form 20-F for the year ended December 31, 2009.

We can give no assurance that the expectations reflected in our forward-looking statements will prove to be correct. Our actual results could differ materially from those anticipated in these forward-looking statements. All written and oral forward-looking statements attributable to us are expressly qualified in their entirety by the factors we disclose that could cause our actual results to differ materially from our expectations. We undertake no obligation to update or revise publicly any forward-looking statements.

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CNH Global N.V.

Revenues and Net Sales

(Unaudited)

	Three Months Ended March 31,		
	2010	2009	% Change
	(in Millions)		
Revenues:			
Net sales			
Agricultural equipment	$ 2,626	$ 2,572	2%
Construction equipment	611	480	27%
Total net sales	3,237	3,052	6%
Financial services	340	258	32%
Eliminations and other	(57)	(44)	
Total revenues	$ 3,520	$ 3,266	8%
Net sales:			
North America	$ 1,299	$ 1,362	(5)%
Western Europe	804	917	(12)%
Latin America	631	320	97%
Rest of World	503	453	11%
Total net sales	$ 3,237	$ 3,052	6%

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CNH GLOBAL N.V.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

AND SUPPLEMENTAL INFORMATION

(Unaudited)

	CONSOLIDATED Three Months Ended March 31,		EQUIPMENT OPERATIONS Three Months Ended March 31,		FINANCIAL SERVICES Three Months Ended March 31,	
	2010	2009	2010	2009	2010	2009
	(in Millions, except per share data)					
Revenues						
Net sales	$ 3,237	$ 3,052	$ 3,237	$ 3,052	$	$
Finance and interest income	283	214	29	34	340	258
Total	3,520	3,266	3,266	3,086	340	258
Costs and Expenses						
Cost of goods sold	2,698	2,627	2,698	2,627		
Selling, general and administrative	394	380	296	293	98	87
Research and development	99	93	99	93		
Restructuring	2	2	2	1		1
Interest expense	202	186	81	79	160	140
Interest compensation to Financial Services			47	42		
Other, net	56	75	32	47	24	31
Total	3,451	3,363	3,255	3,182	282	259
Income (loss) before income taxes and equity in income (loss) of unconsolidated subsidiaries and affiliates	69	(97)	11	(96)	58	(1)
Income tax provision	70	17	60	17	10	
Equity in income (loss) of unconsolidated subsidiaries and affiliates:						
Financial Services	3	2	51	1	3	2
Equipment Operations	7	(21)	7	(21)		
Net income (loss)	9	(133)	9	(133)	51	1
Net income (loss) attributable to noncontrolling interests	(7)	(7)	(7)	(7)		
Net Income (loss) attributable to CNH Global N.V.	$ 16	$ (126)	$ 16	$ (126)	$ 51	$ 1
Weighted average shares outstanding:						
Basic	237.5	237.4				
Diluted	238.2	237.4				
Basic and diluted earnings (loss) per share (EPS) attributable to CNH Global N.V. common shareholders:						
Basic EPS	$ 0.07	$ (0.53)				

Diluted EPS	$ 0.07	$ (0.53)
Dividends per share	$	$

These Condensed Consolidated Statements of Operations should be read in conjuction with the Company s Annual Report on Form 20-F for the year ended December 31, 2009, and the Notes to Condensed Consolidated Financial Statements.

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CNH GLOBAL N.V.

CONDENSED CONSOLIDATED BALANCE SHEET

AND SUPPLEMENTAL INFORMATION

(Unaudited)

	CONSOLIDATED		EQUIPMENT OPERATIONS		FINANCIAL SERVICES	
	March 31, 2010	December 31, 2009	March 31, 2010	December 31, 2009	March 31, 2010	December 31, 2009
	(in Millions)					
Assets						
Cash and cash equivalents	$ 874	$ 1,263	$ 214	$ 290	$ 660	$ 973
Deposits in Fiat affiliates cash management pools	2,185	2,251	2,153	2,144	32	107
Accounts, notes receivable and other - net	14,210	8,426	944	788	13,541	7,952
Intersegment notes receivable			2,485	2,398	489	634
Inventories	3,284	3,297	3,284	3,297		
Property, plant and equipment - net	1,694	1,764	1,691	1,761	3	3
Equipment on operating leases - net	600	646	3	3	597	643
Investment in Financial Services			2,217	2,377		
Investments in unconsolidated affiliates	411	415	329	330	82	85
Goodwill and other intangibles	3,081	3,091	2,923	2,935	158	156
Other assets	2,701	2,055	1,584	1,557	1,117	498
Total Assets	$ 29,040	$ 23,208	$ 17,827	$ 17,880	$ 16,679	$ 11,051
Liabilities and Equity						
Short-term debt	$ 3,098	$ 1,972	$ 72	$ 136	$ 3,026	$ 1,836
Accounts payable	2,094	1,915	2,170	2,061	187	151
Long-term debt, including current maturities	11,842	7,436	3,535	3,532	8,307	3,904
Intersegment debt			489	634	2,485	2,398
Accrued and other liabilities	5,244	5,075	4,800	4,708	456	384
Total Liabilities	22,278	16,398	11,066	11,071	14,461	8,673
Equity	6,762	6,810	6,761	6,809	2,218	2,378
Total Liabilities and Equity	$ 29,040	$ 23,208	$ 17,827	$ 17,880	$ 16,679	$ 11,051
Total debt less cash and cash equivalents, deposits in Fiat affiliates cash management pools and intersegment notes receivables Net Debt (Cash)	$ 11,881	$ 5,894	$ (756)	$ (530)	$ 12,637	$ 6,424

These Condensed Consolidated Balance Sheets should be read in conjuction with the Company s Annual Report on Form 20-F for the year ended December 31, 2009, and the Notes to Condensed Consolidated Financial Statements.

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CNH GLOBAL N.V.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

AND SUPPLEMENTAL INFORMATION

(Unaudited)

	CONSOLIDATED Three Months Ended March 31,		EQUIPMENT OPERATIONS Three Months Ended March 31,		FINANCIAL SERVICES Three Months Ended March 31,	
	2010	2009	2010	2009	2010	2009
			(in Millions)			
Operating Activities:						
Net income (loss)	$ 9	$ (133)	$ 9	$ (133)	$ 51	$ 1
Adjustments to reconcile net income to net cash from operating activities:						
Depreciation and amortization	101	92	71	62	30	30
Intersegment activity			(154)	(89)	154	89
Changes in operating assets and liabilities	(379)	(529)	290	(224)	(669)	(305)
Other, net	(124)	(41)	(99)	(51)	(76)	9
Net cash provided (used) by operating activities	(393)	(611)	117	(435)	(510)	(176)
Investing Activities:						
Expenditures for property, plant and equipment	(32)	(46)	(32)	(46)		
Expenditures for equipment on operating leases	(77)	(44)			(77)	(44)
Net collections from retail receivables	120	699			120	699
Net withdrawals from (deposits in) Fiat affiliates cash management pools	36	577	(37)	563	73	14
Other, net	49	43	(19)	2	48	41
Net cash provided (used) by investing activities	96	1,229	(88)	519	164	710
Financing Activities:						
Intersegment activity			(70)	(91)	70	91
Net decrease in indebtedness	(88)	(576)	(40)	(5)	(48)	(571)
Other, net	4		4		20	
Net cash provided (used) by financing activities	(84)	(576)	(106)	(96)	42	(480)
Effect of foreign exchange rate changes on cash and cash equivalents	(8)	(5)	1	(6)	(9)	1
Increase (decrease) in cash and cash equivalents	(389)	37	(76)	(18)	(313)	55
Cash and cash equivalents, beginning of period	1,263	633	290	173	973	460
Cash and cash equivalents, end of period	$ 874	$ 670	$ 214	$ 155	$ 660	$ 515

These Condensed Consolidated Statements of Cash Flows should be read in conjuction with the Company s Annual Report on Form 20-F for the year ended December 31, 2009, and the Notes to Condensed Consolidated Financial Statements.

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CNH Global N.V.

Notes to Unaudited Condensed Consolidated Financial Statements

1. Principles of Consolidation and Basis of Presentation The accompanying unaudited condensed consolidated financial statements and supplemental information reflect all adjustments, consisting only of normal, recurring adjustments except where noted, that are, in the opinion of management, necessary for a fair presentation of the consolidated results of CNH Global N.V., a Netherlands corporation, and its consolidated subsidiaries (CNH or the Company) in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP); however, because of their condensed nature, they do not include all of the information and note disclosures required by U.S. GAAP or the rules of the Securities and Exchange Commission (SEC) for complete annual or interim period financial statements. These financial statements should be read in conjunction with the audited, consolidated financial statements and notes thereto for the year ended December 31, 2008 included in the Company s Annual Report on Form 20-F filed with the SEC on March 3, 2009. CNH is controlled by Fiat Netherlands Holding N.V., a wholly owned subsidiary of Fiat S.p.A. (Fiat). As of December 31, 2009, Fiat owned approximately 89% of CNH s outstanding common shares.

The condensed consolidated financial statements include the accounts of CNH s majority-owned and controlled subsidiaries and reflect the noncontrolling interests of the minority owners of the subsidiaries that are not fully owned for the periods presented, as applicable. The operations and key financial measures and financial analyses differ significantly for manufacturing and distribution businesses and financial services businesses; therefore, management believes that certain supplemental disclosures are important in understanding the consolidated operations and financial results of CNH. The supplemental financial information captioned Equipment Operations includes the results of operations of CNH s agricultural and construction equipment operations, with the Company s financial services businesses reflected on the equity method of accounting. The supplemental financial information captioned Financial Services reflects the combination of CNH s financial services operations.

2. Recent Accounting Developments As of the beginning of 2009, CNH adopted new accounting guidance on fair value measurements, business combinations and noncontrolling interests. In April 2009, CNH adopted new accounting guidance related to other-than-temporary impairments.

In September 2006, the Financial Accounting Standards Board (FASB) issued new accounting guidance related to fair value measurements. The new guidance defines fair value, establishes a framework for the measurement of fair value, and enhances disclosures about fair value measurements. The guidance does not require any new fair value measures but rather eliminates inconsistencies in previous guidance. The guidance was effective for fiscal years beginning after November 15, 2007. However, in February 2008, the effective date of the guidance was delayed to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). On January 1, 2008, CNH adopted the guidance except as it applied to those nonfinancial assets and nonfinancial liabilities. The adoption of the remaining guidance for all remaining nonfinancial assets and nonfinancial liabilities on January 1, 2009, did not have a material impact to CNH s financial position and results of operations.

In December 2007, the FASB issued new accounting guidance on business combinations which establishes principles and requirements for how an acquirer in a business combination has to recognize and measure in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. The guidance also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. The new guidance is effective for business combinations occurring in fiscal years beginning after December 15, 2008. The adoption of this guidance on January 1, 2009, did not have a material impact on CNH s financial position and results of operations.

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Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

In December 2007, the FASB issued new accounting guidance on noncontrolling interests which establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent s ownership interest, and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. The guidance also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. The guidance was effective for fiscal years beginning after December 15, 2008 and the accounting requirements were applied prospectively to all non-controlling interests, including those that arose before the effective date. The presentation and disclosure requirements were applied retrospectively for all periods presented, as required by the guidance.

In April 2009, the FASB issued new accounting guidance which amends the other-than-temporary impairment model for debt securities. Under this guidance, an other-than-temporary-impairment must be recognized if an investor has the intent to sell the debt security or if it is more likely than not that it will be required to sell the debt security before recovery of its amortized cost basis. In addition, the guidance changes the amount of impairment to be recognized in current-period earnings when an investor does not have the intent to sell or will not be required to sell the debt security, as in these cases only the amount of the impairment associated with credit losses is recognized in income. The guidance is effective for interim and annual reporting periods ending after June 15, 2009. The adoption of the guidance as of April 1, 2009 did not have a material impact on CNH s financial position and results of operations.

In June 2009, the FASB issued new accounting guidance which changes the accounting for transfers of financial assets. The guidance eliminates the concept of a qualifying special-purpose entity, changes the requirements for derecognizing financial assets, and requires additional disclosures in order to enhance information reported to users of financial statements by providing greater transparency about transfers of financial assets, including securitization transactions, and an entity s continuing involvement in and exposure to the risks related to transferred financial assets. The guidance is effective for transactions entered into starting on January 1, 2010. We expect that the impact will be that certain transactions that have historically met the derecognition criteria will no longer qualify for derecognition.

In June 2009, the FASB also issued new accounting guidance which amends the accounting for variable interest entities. The guidance significantly changes the criteria for determining whether the consolidation of a variable interest entity is required. The guidance also addresses the effect of changes required by the new accounting guidance which changes the accounting for transfers of financial assets, increases the frequency for reassessing consolidation of variable interest entities and creates new disclosure requirements about an entity s involvement in a variable interest entity. The guidance is effective for interim and annual reporting periods that begin after November 15, 2009. We will adopt the guidance in 2010. We expect that it will be necessary to consolidate a significant portion, if not all, of our off-book receivables and related liabilities upon adoption of this guidance. The impact is expected to increase assets and liabilities approximately $6.0 billion and decrease equity by approximately $50 million.

3. Stock-Based Compensation Plans Stock-based compensation consists of stock options and performance-based shares that have been granted under the CNH Equity Incentive Plan (CNH EIP) and the CNH Outside Directors Compensation Plan. For the years ended December 31, 2009 and 2008, pre-tax stock-based compensation costs were $14 million and $300 thousand, respectively. For the three months ended December 31, 2009, pre-tax stock-based compensation costs were $6 million. For the three months ended December 31, 2008, CNH recognized pre-tax income of approximately $21 million.

In April 2009, CNH granted approximately 4.1 million performance-based stock options (at targeted performance levels) under the CNH EIP. As specified fiscal 2009 targets were achieved, one-third of the options vested when 2009 results were approved by the Board of Directors in January 2010 (the

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CNH Global N.V.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

Determination Date). The remaining options will vest equally on the first and second anniversary of the Determination Date. Excluding the impact of forfeitures, CNH expects the actual number of options that will vest to be approximately 2.2 million based on CNH s 2009 actual results. This grant has a contractual life of five years from the Determination date. The grant date fair value of $9.03 was determined using the Black-Scholes pricing model. CNH expects to recognized expense over the vesting period of approximately $17 million.

The assumptions used in the Black-Scholes model were:

Risk-free interest rate	1.61%
Expected volatility	70.63%
Expected life	3.73 years
Dividend yield	0.70%

The risk-free interest rate is based on the current U.S. Treasury rate for a bond of approximately the expected life of the options. The expected volatility is based on the historical activity of CNH s common shares over a period equal to the expected life of the options. The expected life is based on the average of the vesting period of each vesting tranche and the original contract term of 69 months. The expected dividend yield is based on the annual dividends which have been paid on CNH s common shares over the past several years.

4. Accounts and Notes Receivable In CNH s receivables securitization programs, certain retail, wholesale finance and credit card receivables are sold and not included in the Company s consolidated balance sheets. The following table summarizes the principal amount of our receivables that are not included in the consolidated balance sheet as of December 31, 2009 and 2008:

	December 31, 2009	December 31, 2008
	(in millions)	
Wholesale receivables	$ 2,316	$ 2,328
Retail and other notes and finance leases	4,207	3,044
Credit card receivables	181	186
Total	$ 6,704	$ 5,558

For the year ending December 31, 2009, utilizing both the public asset securitization and private bank markets, Financial Services closed on $4.0 billion of new retail transactions in North America for a gain of $68 million. In addition, the U.S. wholesale securitization facility closed a TALF eligible $583 million term securitization and a 364-day, $250 million conduit facility, bringing the total U.S. facility size to $1.6 billion at December 31, 2009.

Europe continues to expand its factoring programs in certain European jurisdictions. The amount of outstanding wholesale receivables under these factoring programs was 666 million ($959 million) of which 483 million ($696 million) were sold and, accordingly, removed from the balance sheet.

While the Canadian wholesale securitization facility closed a C$325 million ($309 million) securitization in the fourth quarter, the facility does not qualify for off-book treatment and consequently, is now considered a secured borrowing. In prior years, this facility did qualify as off-book.

Financial Services pretax income for the three months ended December 31, 2009, includes $11 million of adjustments which related to prior quarters.

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CNH Global N.V.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

5. Inventories Inventories as of December 31, 2009 and 2008 consist of the following:

	December 31, 2009	December 31, 2008
	(in millions)	
Raw materials	$ 660	$ 995
Work-in-process	189	323
Finished goods and parts	2,448	3,167
Total Inventories	$ 3,297	$ 4,485

6. Goodwill and Other Intangibles The following table sets forth changes in goodwill and other intangibles for the year ended December 31, 2009:

	Balance at December 31, 2008	Amortization	Foreign Currency Translation and Other	Balance at December 31, 2009
		(in millions)		
Goodwill	$ 2,347	$	$ 27	$ 2,374
Other Intangibles	758	(63)	22	717
Total Goodwill and Other Intangibles	$ 3,105	$ (63)	$ 49	$ 3,091

The construction equipment reporting units experienced operating losses and other business factors that are different than anticipated at year end 2008. As a result, the Company determined that it needed to evaluate whether or not impairment of goodwill existed at June 30 and September 30, 2009. These evaluations indicated that no goodwill impairment existed on the construction equipment businesses at either date.

The Company performed its annual impairment review of all reporting units during the fourth quarter and concluded there was no impairment as of December 31, 2009.

As of December 31, 2009 and 2008, the Company s other intangible assets and related accumulated amortization consisted of the following:

		December 31, 2009			December 31, 2008		
	Weighted Average Life	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
				(in millions)			
Other intangible assets subject to amortization:							
Engineering drawings	20	$ 381	$ 215	$ 166	$ 379	$ 197	$ 182
Dealer network	25	216	87	129	216	78	138
Software	5	386	267	119	371	238	133
Other	10-30	66	35	31	60	27	33

	1,049	604	445	1,026	540	486
Other intangible assets not subject to amortization:						
Trademarks	272		272	272		272
Total other intangibles	$ 1,321	$ 604	$ 717	$ 1,298	$ 540	$ 758

CNH recorded amortization expense related to other intangible assets of approximately $63 million and $65 million for the years ended December 31, 2009 and 2008, respectively.

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CNH Global N.V.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

7. Debt The following table sets forth total debt and Net Debt (Cash) (total debt less cash and cash equivalents, deposits in Fiat affiliates cash management pools and intersegment notes receivable) as of December 31, 2009 and 2008:

	Consolidated		Equipment Operations		Financial Services	
	December 31, 2009	December 31, 2008	December 31, 2009	December 31, 2008	December 31, 2009	December 31, 2008
			(in millions)			
Short-term debt:						
With Fiat affiliates	$ 537	$ 2,240	$ 7	$ 356	$ 530	$ 1,884
Other	1,435	1,240	129	360	1,306	880
Intersegment			161		1,746	1,976
Total short-term debt	1,972	3,480	297	716	3,582	4,740
Long-term debt:						
With Fiat affiliates	2,352	2,984	931	1,766	1,421	1,218
Other	5,084	4,893	2,601	2,075	2,483	2,818
Intersegment			473		652	319
Total long-term debt	7,436	7,877	4,005	3,841	4,556	4,355
Total debt:						
With Fiat affiliates	2,889	5,224	938	2,122	1,951	3,102
Other	6,519	6,133	2,730	2,435	3,789	3,698
Intersegment			634		2,398	2,295
Total debt	9,408	11,357	4,302	4,557	8,138	9,095
Less:						
Cash and cash equivalents	1,263	633	290	173	973	460
Deposits in Fiat affiliag-bottom: 3px; font-family: "Times New Roman", Times, serif; font-size: 10pt; margin-left: 0pt;">	$(5.71)	$ (13.23)				

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The following table sets forth the number of potential common shares excluded from the calculation of net loss per diluted share for the three and nine months ended September 30, 2018 and 2017 because including them would be anti-dilutive:

	Three Months Ended September 30,		**Nine months Ended September 30,**	
	2018	**2017**	**2018**	**2017**
Options to purchase common stock	783,794	176,502	388,377	100,505
Series A convertible preferred stock		42,480		74,651
Series B convertible preferred stock	1,338,916		751,332	
Warrants to purchase common stock	4,716,935	138,365	2,644,946	227,229
Total	6,839,645	357,347	3,784,655	402,385

For the three and nine months ended September 30, 2018 and 2017, the average price of our common stock was less than the exercise price of the vested stock options and exercisable warrants.

NOTE 9: INCOME TAXES

Deferred income tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided for the amount of deferred tax assets that, based on available evidence, are not expected to be realized.

As a result of the Company’s cumulative losses, management has concluded that a full valuation allowance against the Company’s net deferred tax assets is appropriate. No income tax liabilities existed as of September 30, 2018 and December 31, 2017 due to the Company’s continuing operating losses.

NOTE 10: CONCENTRATION OF CREDIT RISK

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash deposits. Accounts at each institution are insured by the Federal Deposit Insurance Corporation (“FDIC”) up to

$250,000. At September 30, 2018 and December 31, 2017, the Company had $12,685,587 and $6,967,469 in excess of the FDIC insured limit, respectively.

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NOTE 11: COMMITMENTS AND CONTINGENCIES

Lease Commitments

On November 1, 2018, the Company entered into an operating lease to pay $3,660 monthly rent for a term of 22 months. The total future minimum lease payments due under this lease are $80,500.

Litigation and Contingencies

On October 10, 2013, a putative securities class action complaint, captioned *Cook v. Atossa Genetics, Inc., et al.*, No. 2:13-cv-01836-RSM, was filed in the United States District Court for the Western District of Washington against us, certain of our directors and officers and the underwriters of our November 2012 initial public offering. The complaint alleged that all defendants violated Sections 11 and 12(a)(2), and that we and certain of our directors and officers violated Section 15, of the Securities Act by making material false and misleading statements and omissions in the offering's registration statement, and that we and certain of our directors and officers violated Sections 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder by making false and misleading statements and omissions in the registration statement and in certain of our subsequent press releases and SEC filings with respect to our NAF specimen collection process, our ForeCYTE Breast Health Test and our MASCT device. The complaint sought, on behalf of persons who purchased our common stock between November 8, 2012 and October 4, 2013, inclusive, damages of an unspecific amount.

On March 23, 2018, the parties filed a stipulation of settlement with the court to settle the matter for $3.5 million, completely funded by defendants' insurers, and on July 20, 2018 the Court approved the settlement. This case is considered closed as of September 30, 2018.

We are subject to other legal proceedings and claims that arise in the normal course of business. We believe these matters are either without merit or of a kind that should not have a material effect, individually or in the aggregate, on our financial position, results of operations or cash flows.

NOTE 12: STOCK BASED COMPENSATION

Stock Option and Incentive Plan

On September 28, 2010, the Board of Directors approved the adoption of the 2010 Stock Option and Incentive Plan the ("2010 Plan") to provide for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. Awards of incentive options may be granted under the 2010 Plan until September 2020. No other awards may be granted under the 2010 Plan after the date that is 10 years from the date of stock-holder approval. An aggregate of 5,556 shares were initially reserved for issuance in connection with awards granted under the 2010 Plan and on May 18, 2016, an additional 11,111 shares were reserved for issuance under the 2010 Plan. On May 9, 2017, the stockholders approved an additional 125,000 shares for issuance under the 2010 Plan. On April 12, 2018, the stockholders approved an additional 500,000 shares for issuance under the 2010 Plan.

The following table presents the automatic additions to the 2010 Plan since inception pursuant to the "evergreen" terms of the 2010 Plan:

January 1,	**Number of shares**
2012	2,502
2013	2,871
2014	4,128
2015	5,463
2016	18,368
2017	12,623
2018	106,076

Total additional shares	152,031

The Company did not grant options to purchase shares of common stock during the three months ended September 30, 2018 or 2017. No options were exercised during the three or nine months ended September 30, 2018. There are 3,197 shares available for grant under the 2010 Plan as of September 30, 2018.

Compensation costs associated with the Company's stock options are recognized, based on the grant-date fair values of these options, over the requisite service period, or vesting period. Accordingly, the Company recognized stock-based compensation expense of $332,063 and $224,254 for the three months ended September 30, 2018 and 2017, respectively and $726,252 and $560,369 for the nine months ended September 30, 2018 and 2017, respectively (excluding the liability options discussed below).

Options issued and outstanding as of September 30, 2018 under the 2010 Plan and their activities during the nine months then ended are as follows:

	Number of Underlying Shares	**Weighted-Average Exercise Price Per Share**	**Weighted-Average Contractual Life Remaining in Years**	**Aggregate Intrinsic Value**
Outstanding as of January 1, 2018	172,510	$ 49.27		$
Granted	611,668	2.39		
Forfeited	(417)	5.64		
Expired				
Outstanding as of September 30, 2018	783,761	12.70	9.42	$
Exercisable as of September 30, 2018	199,949	40.62	8.95	$
Vested and expected to vest	783,761	12.70	9.42	$

At September 30, 2018, there were 583,812 unvested options outstanding and the related unrecognized total compensation cost associated with these options was approximately $1,479,610. This expense is expected to be recognized over a weighted-average period of 1.56 years.

Option Grants Classified as Liabilities ("Liability Grants")

On June 27, 2018, the Company granted 2,300,000 options to the Chief Executive Officer and 700,000 to the Chief Financial Officer. Each option is exercisable for an equivalent number of shares of Company common stock. The options were granted pursuant to an option award agreement and were granted outside the Company's 2010 Plan; however, they are subject to the terms and conditions of the 2010 Plan.

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The Liability Grants are exercisable for shares of common stock at an exercise price of $2.38 per share, which was the fair market value on the date of grant. The options have an exercise period of ten years from their date of issuance. If at the time the options are exercised the Company cannot deliver shares of common stock to the optionee including, for example, if there are insufficient shares available under the Plan at the time of exercise, then in lieu of the optionee paying the exercise price and the Company issuing shares of stock, the option may only be exercised on a cash “net basis” so that the Company will pay cash in an amount equal to the excess of the fair market value of the common stock over the option exercise price. There currently are not sufficient shares available under the Plan and the Company would be obligated to settle these options in cash if they were exercised. Because these options contain provisions that could require the Company to settle the options in cash in an event outside the Company’s control, they are accounted for as liabilities.

The Liability Grants are subject to vesting requirements. Twenty-five percent of the options have vested as of the grant date, 50% of the options will vest quarterly over two years, and the remaining 25% vest upon achievement of certain milestones related to clinical trial progress. As of September 30 2018, 80% of the options that vest upon achievement of clinical trial milestones are vested.

Compensation costs associated with the Liability Grants are initially recognized, based on the grant-date fair values of these options, over the requisite or vesting period for time-based options or when it is probable the performance criteria will be achieved for options that vest based on performance. Compensation cost is remeasured each period based on the market value of our underlying stock until award vesting or settlement.

For the three and nine months ended September 30, 2018, the Company recognized compensation expense related to these options of $623,496 and $2,180,659, respectively.

The fair value of liability options granted for the nine months ended September 30, 2018 was calculated using the Black-Scholes option-pricing model applying the following assumptions:

	Nine months ended September 30, 2018	
Risk free interest rate	2.94	%
Expected term (in years)	4.75	
Stock price	$1.75	
Dividend yield		%
Expected volatility	122.0	%

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NOTE 13: RESTATEMENT TO PREVIOUSLY ISSUED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The Company has corrected an inadvertent error in the calculation of the deemed dividend on Series B convertible preferred stock in the financial statements for the three and six months ended June 30, 2018 that were included in the Company's Form 10-Q filed on August 13, 2018 (the "Original Form 10-Q"). Accounting principles generally accepted in the United States of America require that we allocate the proceeds from the May 2018 financing to the warrants and preferred stock issued in the financing and that we estimate and record any discount on the securities as a deemed dividend. In the financial statements included in the Original Form 10-Q, we did not properly allocate the proceeds to the warrants, and we did not properly record the deemed dividend related to the warrant discount as additional paid in capital to common stock. The Company incorrectly stated the deemed dividend for the three and six months ended June 30, 2018 as $4,782,100, rather than $11,479,308. The corrections result from application of technical accounting rules and do not impact cash or operations.

In accordance with applicable generally accepted accounting principles, the Company has calculated and recognized adjustments accordingly. The following table shows the effect of the restatement on certain line items within the Company's Condensed Consolidated Statement of Operations for the three months and six months ended June 30, 2018:

	For the Three Months Ended June 30, 2018		**For the Six Months Ended June 30, 2018**	
	Previously Reported	**Restated**	**Previously Reported**	**Restated**
Deemed dividend attributable to preferred stock	$(4,782,100)	$(11,479,308)	$(4,782,100)	$(11,479,308)
Net loss applicable to common stockholders	$(8,924,677)	$(15,621,885)	$(10,799,059)	$(17,496,267)
Loss per common share -basic and diluted	$(2.90)	$(5.08)	$(3.77)	$(6.11)

The following table shows the effect of the restatement on certain line items within the Company's Condensed Consolidated Statement of Stockholders' Equity for the six months ended June 30, 2018:

	Preferred Stock Additional Paid-in Capital		**Common Stock Additional Paid-in Capital**	
	Previously Reported	**Restated**	**Previously Reported**	**Restated**

Issuance of Series B convertible preferred stock, net of issuance costs	$12,290,537	$6,926,778	$0	$5,363,759
Deemed Dividend on Series B convertible preferred stock	$4,782,100	$11,479,308	$(4,782,100)	$(11,479,308)
Conversion of Series B convertible preferred stock to common stock	$(7,056,421)	$(7,821,992)	$6,656,442	$7,422,013

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of the financial condition and results of operations should be read in conjunction with the financial statements and the related notes included elsewhere in this report. This discussion contains forward-looking statements, which are based on assumptions about the future of the Company's business. The actual results could differ materially from those contained in the forward-looking statements. Please read "Forward-Looking Statements" included below for additional information regarding forward-looking statements.

Forward-Looking Statements

This report contains, in addition to historical information, certain information, assumptions and discussions that may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We have made these statements in reliance on the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are subject to certain risks and uncertainties, which could cause actual results to differ materially from those projected or anticipated. Although we believe our assumptions underlying our forward-looking statements are reasonable as of the date of this report, we cannot assure you that the forward-looking statements set out in this report will prove to be accurate. We typically identify these forward-looking statements by the use of forward-looking words such as "expect," "potential," "continue," "may," "will," "should," "could," "would," "seek," "intend," "estimate," "anticipate" or the negative version of those words or other comparable words. Forward-looking statements contained in this report include, but are not limited to, statements about:

whether we can obtain approval from the U.S. Food and Drug Administration ("FDA") and foreign regulatory bodies, to sell, market and distribute our therapeutics and devices under development;

our ability to successfully complete clinical trials of our pharmaceutical candidates under development, including Endoxifen and our intraductal microcatheter technology to administer therapeutics, including our study using fulvestrant;

the success, cost and timing of our product and drug development activities and clinical trials, including whether the ongoing clinical study using our intraductal microcatheters to administer fulvestrant and other studies will enroll a sufficient number of subjects or be completed in a timely fashion or at all;

our ability to contract with third-party suppliers, manufacturers and service providers, including clinical research organizations, and their ability to perform adequately;

- our ability to successfully develop and commercialize new therapeutics currently in development or that we might identify in the future and in the time frames currently expected;

- our ability to establish and maintain intellectual property rights covering our products;

- our expectations regarding, and our ability to satisfy, federal, state and foreign regulatory requirements;

- the accuracy of our estimates of the size and characteristics of the markets that our products and services may address;

- our expectations as to future financial performance, expense levels and capital sources;

- whether the final study results will vary from preliminary study results that we may announce; and

- our ability to attract and retain key personnel.

These and other forward-looking statements made in this report are presented as of the date on which the statements are made. We have included important factors in the cautionary statements included in this report, particularly in the section titled "ITEM 1A. RISK FACTORS," that we believe could cause actual results or events to differ materially from the anticipated results as set forth in the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any new information, future events or circumstances that may affect our business after the date of this report. Except as required by law, we do not intend to update any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events or circumstances or otherwise.

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Company Overview

We are a clinical-stage biopharmaceutical company focused on developing novel, proprietary therapeutics and delivery methods for the treatment of breast cancer and other breast conditions. We are developing Endoxifen with two routes of delivery: a topical formulation, applied like a lotion, for the treatment of a condition called mammographic breast density (or, MBD) and a breast disorder in men called gynecomastia; and an oral formulation to treat stage 1 or 2 breast cancer in the "window of opportunity" between diagnosis and surgery and for breast cancer survivors who do not benefit from taking oral tamoxifen, a current FDA-approved standard of care. We are also developing our patented intraductal microcatheter technology to potentially target the delivery of therapies, including fulvestrant, immunotherapies and Chimeric Antigen Receptor T-cell therapies (CAR-T therapies), directly to the site of breast cancer.

In 2017, we completed a Phase 1 placebo-controlled clinical study of our proprietary oral and topical formulations of Endoxifen in 48 healthy women. All objectives were met: there were no clinically significant safety signals and no clinically significant adverse events, and both the oral and topical Endoxifen were well tolerated. In the topical arm of the study, low but measurable Endoxifen levels were detected in the blood in a dose-dependent fashion. In the oral arm of the study, participants exhibited dose-dependent Endoxifen levels that met or exceeded the published therapeutic level. The median time for patients in the study to reach the steady-state serum levels of Endoxifen while taking daily doses of oral Endoxifen was 7 days. Published literature indicates that it takes approximately 50-200 days for patients to reach steady-state Endoxifen levels when taking daily doses of oral tamoxifen. In September 2018, we completed a Phase 1 placebo-controlled clinical study of our proprietary topical Endoxifen in 24 healthy men. Preliminary results from that study indicate that all of our objectives of safety, tolerability and pharmakinetics were successfully met. Based on these positive preliminary results, we are advancing our topical Endoxifen into a Phase 2 study to reduce gynecomastia and/or improve quality of life in men starting prostate cancer therapy.

We are currently conducting a Phase 2 study at Montefiore Medical Center, Bronx, New York, using our intraductal microcatheter technology to deliver fulvestrant. Our program to use our intraductal microcatheters to deliver CAR-T and other immunotherapies is in the research and development phase.

We are currently conducting two Phase 2 studies of our proprietary Endoxifen: one in Stockholm, Sweden using our topical Endoxifen for MBD and another in Australia using our oral Endoxifen for patients in the window of opportunity between diagnosis of breast cancer and surgery. In October 2018, the MBD study in Sweden was fully-enrolled with all 90 participants: 60 participants on two different dose levels and 30 participants on placebo. Some participants have reported skin rashes and irritation and have withdrawn from the study. Skin reactions were also reported in the Phase 1 studies of the same product. We are evaluating approaches to reduce skin reactions and maximize participation in the study; however, additional study participants could experience these and other more serious side effects and the study may not be successfully completed for these or other reasons.

Our key objectives are to advance our programs through Phase 2 trials and then evaluate further development independently or with partners.

Research and Development Phase

We are in the research and development phase and are not currently marketing any products or services. We do not anticipate generating revenue unless and until we develop and launch our pharmaceutical programs.

Critical Accounting Policies and Estimates

In our Annual Report on Form 10-K for the year ended December 31, 2017, we disclosed our critical accounting policies and estimates upon which our financial statements are derived. There have been no changes to these policies since December 31, 2017. Readers are encouraged to review these disclosures in conjunction with the review of this report.

Results of Operations

Three and Nine months Ended September 30, 2018 and 2017

Revenue and Cost of Revenue:

For the three and nine months ended September 30, 2018 and 2017, we had no revenue and no associated cost of revenue.

Operating Expenses: Total operating expenses were approximately $3.3 million and $9.3 million for the three and nine months ended September 30, 2018, respectively, consisting of research and development (R&D) expenses of approximately $1.4 million and $3.4 million, respectively, and general and administrative (G&A) expenses of approximately $1.9 million and $6.0 million, respectively. Total operating expenses were approximately $2.1 million and $5.7 million for the three and nine months ended September 30, 2017, respectively, consisting of R&D expenses of $0.7 million and $2.1 million, respectively, and G&A expense of approximately $1.3 million and $3.5 million, respectively.

Total operating expenses for the three and nine months ended September 30, 2018 as compared to the same periods of 2017 increased approximately $1.3 million, or 61%, and increased $3.7 million, or 65%, respectively.

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Research and Development Expenses: R&D expenses for the three months ended September 30, 2018 were approximately $1,422,000, an increase of $680,000, or 92%, from approximately $742,000, for the same period in 2017. R&D expenses for the nine months ended September 30, 2018 were approximately $3,361,000, an increase of $1,250,000 or 59%, from approximately $2,111,000 for the same period in 2017. The increase in R&D expenses is mainly attributable to an increase in stock-based compensation expense. R&D expenses primarily consist of salaries, manufacturing and clinical trial expenses associated with our Endoxifen program. Our R&D expenses have increased over the same periods in 2017 because of a 2018 increase in stock-based compensation of $0.9 million and because we commenced two Phase 2 studies of our proprietary Endoxifen in 2018 (one of which enrollment was fully completed in 2018) as compared to no Phase 2 studies of Endoxifen in the prior year.

General and Administrative Expenses: G&A expenses for the three months ended September 30, 2018 were approximately $1,888,000, an increase of $575,000 or 44%, from approximately $1,313,000, for the same period in 2017. G&A expenses for the nine months ended September 30, 2018 were approximately $5,967,000, an increase of $2,422,000 or 68%, from approximately $3,545,000 for the same period in 2017. G&A expenses consist primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses. The increase in G&A expenses for the nine months ended September 30, 2018 is mainly attributed to an increase in stock-based compensation expense of $1.4 million, payroll expenses resulting from salary increases, bonus payments of $350,000 and increased legal and professional consulting expenses of $550,000 over the prior year.

Warrant Financing Costs and Change in Fair Value of Common Stock Warrants: The April 2017 financing included the issuance of common stock liability warrants. The Company incurred financing costs associated with these common stock liability warrants of $192,817 upon issuance. The Company also recorded changes in the fair value of the liability warrants during the three months and nine months ended September 30, 2017 of $128,300 and $280,747, respectively. There were no common stock liability warrants issued during the three and nine months ended September 30, 2018.

Liquidity and Capital Resources

We have a history of operating losses as we have focused our efforts on raising capital and building our products and services in our pipeline. The Company's consolidated financial statements are prepared using generally accepted accounting principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses and negative operating cash flows since inception. For the nine months ended September 30, 2018, the Company recorded a net loss of approximately $9.3 million, and used approximately $6.5 million of cash in operating activities. As of September 30, 2018, the Company had approximately $12.9 million in cash and cash equivalents and working capital of approximately $10.4 million. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. The Company can give no assurances that any additional capital that it is able to obtain, if any, will be sufficient to meet its needs, or that any such financing will be obtainable on acceptable terms. If the Company is unable to obtain adequate capital, it could be forced to cease operations or substantially curtail its commercial activities. These conditions raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern.

As of the date of filing this quarterly report, we expect that our existing resources will be sufficient to fund our planned operations for the next 9 to 15 months; however, additional capital resources will be needed to fund operations longer-term.

Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities or by selling debt securities, if convertible, further dilution to our existing stockholders would result. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our future cash needs through public or private equity offerings, collaboration agreements, debt financings or licensing arrangements.

If adequate funds are not available, we may be required to terminate, significantly modify or delay our development programs, reduce our planned commercialization efforts, or obtain funds through collaborators that may require us to relinquish rights to our technologies or product candidates that we might otherwise seek to develop or commercialize independently. Further, we may elect to raise additional funds even before we need them if we believe the conditions for raising capital are favorable.

Cash Flows

As of September 30, 2018, the Company had cash and cash equivalents and restricted cash of approximately $13.0 million.

Net Cash Flows from Operating Activities: Net cash used in operating activities was approximately $6.5 million for the nine months ended September 30, 2018, compared with approximately $4.9 million for the nine months ended September 30, 2017. The increase in the 2018 period as compared to 2017 results primarily from 2018 increases in clinical study costs, compensation expenses, consulting fees, and patent expenses.

Net Cash Flows from Investing Activities: Net cash used in investing activities was approximately $54,000 for the nine months ended September 30, 2018, compared with no cash used for the nine months ended September 30, 2017. The increase in 2018 was attributable to the purchases of fixed asset equipment in 2018 for R&D activities. There were no corresponding purchases during the corresponding 2017 period.

Net Cash Flows from Financing Activities: Net cash provided by financing activities generated proceeds of $12.3 million for the nine months ended September 30, 2018, as compared with $4.6 million for the nine months ended

September 30, 2017. The increase is mainly attributed to our larger completed rights offering in 2018 as compared to the same period in 2017.

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Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts.

Recent Accounting Pronouncements

In February 2016, Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Lease Accounting Topic 842.* This ASU requires a lessee to recognize lease assets and liabilities on the balance sheet for all arrangements with terms longer than 12 months. The new standard applies a right-of-use (ROU) model that requires a lessee to record, for all leases with a lease term of more than 12 months, an asset representing its right to use the underlying asset for the lease term and a liability to make lease payments. The lease term is the non-cancellable period of the lease, and includes both periods covered by an option to extend the lease, if the lessee is reasonably certain to exercise that option, and periods covered by an option to terminate the lease, if the lessee is reasonably certain not to exercise that termination option. For leases with a lease term of 12 months or less, a practical expedient is available whereby a lessee may elect, by class of underlying asset, not to recognize an ROU asset or lease liability. A lessee making this accounting policy election would recognize lease expense over the term of the lease, generally in a straight-line pattern. The lessor accounting remains largely consistent with existing GAAP. The new standard takes effect in 2019 for public entities. The Company has not currently adopted the provisions of ASU No. 2016-02 and believes that the impact of adopting ASU 2016-02 will not be material to its consolidated financial statements, though will require the recognition of an operating lease liability and right-of-use asset upon adoption, based on the lease composition disclosed in Footnote 11.

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In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows*, amending the presentation of restricted cash within the statement of cash flows. The new guidance requires that restricted cash be included within cash and cash equivalents on the statement of cash flows. The Company adopted the provisions of ASU No. 2016-18 as of January 1, 2018 and has included restricted cash within cash and cash equivalents in the statements of cash flows. For the three and nine months ended September 30, 2018 and September 30, 2017, we included $55,000 of restricted cash in cash and cash equivalents on the statement of cash flows. The restricted cash represents a required deposit for the Company credit card and is restricted until the Company no longer has the credit card or the limit changes on the credit card.

In July 2017, the FASB issued ASU 2017-11, *Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. Part I of this ASU addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of future equity offerings. Current accounting guidance requires financial instruments with down round features to be accounted for at fair value. Part II of the Update applies only to nonpublic companies and is therefore not applicable to the Company. The amendments in Part I of the Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity’s own stock. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity-classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. This Update is effective for public entities for fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company early adopted the provisions of ASU No. 2017-11 as of January 1, 2018. As the Company does not have any financial instruments with down round features, this ASU and it did not have a material impact on the financial statements upon adoption.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation Improvements to Nonemployee Share Based Payment Accounting*. This ASU simplifies several aspects of the accounting for non-employee share-based payment transactions resulting from expanding the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost. The amendments also clarify that Topic 718 does not apply to share-based payments used to effectively provide financing to the issuer or was granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606, *Revenue from Contracts with customers*. This update is effective for public entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoptions is permitted. The Company early adopted the provisions of ASU No. 2018-07 as of April 1, 2018 and it did not have a material impact on the financial statements upon adoption.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (“Exchange Act”), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer concluded that, as of September 30, 2018, the Company’s disclosure controls and procedures were not effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended September 30, 2018, that has materially affected, or is reasonably likely to materially affect our disclosure controls and procedures

For the quarter ended June 30, 2018, we identified a material weakness in the internal controls over the calculation of the deemed dividend on Series B convertible preferred stock (the “deemed dividend”) for the three and six months June 30, 2018. Because of this error, an incorrect deemed dividend was included in net loss applicable to common stockholders which caused an incorrect calculation of loss per common share, basic and diluted. Management misinterpreted the technical guidance contained in *ASC 470- Debt* in calculating the deemed dividend. An appropriately detailed knowledge of *ASC 470 -Debt* was not present to prevent or detect this error. We incorrectly stated the amount of the deemed dividend as $4,782,100, rather than $11,479,308, for the three and six months ended June 30, 2018. We also incorrectly stated the loss per common share - basic and diluted, for the three and six months ended June 30, 2018 as $(2.90) and $(3.77) respectively, rather than the correct amount of $(5.08) and $(6.11), respectively.

Management’s remediation plan is to enhance the procedures performed to independently review technical accounting memorandums for accuracy and completeness including when appropriate with an outside independent accounting firm in future periods.

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PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Litigation and Contingencies

On October 10, 2013, a putative securities class action complaint, captioned *Cook v. Atossa Genetics, Inc., et al.*, No. 2:13-cv-01836-RSM, was filed in the United States District Court for the Western District of Washington against us, certain of our directors and officers and the underwriters of our November 2012 initial public offering. The complaint alleged that all defendants violated Sections 11 and 12(a)(2), and that we and certain of our directors and officers violated Section 15, of the Securities Act by making material false and misleading statements and omissions in the offering's registration statement, and that we and certain of our directors and officers violated Sections 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder by making false and misleading statements and omissions in the registration statement and in certain of our subsequent press releases and SEC filings with respect to our NAF specimen collection process, our ForeCYTE Breast Health Test and our MASCT device. The complaint sought, on behalf of persons who purchased our common stock between November 8, 2012 and October 4, 2013, inclusive, damages of an unspecific amount.

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On March 23, 2018, the parties filed a stipulation of settlement with the court to settle the matter for $3.5 million, completely funded by defendants' insurers, and on July 20, 2018 the Court approved the settlement. This case is considered closed as of September 30, 2018.

We are subject to other legal proceedings and claims that arise in the normal course of business. We believe these matters are either without merit or of a kind that should not have a material effect, individually or in the aggregate, on our financial position, results of operations or cash flows.

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ITEM 1A. RISK FACTORS

There have been no material changes to the risk factors described in our Annual Report on Form 10-K, as filed with the SEC on March 8, 2018.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

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ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

(a) Exhibits

		Incorporated by Reference Herein	
Exhibit No.	**Description**	**Form**	**Date**
31.1	Certification pursuant to Rule 13a-14(a) under the securities Exchange Act of 1934 of Steven C. Quay	Filed herewith	
31.2	Certification pursuant to Rule 13a-14(a) under the securities Exchange Act of 1934 of Kyle Guse	Filed herewith	
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Steven C. Quay	Filed herewith	
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Kyle Guse	Filed herewith	
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T	Filed herewith	

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 13, 2018

/s/ Steven C. Quay
President and Chief Executive Officer
(On behalf of the Registrant)

/s/ Kyle Guse
Kyle Guse
Chief Financial Officer, General Counsel and Secretary
(As Principal Financial and Accounting Officer)

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