

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(D)
of the Securities Exchange Act of 1934**

March 22, 2023

Date of report (Date of earliest event reported)

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36464
(Commission
File Number)

23-2936302
(IRS Employer
Identification No.)

500 College Road East, Suite 310
Princeton, New Jersey
(Address of principal executive offices)

08540
(Zip Code)

Registrant's telephone number, including area code **(609) 683-1880**
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	AGRX	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On March 22, 2023, Agile Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the three months and fiscal year ended December 31, 2022 and an update on the Company’s operations. The Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information included in this Item 2.02, including Exhibit 99.1 hereto, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits.**

Exhibit Number	Description
99.1	Press Release dated March 22, 2023
104	Cover Page Interactive Data File (Embedded within the Inline XBRL Document).

SIGNATURES

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

Agile Therapeutics, Inc.

Dated: March 22, 2023

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairman and Chief Executive Officer

AGILE THERAPEUTICS REPORTS FOURTH QUARTER & FULL YEAR 2022 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

Fourth Quarter 2022 Net Revenue Increased 33% from Third Quarter 2022 While GAAP Quarter-Over-Quarter OPEX Decreased 55% and Non-GAAP OPEX Remained Unchanged

Twirla Demand and Factory Sales Up 25% and 30% Respectively in Fourth Quarter 2022 vs Third Quarter 2022

Company Reaffirms Expected Full Year 2023 Net Revenue in Range of \$25-\$30 Million

Management to Host Conference Call Today, Wednesday, March 22, 2023 at 4:30 p.m. ET

PRINCETON, N.J., March 22, 2023 (GLOBE NEWSWIRE) – Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three and twelve months ended December 31, 2022 and provided a corporate update.

"2022 was a turning point for Agile as we continued to advance revenue growth for Twirla and transformed and streamlined our operating model to reduce expenses, which we believe sets Agile up for a strong year of continued revenue growth in 2023," said Agile Therapeutics Chairman and Chief Executive Officer Al Altomari. "We continue to believe we will reach our goal of 2023 net revenue in the range of \$25-\$30 million."

Fourth Quarter & Full Year 2022 Performance Updates

- **Twirla delivered \$4.0 million in net revenue for the fourth quarter 2022.** This was an increase of 33% from the \$3.0 million reported for the third quarter 2022. Net revenue for the full year 2022 was \$10.9 million, a 165% increase from 2021 net revenue of \$4.1 million. Fourth quarter and full year 2022 net revenue growth reflects improvements in the following key areas:
 - *Continued Twirla Demand Growth*
 - **Twirla demand for the fourth quarter was 37,452 total cycles, a 25% increase from the third quarter 2022.**
 - For the full year 2022, Twirla demand was 105,741 total cycles, a 213% increase from 2021.
 - *Significant Twirla Factory Sales Growth*
 - **Twirla factory sales for the fourth quarter were 43,230 total cycles, a 31% increase from the third quarter 2022.**
 - For the full year 2022, Twirla factory sales were 114,546 total cycles. This total exceeded the 113,600 total cycles we originally expected for 2022 and represents a 226% increase from 2021.
 - *Company Operating Expenses*
 - **Fourth quarter GAAP operating expenses were \$9.2 million for 2022, a decrease of 55% from the \$20.3 million reported for the third quarter 2022.**
 - Fourth quarter Non-GAAP operating expenses for 2022 were \$9.2 million and remained substantially unchanged from the \$9.2 million for the third quarter 2022. A reconciliation of non-GAAP to GAAP operating expenses is provided in the tables accompanying this press release.
 - Full year 2022, GAAP operating expenses were \$56.6 million, compared to \$64.4
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- million for the full year 2021, representing a 12% decrease year on year.
 - Full year 2022, Non-GAAP operating expenses were \$45.5 million, compared to \$64.4 million for the full year 2021, representing a 29% decrease year on year.
 - The Company expects operating expenses for full year 2023 to be lower than full year 2022.
- The fourth quarter 2022 improvements in net revenue, Twirla demand, and Twirla sales reflect a continued increase in sales in the non-retail channel through the Company's collaboration with Afaxys.
 - Collaboration with Afaxys
 - **Non-retail cycles purchased in the fourth quarter of 2022 were 15,420, a 42% increase from the 10,842 non-retail cycles sold in the third quarter 2022.**
 - The meaningful non-retail channel growth is the product of the efforts being made by Afaxys to expand Twirla in the Planned Parenthood network.
 - In the second half of 2022, the Company began to see conversion of large Planned Parenthood accounts in California.

Potential Future Upside from Twirla Business Plan

- The Company remains focused on achieving its key goals of growing Twirla, attaining 2023 net revenue in the range of \$25-\$30 million and, ultimately, generating positive cash flow. The Company remains confident it can accomplish these key goals by:
 - Targeting Promotional Efforts on Five Key States
 - The Company continues to focus its Twirla promotional efforts on the five states that have high levels of reimbursement potential for Twirla and are estimated to reach 45% of U.S. women between the ages of 18 and 24.
 - Increasing Footprint in Telemedicine
 - In 2023, the Company expects to see an impact in the retail channel from its collaboration with female telehealth leader Nurx. From the third quarter 2022 to the fourth quarter 2022, retail channel sales grew 25%.
 - Nurx has provided contraception to more than 1 million patients and the Company's vision and ambition is that Nurx can accelerate retail channel growth similar to the way Afaxys accelerated non-retail channel growth.
 - Capturing Greater Volume Growth
 - After achieving non-retail channel sales growth of 42% in the fourth quarter 2022, the Company believes it can continue momentum throughout 2023 from both new and returning orders.
 - The Company believes there is additional potential for Twirla volume growth in this channel based on the reach of the Afaxys customer network, which includes Planned Parenthood and student health centers.
 - The Company also believes it will start to experience increased growth in the retail channel from physicians who gain more clinical experience with Twirla in the Planned Parenthood setting and become more comfortable prescribing Twirla in their other practices.
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Fourth Quarter & Full Year 2022 Financial Results

- **Net Revenue:** In the fourth quarter 2022, the Company realized net product sales revenue of \$4.0 million, an increase of 33% as compared to the third quarter 2022 revenue of \$3.0 million. Full year 2022 net revenue was \$10.9 million, a 166% increase from the \$4.1 million reported for full year 2021.
 - **Cost of Goods Sold (COGS):** Cost of goods sold, which consists of direct and indirect costs related to the manufacturing of Twirla, were \$1.7 million for the fourth quarter and \$6.8 million for the full year 2022, lower compared to the \$5.7 million and \$10.7 million reported for the same periods in 2021. The decrease in COGS is attributable to improved inventory management as there were no obsolescence charges throughout 2022.
 - **Total GAAP operating expenses:** Total GAAP operating expenses were \$9.2 million for the quarter ended December 31, 2022, compared to \$18.2 million for the comparable period in 2021 – a decrease of 49%. The GAAP operating expenses for the fourth quarter 2022 represent a decrease of 55% from the \$20.3 million of GAAP operating expenses reported for the third quarter 2022. For the full year 2022, GAAP operating expenses were \$56.6 million, compared to \$64.4 million for the full year 2021, representing a 12% decrease year on year.
 - **Total Non-GAAP operating expenses:** The non-GAAP operating expenses for the fourth quarter were substantially unchanged to the \$9.2 million of non-GAAP operating expenses reported for the third quarter 2022. For the full year 2022, non-GAAP operating expenses were \$45.5 million, compared to \$64.4 million for the full year 2021, representing a 29% decrease year on year. A reconciliation of non-GAAP to GAAP operating expenses is provided in the tables accompanying this press release.
 - **Cash:** As of December 31, 2022, the Company had \$5.2 million of cash, compared to \$19.1 million of cash and cash equivalents as of the end of the fourth quarter 2021. In addition to the \$75 million at-the-market (ATM) arrangement, the Company will continue to evaluate all available options to finance the Company and continue to explore all opportunities that can potentially accelerate the timeline to generating positive cash flow.
 - **GAAP Net loss:** GAAP net loss was \$3.9 million, or \$0.10 per share, for the quarter ended December 31, 2022, compared to a GAAP net loss of \$19.5 million, or \$6.63 per share, for the comparable period in 2021. For full year 2022, net loss was \$25.4 million, or \$1.18 a share, compared to \$71.1 million, or \$29.28 per share in the full year 2021. These results reflect the reclassification of certain warrants issued in connection with financings in 2021 and 2022. The reclassification of the warrants as liabilities resulted in \$3.8 million in other income for 2021 and \$25.5 million in other income for 2022. Moving forward, the Company expects to see fluctuations in GAAP net income or loss depending on the valuation of these warrants, which will need to be assessed on a quarterly basis and are expected to result in non-cash accounting adjustments.
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- **Non-GAAP Net Loss:** Non-GAAP net loss was \$7.3 million, or \$0.18 per share, for the quarter ended December 31, 2022, compared to a non-GAAP net loss of \$23.4 million, or \$7.92 per share, for the comparable period in 2021. For full year 2022, non-GAAP net loss was \$39.8 million, or \$1.84 a share, compared to \$74.9 million, or \$30.86 per share in the full year 2021. These results reflect the exclusion of the \$3.8 million in other income for 2021 and \$25.5 million in other income for 2022 resulting from the reclassification of certain warrants issued in connection with financings in 2021 and 2022. A reconciliation of non-GAAP to GAAP net loss is provided in the tables accompanying this press release.
 - **Shares Outstanding:** As of December 31, 2022, Agile had 42,970,134 shares outstanding and 21,610,947 weighted average shares of common stock outstanding.
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Conference Call and Webcast

Date Wednesday, March 22, 2023

Time 4:30 p.m. ET

Webcast (live and archived) [Events & Presentations](#)

Registration Link [Register Here](#)

A live webcast of the conference call may be accessed via the Investor Relations portion of the Agile Therapeutics website at <https://ir.agiletherapeutics.com/events-and-presentations>.

To participate in the live conference call via telephone, please register [here](#). Upon registering, a dial-in number and unique PIN will be provided to join the conference call.

About Agile Therapeutics, Inc.

Agile Therapeutics is a women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our product and product candidates are designed to provide women with contraceptive options that offer freedom from taking a daily pill, without committing to a longer-acting method. Our initial product, Twirla®, (levonorgestrel and ethinyl estradiol), a transdermal system, is a non-daily prescription contraceptive. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to allow drug delivery through the skin. For more information, please visit the company website at www.agiletherapeutics.com. The Company may occasionally disseminate material, nonpublic information on the Company's website, Twitter account (@agilether), and [LinkedIn](#) account.

About Twirla®

Twirla (levonorgestrel and ethinyl estradiol) transdermal system is a once-weekly combined hormonal contraceptive (CHC) patch that contains the active ingredients levonorgestrel (LNG), a type of progestin, and ethinyl estradiol (EE), a type of estrogen. Twirla is indicated for use as a method of contraception by women of reproductive potential with a body mass index (BMI) < 30 kg/m² for whom a combined hormonal contraceptive is appropriate. Healthcare providers (HCPs) are encouraged to consider Twirla's reduced efficacy in women with a BMI ≥ 25 to <30 kg/m² before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m². Twirla is also contraindicated in women over 35 years old who smoke. Cigarette smoking increases the risk of serious cardiovascular events from CHC use. Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch.

About Prescription Data

The Company receives prescription data for Twirla from Symphony Health Solutions, and the data are not created or owned by the Company. Prescription data are available through other subscription services as well, such as IQVIA. Unless otherwise noted, the prescription data results reported in this press release are reported as of December 31, 2022, by Symphony Health Solutions. The prescription data terms are defined as follows: Twirla cycles dispensed are the number of 3-patch packages dispensed.

Each 3-patch package represents one 28-day cycle of therapy. Total Cycles Dispensed represents every cycle dispensed from both retail and non-retail channels. Retail channels include retail pharmacies, mail order, and long-term care while non-retail channels include clinics and hospitals and other entities where prescriptions are dispensed directly to the patient. Total prescriptions (TRx) are the total number of prescriptions dispensed through the retail channels. This represents both new and refill prescriptions. New prescriptions (NRx) are new prescriptions dispensed through retail channels. Refill prescriptions (RRx) are refill prescriptions filled through retail channels. Total prescribers are the cumulative number of prescribers whose prescriptions were filled through retail channels since launch. Not all prescription demand in the non-retail channel is reported into third parties like Symphony Health Solutions and IQVIA. The factory sales reported from Twirla wholesalers do include sales to the non-retail channel and, therefore, the Company believes factory sales more closely represent the total demand for Twirla across all channels.

Use of Non-GAAP Financial Measures

To supplement our consolidated financial statements, which are prepared and presented in accordance with U.S. generally accepted accounting principles (GAAP), we use non-GAAP operating expenses and non-GAAP net loss to measure our financial performance. We define the term non-GAAP operating expenses as GAAP operating expenses excluding one-time, non-cash charges incurred in connection with the loss on disposition of assets. We define the term non-GAAP net loss as GAAP net loss excluding recurring unrealized gains or losses pertaining to liability classified warrants and one-time non-cash charges incurred in connection with the loss on disposition of assets. We believe that the presentation of these non-GAAP financial metrics provides useful information about our operating results, enhances the overall understanding of past financial performance and future prospects, allows for greater transparency with respect to metrics used by our management in its financial and operational decision-making and produces a useful measure for period-to-period comparisons of our business.

The presentation of these non-GAAP financial measures are not intended to be a substitute for, or superior to, the financial information prepared and presented in accordance with GAAP and may be different from non-GAAP financial measures used by other companies, and therefore, may not be comparable among companies. We believe the presentation of these non-GAAP financial measures provides meaningful supplemental information regarding our performance; however, we urge investors to review the reconciliation of this financial measures to the comparable GAAP financial measures included in the accompanying tables, and not to rely on any single financial measure to evaluate our business.

Forward-Looking Statements

Certain information contained in this press release includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We may in some cases use terms such as “predicts,” “believes,” “potential,” “continue,” “anticipates,” “estimates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “likely,” “will,” “should” or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Our forward-looking statements are based on current beliefs and expectations of our management team that involve risks, potential changes in circumstances, assumptions, and uncertainties, including statements regarding our ongoing and planned manufacturing and commercialization of Twirla®, the potential market acceptance and uptake of Twirla, including the increasing demand for Twirla in 2023, our partnership with Afaxys and its ability to promote growth, our product supply agreement with Nurx and its ability to educate patients about Twirla, our connected TV (CTV) campaign and its ability to promote growth, our prospects for future financing arrangements, our net revenue and expected operating expenses for 2023, and our financial condition, growth and strategies. Any or all of the forward-looking statements may turn out to be wrong or be affected by inaccurate assumptions we might

make or by known or unknown risks and uncertainties. These forward-looking statements are subject to risks and uncertainties including risks related to our ability to maintain regulatory approval of Twirla and the labeling under any approval we obtain, the ability of Corium to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla, our ability to successfully enhance the commercialization of and increase the uptake for Twirla, the size and growth of the markets for Twirla and our ability to serve those markets, regulatory and legislative developments in the United States and foreign countries, our ability to obtain and maintain intellectual property protection for Twirla and our product candidates, the lingering effects of the COVID-19 pandemic on our commercialization efforts, clinical trials, supply chain, operations and the operations of third parties we rely on for services such as manufacturing, marketing support and sales support, as well as on our potential customer base, our ability to maintain compliance with the listing requirements of the Nasdaq Capital Market and the other risks set forth in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as of the date of this press release. We undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

Contact:

Matt Riley

Head of Investor Relations & Corporate Communications

mriley@agiletherapeutics.com

Agile Therapeutics, Inc.
Balance Sheets
(in thousands, except par value and share data)

	December 31, 2022	December 31, 2021 (Restated)
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,246	\$ 19,143
Accounts receivable, net	3,377	1,533
Inventory, net	1,332	966
Prepaid expenses and other current assets	1,403	2,283
Total current assets	11,358	23,925
Property and equipment, net	177	12,447
Right of use asset	695	949
Other non-current assets	2,012	2,012
Total assets	\$ 14,242	\$ 39,333
Liabilities and stockholders' equity		
Current liabilities:		
Long-term debt, current portion	\$ 1,426	\$ 16,833
Accounts payable	7,734	8,707
Accrued expenses	3,908	3,563
Lease liability, current portion	319	175
Total current liabilities	13,387	29,278
Lease liabilities, long-term	466	784
Warrant liability	5,934	5,356
Total liabilities	19,787	35,418
Stockholders' equity		
Preferred stock, \$.0001 par value, 10,000,000 shares authorized, 4,850 issued and no shares outstanding at December 31, 2022 and no shares issued and outstanding at December 31, 2021	-	-
Common stock, \$.0001 par value, 300,000,000 shares authorized, 42,970,134 and 3,034,901 issued and outstanding at December 31, 2022 and December 31, 2021, respectively	4	-
Additional paid-in capital	403,153	387,205
Accumulated deficit	(408,702)	(383,290)
Total stockholders' equity	(5,545)	3,915
Total liabilities and stockholders' equity	\$ 14,242	\$ 39,333

Agile Therapeutics, Inc.
Statement of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Three Months Ended December 31, (Unaudited)		Year Ended December 31,	
	2022	2021 (Restated)	2022	2021 (Restated)
Revenues, net	\$ 3,996	\$ 1,514	\$ 10,884	\$ 4,101
Cost of product revenues	1,653	5,702	6,836	10,718
Gross profit (loss)	2,343	(4,188)	4,048	(6,617)
Operating expenses:				
Research and development	\$ 352	\$ 1,656	\$ 3,253	\$ 6,246
Selling and marketing	6,844	12,670	30,369	43,444
General and administrative	2,023	3,846	11,860	14,698
Loss on disposition of assets	-	-	11,122	-
Total operating expenses	9,219	18,172	56,604	64,388
Loss from operations	(6,876)	(22,360)	(52,556)	(71,005)
Other income (expense)				
Interest income	30	1	80	25
Interest expense	(432)	(999)	(3,131)	(3,914)
Unrealized gain on warrant liability	3,349	3,827	25,520	3,827
Total other income (expense), net	2,947	2,829	22,469	(62)
Loss before benefit from income taxes	(3,929)	(19,531)	(30,087)	(71,067)
Benefit from income taxes	-	-	4,675	-
Net loss	<u>\$ (3,929)</u>	<u>\$ (19,531)</u>	<u>\$ (25,412)</u>	<u>\$ (71,067)</u>
Net loss per share (basic and diluted)	<u>\$ (0.10)</u>	<u>\$ (6.63)</u>	<u>\$ (1.18)</u>	<u>\$ (29.28)</u>
Weighted-average common shares (basic and diluted)	<u>41,232,562</u>	<u>2,947,944</u>	<u>21,610,947</u>	<u>2,426,821</u>
Comprehensive loss:				
Net loss	\$ (3,929)	\$ (19,531)	\$ (25,412)	\$ (71,067)
Other comprehensive income:				
Unrealized (loss) gain on marketable securities	-	-	-	(3)
Comprehensive loss	<u>\$ (3,929)</u>	<u>\$ (19,531)</u>	<u>\$ (25,412)</u>	<u>\$ (71,070)</u>

Agile Therapeutics, Inc.
Reconciliation of GAAP Operating Expenses to Non-GAAP Operating Expenses
(Unaudited)
(in thousands)

	Three Months Ended					Twelve Months Ended	
	12/31/2022	9/30/2022	6/30/2022	3/31/2022	12/31/2021	12/31/2022	12/31/2021
GAAP Operating expenses	\$ 9,219	20,285	11,293	15,807	18,170	\$ 56,604	\$ 64,388
Non-GAAP adjustment: Loss on disposition of assets	\$ -	11,122	-	-	-	\$ 11,122	-
Non-GAAP operating expenses	\$ 9,219	9,163	11,293	15,807	18,170	\$ 45,482	\$ 64,388

Agile Therapeutics, Inc.
Unaudited Reconciliation of Net Loss (GAAP) to adjusted Net Loss (non-GAAP)
(in thousands)

	Three Months Ended					Twelve Months Ended	
	3/31/2022 (Restated)	6/30/2022 (Restated)	9/30/2022 (Restated)	12/31/2022	12/31/2021 (Restated)	12/31/2022	12/31/2021 (Restated)
GAAP Net Loss	\$ (10,385)	(5,168)	(5,930)	(3,929)	(19,531)	\$ (25,412)	\$ (71,067)
Unrealized gain on warrant liability	1,384	7,051	13,736	3,349	3,827	25,520	3,827
Loss on disposition of assets	-	-	(11,122)	-	-	(11,122)	-
Non-GAAP Net Loss	\$ (11,769)	(12,219)	(8,544)	(7,278)	(23,358)	\$ (39,810)	\$ (74,894)
Non-GAAP Net Loss Per Share	\$ (3.78)	(2.71)	(0.23)	(0.18)	(7.92)	\$ (1.84)	\$ (30.86)
Weighted avg shares	3,115,211	4,510,219	36,997,836	41,232,562	2,947,944	21,610,947	2,426,821