

16.12.28R. Analysis of the, NeuVax, (or “E75”), Phase III Trial results presented by GALE in, its, 3rd Quarter, 2016, report, (or “GALE Q3”).

Colonel, (R), Dr. George E. Peoples, MD, PhD, Inventor and Surgeon,
Faculty, Professor, MD Anderson Cancer Center, The University of Texas System, US Army Med Center, San Antonio,
Texas, USA, 3851 Roger Brooke Dr # 3600, Fort Sam Houston, TX, 78234, **Phone:(210) 916-4235,**

Dr. Mark W. Schwartz, PhD, mwschwartz@galenabiopharma.com President & CEO,
Galena Biopharma Inc, (“GALE”, **Nasdaq**), USPS Certified: 2315 1670 0000 5225 6250 received January 3,2017.

cc: **Thomas J. Knapp, Chief Legal Counsel, GALE, By US Mail 1st class.**
2000 CROW CANYON PLACE, SUITE 380 | SAN RAMON, CA 94583 | 1-855-855-GALE |

Dear Dr. Peoples and Dr. Schwartz:

1. Since the E75 Phase II Trial showed significant protection from metastases with, $p < 0.035$, instead of expected, $p < 0.050$, we anticipate, in, Phase III Trial, in, the worse case scenario, $p < 0.055-0.060$, but, the same trend as, in Phase II. **GALE, Q3** shows, that, Control arm, (or “Control”) performed better than E75 arm, (or “E75”). Shows results from, only 9.36% of the patients treated with E75 for average 19.7 months. Lists: **Disease relapse, (or “DFS”):** E75 + GM-CSF = 9.57%, (36: 376). Control, (GM-CSF only: 6.02%, (23: 382).

2. I added the 2nd decimal. Patients, which, recurred for other reasons were not removed from the total. If they would have been removed, DFS would have been: E75 = 9.729 %, (36: 369). Control= 6.100%, (23: 377).

3. *First*, the use of the term DFS by the GALE managers concerns me and should concern to you. DFS, in scientific literature, means “*disease free survival*”. GALE changed DFS designation to indicate “*disease relapse*”. We should use, the term, *time to recurrence in months*, (or “**TTR-m**”), to designate all patients which recurred by PR and CD, (definitions in, ¶ 4,5 below), the term disease relapse only for the patients which recurred by Clinical Diagnosis, (or “**DR-CD**”), and the consensus term **PR** for the patients which recurred, as, detected by X-Rays only, but not by clinical diagnosis, MRI and CAT scan.

4. The E75 Group contains mostly patients, which show **pseudo-progression**, (or “**PP**”), or **pseudo-recurrence**, (**GALE-Q3**), (or “**PR**”). There is a semiotic difference between “*progression*” and “*recurrence*”. The term “*progression*” is used in the scientific literature to indicate that, patients’ vital characteristics worsened. The term “*recurrence*” denotes that, the disease/ malignancy is detected again in the patients, which were declared free of cancer, before the Clinical trial started. But, GALE **did not quantify the size of the recurrence.**

5. It is unclear whether, PR is, a real recurrence, (calculations page 3-4, references page 4). If **PR**, detected by, “by X-Rays”, but, not by MRI, (? , **GALE, Q3, page 11**), is excluded, E75 performed better, in 2nd year, (Group V, page 2-3, ¶ 16). If PR, in months 13-24, is attributed to, E75, E75 performed better than control: DFS by **clinical diagnosis, (or “CD”)** is, **E75 = 1.355%, Control: 5.036%; Alternate: E75 = 0.006%, Control: 3.783%.** Differences are statistically significant, because the control value is more than double the E75 value.

6. If PR, 2nd year is attributed to both E75 and control, (GM-CSF), in the same ratio, as in 1st 12 months, (or 1st year), E75 still performed better than control. **DFS, (E75) = 2.439%, Control = 3.978%, or, Alternate: E75: 1.724%; Control: = 2.702%.** Differences could be significant, but needs more data.

7. GALE’s independent monitoring committee, (or “**IDMC**”), did not define, “*systematic reversal*”. *Expected* all patients to do better in, 1st year and worse, in the 2nd year? If yes, the rationale of the immunotherapy either was not explained well or is misunderstood. The results show that, patients, in whom cancer did not recur, in the 1st year, did better in the 2nd year.

1. Most of the 71 patients failed in the 1st 12 months. I suspect that, these patients had metastases when they received vaccine.
2. In, months, 22-30, E75 induced similar protection from recurrence with, *Ipilimumab*, (*anti-CTLA-4*).

8. **IDMC** recommended “**the study be stopped** for futility unless it is determined that there has been **a systematic reversal** in the study drug treatments in the two arms, in which case the **IDMC** should reevaluate the clinical evidence.

9. IDMC report raised 6 issues including its credibility or expertise:

1. **There is no study to be stopped.** All vaccinations with E75 were completed in 2015.
2. **There is no need to repeat the study.** That, the study was un-blinded after IDMC report is not an issue.
3. If we remove 47 patients, [12 patients, (another cancer + death from another cause) + 35 PR patients year 1)], you have 700 patients to be evaluated.
4. Patient Group V, (page 3, ¶ 16,17), which, performed better with E75, is not characterized.
5. IDMC is anonymous. Raise questions of credibility. IDMC consist of a Breast Medical Oncologist, Radiologist and Statistician?
6. The Ir RECIST measurements are not shown.

RECIST (Response Evaluation Criteria In Solid Tumors) is a set of published rules that define when cancer patients improve ("respond"), stay the same ("stable") or worsen ("progression") during treatments. RECIST 1.1, published in January 2009, is an update to the original criteria. Today, the majority of clinical trials evaluating cancer treatments for objective response in solid tumors are using RECIST. While the RECIST rules are highly dependent upon measurement of tumor size, different clinicians may vary greatly in their methods of performing these measurements. Consistency in following the imaging requirements and rules is even more challenging. When investigators vary in how they follow RECIST as a trial endpoint, the study results may be placed in jeopardy by significant levels of variability.

10. PR is not indication of failure, but suggests that patients enrolled in the trial had advanced disease, tumor necrosis and cysts, (*in lay terms*), due to radiation and hormone treatment before E75. Overall, **PR** is, 6.30%, [47:746,(376+382-7-5)], or in, the range of **PP** observed with other therapies,(References 1-3).

11. DFS appears at, 12 months, as, PR in 35,(49.22%),of 71 patients,(A, below page 2), mostly E75-treated, before 2nd injection of vaccine: % DFS by PP : E75 = 60%, Control = 32 %, (GALE, Q3, page 10). 12 more patients show PP, months, 13-24.

12. **Fast progression in, the earliest, 2011-2012, E75-treated patients, suggests:**

1. Radiation treatment of breast cancer patients, before E75, induced PR. GM-CSF mobilizes macrophages in blood circulation.
2. **Poor quality of the E75 initially used in, 2012-2013.** Alternatively, E75 used late, 2014-2015, was of, poor quality. 91% of recently vaccinated patients did not relapse. I can explain you the effects of the poor quality of E75 and analyze for you the chemical composition of the E75.
3. E75 induced death, (TCR-mediated apoptosis), of the E75 primed cells in Group A1, (page 3). If these patients had metastases, they were already tolerant. E75-stimulation induced death of the effector lymphocytes.
4. Different HER-2 protein levels in E75 and Control arms affected the response?
5. Pathology results from these 71 patients must be analyzed. Patients with low HER-2 protein levels,(1-10 times more than normal) do not recur, while, patients with higher HER-2, protein levels,(11-100 more than normal), recurred ?
6. **Is possible that, the fast recurring patients have HER-2^{Hi} (HER-2 protein 200 higher than normal).**
7. Disease stage, number of metastases and levels of HER-2, in Group V must differ from Groups I–III. Metastases" detected by PR are in different sites in the E75 than, in the Control Arm?
8. More ill patients treated with E75, at sites, other than, MD Anderson, (or "MDACC"), Walter Reed,(or "WR"), and Fort Hood. Page 3, Q3-GALE shows that, 7 E75-treated patients relapsed in 6 months.

13. **Facts. Reversal of, the trend to disease recurrence, ("DFS"), by E75 in 4 patients, months 22-30.**

14. GALE, Q3, page 8, lists median time in the trial of 19.7 months. 19.7 months is less than, the half-time of, 25 months, to, project responses at 42-45 months. Most patients were in the trial 12 months or less before they recurred.

15. GALE, Q3, page 10, identifies 5 groups of responses based on DFS: I. (0-7 months), II. (8-10 months), III. (10-12 months), IV.(13-19 months) and V.(23-30 months).

16. **Group V received complete treatment with E75. Paired Student's t- test, shows E75 significant.**

17. **Group V** has 4 patients in E75 and 4 in Control. Average DFS is, 27.25 months in, E75, (30,29,27,23, respectively), and 23.375 months in Control,(25,24,22.5,22 respectively). T-test: Unpaired: p:0.062, Paired: p= 0.028*.

18. **Group IV** has 3 patients in, the E75 and 3 in, the Control. The average DFS is 18 months in E75,(19,19,16), and 15.33 months in Control,(17,16,13).T-test: unpaired: p= 0.16; paired p= 0.016*
*To accept paired t- test results, characterize patients in each arm to determine whether they are similar.

19. **Group III** has 8 patients in E75 and 9 in Control Arm. **Group III shows a 2-week** benefit from E75, although there is no confidence interval. The average DFS is 10.875 months in the E75,(12,11,11,10.7,10.6, 10.6, 10.6,10.5), and,10.333 in the Control, (11.5,11,10.5, 10,10, 10,10,10,10).

20. Recommendation:

1. Patients and GALE will benefit from extended clinical monitoring for, 2 more years. You know who, received E75 and who received control.
 2. GALE could contribute, financially for extended clinical monitoring and analysis of more patients.
 3. Drs. Mittendorf and you have, in MDACC, WR, and Fort Hood 50 patients. Patients are scheduled to return every 6 months. If, 3 distant sites provide 50 patients you will have 100 patients for long-term clinical monitoring. Groups IV and V include 14 patients. I anticipate that in 100 patients you will identify another 16 patients to be included in Groups IV and V. 30 patients would define a population where E75 is effective by Clinical Criteria.
 4. Patient insurances, pay for visits and tests. MDACC has at least \$ 500,000 from, my royalty, to be spent on research and education. Since there are 100 patients, this makes \$ 10,000 per patient, on top of, what the insurances pay. MDACC documents obtained through the Freedom of information act, show that, GALE paid MDACC for, Dr. Mittendorf trial, less than \$ 100,000.
21. Halting clinical monitoring and analysis, in, breast cancer trial, directed by Dr. Mittendorf, woman-physician and not following MDACC, Fort Hood and WR patients would be biased.
22. With a Woman President of the National Academy of Sciences, and reports that, patients treated by women do better, I can help you with the Breast Cancer Society and the US Congress.
23. I can write the scientific part for a grant from the " Moonshot program". I can contact the companies, such as Microsoft, Netflix and the Clinton Foundation.
24. In 2 more years you will analyze 100 more patients. Data from 171 patients will be more significant than, from 71. The data will help you manage your trials with E75 and E75 plus Herceptin. The data will help with FDA approval and investments. Only part of your E75, Phase III trial will be repeated.

25. I analyze the data presented by GALE.

A. Page 10, GALE Q3. 35 Patients relapsed as, PP, detected by Proactive imaging:

A1. E75: $43 \times 0.60, (60\%) = 26.$

A2. Control: $28 \times 0.32, (32\%) = 9.$

A3. Total patients relapsed detected by PP: E75, (A1) + Control,(A2) = 35.

B. 36 patients relapsed detected by clinical diagnosis, (or "CD") Error ?

B1. E75: $43 - (\text{minus}) - 26, (A1 \text{ above}) = 17.$

B2. Control: $28 - (\text{minus}) - 9, (A2 \text{ above}) = 19.$

B3. Total patients relapsed detected by CD according to GALE = 36,(B1 + B2).

B4. GALE,Q3, page 9, lists only 24 patients where the relapse was detected by CD.

C. DFS adjudicated events. Page, 9, GALE Q3, contradicts results reported in, GALE Q3, page 10.

C1. Diagnosed by PP = 47 instead of 35 calculated above, (A3). 12 more patients diagnosed by PP.

C2. Diagnosed by CD = 24 instead of 36 calculated above, (B3).

C3. 12 patients,(C1), relapsed by CD continued to receive E75 after 12 months.

C4. 5 E75 patients, [17, (B1) -12, (C1)], relapsed detected by CD versus 19 Patients Control,(A2).

D. In the case GALE Q3, page 9, the evaluated patients are:

D1.E75: 369, {Total 376 – [5 + 2,(Not evaluated)]}

D2.Control: 377, {Total 382 - [4 + 1,(Not evaluated)]}

E. DFS by CD: E75-Vaccinated patients do better by Clinical Presentation, than, Control:

E1: E75: 5,(C4): 369,(D1) = **1.355%**
 E2: Control: 19,(B2): 377,(D2) = **5.039%**

F. DFS by CD if 12 PP, detected months, 12-24, are distributed, as in the 1st year 60 to 32:

F1. We have 8,(E75)
 F2. We have 4,(Control).
 F3. CD,(E75) = 17,(B1) – 8,(F1) = 9.
 F4. CD,(Control) = 19, (B2) – 4,(F2) = 15.
 F5. E75: 9, (F3): 369, (D1) = **2.439%**
 F6. Control: 15, (F4): 377,(D2) = **3.978%**

G. Alternative calculations**H. Count only patients, which, relapsed in, the 1st year.**

H1. E75 = 35, [43 – (4 (Group IVB)-3 (Group 4A) – 1(Group III)]
 H2. Control = 21, [28 - (4(Group IVB)-3(Group 4A)]

I. Patients relapsed by PP:

I1.E75: 35 x 0.60 = 21.
 I2.Control: 21 x 0.32 = 7.

I 3. Subtract relapse by PP. Relapse by CD in 1 year is:

I4.E75: 35- 21 (I1) = 14.
 I5.Control: 21- 7 (I 2) = 14.

J. No difference in % DFS by CD, year 1.Patients with other cancers and death from other cause included:

7,(E75), 5,(Control).
 J1. E75: 14: 376 = **3.723%**
 J2. Control: 14: 382 = **3.664%**

2nd year relapse: E75 significant protection**K. Exclude PP in 2nd year only from E75 treated patients. The Patients which, failed by CD are**

K1. E75: 14 -12 = 2.
 K2. Control: 14 - 0 = 14.

L. Exclude patients section I, 7 E75 and 5 Control patients. E75 protects significantly compared with control. Patients which failed by CD are:

L1. %DFS: E75: 2 : 348,[(369-21,(I1) = **0.006%**
 L2. %DFS: Control: 14 : 370,[(377- 7, (I2) = **3.783%**

M. Patients Distribute 12 PP patients, 2nd year, as in 1st year, (60 % E75, 32 % Control). Patients which, failed by CD are:

M1.E75: 14-8 = 6.
 M2.Control: 14- 4 = 10.

N. E75 protects significantly, compared with control. % of Patients which, failed by CD.

N1. % DFS: E75: 6: 348 = **1.724%**
 N2. % DFS: Control: 10: 370 = **2.702%**

References:

- 20 % of patients with malignant gliomas show PP.*Int. J. Mol. Sci.* 2014, 15, 11832
- 6.7% of patients treated with, pembrolizumab, 9.7% treated with Imilumab, anti **CTLA-4**, (**Allison**), and, 10% treated with nivolumab had PP.*JCO*, 33,3541,2015.
- 2% PP with RECIST but, 6% PP with irRC, Conclusion: **PP**, is uncommon and indicates a high likelihood of > 1 year survival. Complete course of progression from nadir followed by response from peak can take up to 1 year, 2016,ASCO abstract),
- PP = No metastases. Case report. *J. Cancer Prev. & Cur. Res.*, 2016, 5(6): 00185

17.02.06. Recommendations to the Chairman of the Board of GALE Biopharma, in support of continuation of Clinical Trials and Studies in Immunotherapy Vaccines directed by Drs. Mittendorf and Peoples.

Sanford J. Hillsberg, J.D, Chairman of the Board at Galena Biopharma Inc, ("GALE", Nasdaq),
 2000 Crow Canyon Place, Suite 380, San Ramon, CA 94583, Tel: 1-855-855-GALE
 1801 Century Park, E # 1600, Los Angeles, CA 90067, **Phone: (310) 553-4441**, shillsberg@troygould.com
 USPS Certified Signature: 2315 1470 0000 2181 6739 delivered February 9 2017 signed by: R PARADA // LOS ANGELES, CA 90067 // 12:02 pm

From: Professor Constantin G. Ioannides, MSc, PhD, Attorney Pro-Se, Inventor, Inventors-Advocate,
 1989-2009, Federally Funded, Principal Investigator-Contractor, Inventor US Patents, '942, 618, 261,'759,'256.
constantinioannides@gmail.com, constantinioannides1949@yahoo.com, Owner Website: [Ikaros Cancer Vaccines](http://IkarosCancerVaccines.com),
 4062 Tartan Lane, Houston, TX, 77025-2919, Tel: 713-660-8907
 1991-Present, 4143 citations of my published research, Index: G= 13,H=33, I= 70,(Google Scholar)
 2010-Present, 1433 citations of my published research, 2015-Present, 7355 visits to *Ikaros Cancer Vaccines* Website,
 1985-2010, MD Anderson Cancer Center, 2013-2018, Adjunct Professor, Suchow University, China.

Dear Chairman and Distinguished members of the Board of Directors of GALE,

My English is poor and my vocabulary elliptic. I am 68 years old. I have no time or intention to enrich myself. I have no children. I have no conflict of interest. I do not own any stock; I divided inventor royalty equally, regardless of contribution of each co-inventor. MD Anderson Cancer Center, (or "MDACC"), still owes me my personal royalty for 2008 and 2009.

I did not accept GALE stock offered by Dr. Schwartz. I consulted Dr. Schwartz in 2010 and requested pay the fee he thought for me, to Dr. Peoples' research. I consulted and was member of IMUC Board. I did not accept remuneration, stock or options. I asked IMUC pay my remuneration to Dr. Peoples' research.

In 2013, between two lawsuits against me, by Messers Short, Lilly and others, (Troy-Gould), your law-firm on behalf of Mr. Ahn and Dr. Schwartz, I turned down Mr. Ahn offer to meet and be paid. I sent him pay MDACC. He sued me again, but, I prevailed in, Federal Court. The Federal Judge noted that, I was concerned of GALE activities. In fact I had expressed my confidence in Dr. Peoples trial.

I read in, San Francisco Business Times, <http://www.bizjournals.com/sanfrancisco/news/2017/02/01/galena-biopharma-gale-fentanylmark-schwartz.html>, Mr. Leuty article, "**Biopharma CEO exits as pain drug marketing probe deepens**". Mr. Leuty cites you, "After critical assessment of the current status of the company, we believe that it is the right time to run a strategic evaluation of the opportunities as we look to maximize value for our shareholders," Chairman Sanford Hillsberg said in a press release....."Galena said Tuesday that it had hired an independent advisory firm to look at strategic alternatives, including selling or combining the company, a merger or reverse merger or continuing to advance its current drug programs on its own. **Cancer immunotherapy clinical trials led by academic investigators will continue during the strategic overview, the company said."**

I commend you for continuing the clinical trials with my compounds during the GALE-review. I encourage you continue the E75 trials, thereafter. It is speculated that, E75-Present Trial Failed, (*Enclosure 4B page 8*), and consequently, ongoing Trials E75 with Herceptin will fail. Qualifications of the data analyst and the relevant facts to judge are not shown. I advise you correctly for objective reasons:

1. My analysis of the results presented by GALE, (enclosed), identified 8 of 36 patients, (22 %), in whom E75 delayed cancer progression, (*Page 3, ¶17-18, compare with 17 patients, ¶19*).
2. My calculations show that, if we assign what, GALE named, allegedly, Pseudo-recurrence (or "PR"), to the E75 arm and Control arm in the proportion reported by GALE, by "**proactive imaging**", (60 % E75 and 32 % control), then E75 significantly protected from cancer progression. DFS by clinical diagnosis, (or "CD") is, **E75 = 1.355%, Control: 5.036%; Alternate: E75 = 0.006%, Control: 3.783%**. **Differences are statistically significant, because the control value is more than double the E75 value.** (*See page 4, Sections E and L*)

A. GALE credibility would be strengthened, the confidence of investors in you increase, if you will co-opt Eponymous Breast Medical Oncologists and Surgeons.

3. Scientific terms used, indicate that, GALE administrators lack familiarity with immunotherapy of

human cancer and graduate level, statistical analysis. Humans are not congenic mice presenting transplanted tumors of equal starting size. Patients must be assigned to groups based on medical criteria; tumor grade, size, HER-2 protein expression, number of metastatic lymph nodes, etc.

4. **Ad-hoc**, scientific terms, (“X-rays”, “proactive imaging”), permit me hypothesize naïveté.
5. Physicians, or scientists, (employed by investor and pharmaceuticals), are not familiar with such terms.
6. GALE independent monitoring committee, (or “IDMC”), is anonymous. Does not disclose conflict of interest. **This is the biggest concern of any investor.**
7. Drs. Mittendorf and Peoples did not sign, to show that, concurred with IDMC, nor, IDMC and GALE include a Breast Oncologist and a Woman, Breast Cancer Advocate.
8. No peer-reviewed abstract or article with the results shown to the IDMC, in June 2016, was published or submitted **in the last 9, (eight months).**
9. **Points 7 and 8 above, alone, raise concerns that, IDMC and GALE had ulterior reasons to halt the trials conducted by Drs. Peoples and Mittendorf. See page 7 bottom and 8.**
10. GALE, continuous refocus on unrelated ventures, concerns, that, investments in cancer treatment by GALE were directed to other programs.
Could GALE predict in 2013 that a blind study will fail that focused on sales of fentanyl?

B. To be fair, objective reasons for the failure, outside the lack of expertise of GALE and IDMC may be included in your investigation.

11. The extreme difference between the superb results of the Phase II and the partial results of the Phase III Trial may be due to two main hypotheses and one alternative:
12. **1. Poor quality of E75 used in Phase III trial versus outstanding quality of E75 used in Phase II.**
13. Dr. Sinkule informed me that, **PolyPeptide Labs**, Torrence, California, (or “PPL”), made the GMP peptides for the Phase III.
14. PPL acquired the small San Diego company that, was making E75 for Dr. Peoples, Phase I-II studies (called Multiple Peptide Systems, (or **MPS**). Robert Hagopian is the contact person at MPS. He thinks that, PPL, did all the work, (or they were supposed to do all the manufacturing).
15. If GALE changed contractor, to a cheaper provider peptide quality may have suffered.
16. I could elaborate on the technical aspects. I am Chemist by profession, not a holder of B.Sc. degree.
17. **2. Since GALE use the term “ detection”, but not “ quantification”, different trial sites lacked highly sensitive medical equipment, quantitative radiology and pathology laboratories to quantify metastases and high HER-2 protein levels in biopsies.**
18. Patients, which, should have been excluded from the study, because their metastases have spread were automatically included.
19. The size of metastases could not be measured because of lack of equipment, (see *Page 2, ¶, 6*).
20. **Quantitative radiology measurements, (volumetric, multi-dimensional and multi-modality image sets) should have been performed, but patient insurance did not pay.
GALE did not compensate the clinic which could quantitate metastases because was outside the patient payment plan?**
21. **3. Alternatively, at distant, remote sites, patients with advanced disease, not eligible for the study were included on a compassionate basis.** This happened before, in other trials, but the surgeon involved was commended. The NIH administrator was terminated, the trial continued.
22. **My 1st hypothesis, (¶ 12.1, above), is supported by 40 patients with metastases of total 71 metastases reported , in the first 7,(seven) months and 56 of 71, in the first 11 months, after only 1 vaccine treatment, (Page 3, ¶19).**
23. Patients which progressed fast, either had HER-2^{Hi} (should have been treated with Herceptin), or, had inflammatory/triple negative breast cancer, (ER⁻, PR⁻, HER-2⁻).
24. If most of the 51 patients, (¶19, above), was vaccinated with E75 in, 2011-2012 or, 2014-2015, and

the peptide supplier changed, these patients must be excluded from trial conclusions.

25. On the positive side, the majority, 91 %, or 700 patients, are disease-free more than 18 months after were treated with E75. Analysis of these patients would provide important information how to advance immunotherapy.
26. Even if the evaluable patients decrease by another 10 %, in the average months, 20-30, in the trial, the remaining 630 patients are more than enough to conclude that E75 is effective.
27. If necessary, the trial could add 50-100 more patients, and part of the results of the Phase II and Phase III could be combined, (also ¶ 33, below).
28. **My 2nd hypothesis, (¶,17. 2, above),** points the support that, Drs. Mittendorf and Peoples need to continue the immunotherapy trials. Assume that, a quantitative radiology exam costs \$ 2,500, which is not reimbursed by Medical Insurance. For 730 patients, (630 + 100, ¶,25-26 above), your costs would be \$ 1,825,000 in the next 2 years. Add \$ 100,000 to repeat pathology exams, a Research Nurse, a PhD, research coordinator, a PhD statistician with annual salary, (benefits included) of 150,000 a year, this makes a total of \$1,000,000.
29. Your total costs would be \$ 2,825,000 for 2 years give and take 10 %. This amount is far below the \$ 8,000,000, allegedly, spent per quarter on undefined “ Research and Clinical Trials”. You could also negotiate with MDACC to obtain for Dr. Peoples research at least \$ 500,000 of my research royalty, which currently pays no research at all.
30. My calculations and analysis is included, in pages 1-3, Dr. Schwartz received my letter by E-mail PDF, then certified in January 3, 2017. I asked Drs. Schwartz, Nejadnik and Knapp send me any objection. Receiving no objections, for 10 business days, I published my letter in my Web site.
31. **GALE stock went up to \$ 1.84 a share.** My letter triggered significant interest as demonstrated by more than 190 visits and 310 sessions to, my Website, in 3weeks from the USA and Europe. Summary of the most frequent visits between 1/15/2017 and 2/03/2017 is below

Countries	Sessions	Countries	Sessions
1.United States	93	4.Ukraine	13
2.Russia	15	5.France	15
3.Germany	10	6. United Kingdom	9

32. I would be pleased to serve *pro-bono*, in your Advisory Committee, as Inventors representative, help your statistical analysis, sort the results and analyze of the quality of E75 used in the trial particularly. My scientific reputation is impeccable as demonstrated by the citations of my scientific research and my patents. Bringing inventors in the board increases the respect of the public and inventors in you. They contribute knowledge and respectability. Two scientific journals already asked me for articles on the topic.

33. The analysis and continuation, which, I propose, would elucidate the meaning of **pseudo-recurrence versus pseudo-progression**. If quantitative 3-Dimensional radiology show that, effector lymphocytes decorate, but do not kill the tumor, (*in lay terms*), the ongoing trials could be complemented with help for lymphocytes to produce tumor-lytic enzymes. I would be pleased to present to your Board such complementary aides.

34. You can use my Website at no cost (I pay 1&1 for its maintenance and security), to communicate with Investors and the public. Please let me know how else I can help you. This letter is unsolicited. Sincerely.

Enclosures:

- GALE-Q3, pages 8-10
- Pseudoprogression and Immune-Related Response in Solid Tumors, Victoria L. Chiou and Mauricio Burotto, *Center for Cancer Research, National Cancer Institute, J. Clinical Oncology, 33,31,3541-3543.*
- IDMC report.** To whom it may concern: “On 24 June 2016, the assembled Independent Data Monitoring Committee met to review the efficacy and safety data **available** for the aforementioned protocol. At this time the DMC recommends that **the study be stopped** for futility unless it is determined that there has been **a systematic reversal** in the study drug treatments in the two arms, in which case the IDMC should reevaluate the clinical evidence.

The IDMC recommends that this be investigated as quickly as possible and, in the meantime, that this information be disclosed **only to any individual(s)** with a need to know about the procedures used to clarify the current situation. Finally, the IDMC requests that Galena Biopharma inform the IDMC members of the outcome of this investigation and **any decision with respect to discontinuation** of the clinical trial as soon as possible”

4. A. **Dr. Schwartz report:** “So the IDMC has been **very fastidious** about adhering to their charter and their communications with us. So the letter that we attached to our filing when we announced the stoppage of the trial is what we've received from the IDMC, and the communications that we had with the IDMC and the Chairman who is tasked with communicating with us. So we've read that and interpreted that and I think in our view the wording of that communication with the unless there is a systemic reversal, implies to us that whatever the **IDMC saw may imply to them that there is a potential for something other than the inactivity of the compound or less than suitable activity of the compound.**

B.... the **IDMC did not do a full efficacy analysis. They did a prospectively defined interim analysis that was a very limited bio-statistical review looking at futility. They did not do a full efficacy analysis.** So their futility analysis, based on what they said obviously failed. However they appeared to indicate that there may have been a reversal of the course. That's all that we know and I think it's incumbent upon us to do as a extensive investigation find out if there is a reason for, or that is in fact the true performance of the drug. At this time we don't know. But it is our intent to do as much work as we can to verify that all the operations were correct or uncover the problem if there was one.

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