



February 9, 2021

Town of Boxborough Planning Board
Attn: Mr. Simon Corson, Town Planner
29 Middle Road
Boxborough, MA 01719

Re: Vibalogics Site Plan Review
1414 & 1320 Massachusetts Avenue; 244A & 244B Adams Place; 984, 984A, 984B,
984C, 1451, 1497 & 1634 Hazard Lane; 328 & 1451 Rear Hazard Lane
Boxborough, MA 01719
Assessor Parcel Numbers: 12-027, 12-028, 12-030, 13-004, 13-022, 17-005, 17-009,
17-010, 17-022, 17-023, 17-024, 17-025, 18-001
LDG File No. 1869.00

Mr. Corson and Members of the Board:

Level Design Group, L.L.C. (LDG), on behalf of Vibalogics (Applicant), is submitting an application for Site Plan Approval in Accordance with Section 8000 of the Town of Boxborough Zoning Bylaws and the Planning Board's Site Plan Approval Rules and Regulations. There are no proposed exterior site improvements or modification to the existing facility. The within application is being submitted in compliance with the sentence within Section 8002 of the Zoning Bylaw that reads: "Site plan approval shall also be required for the resumption of any use discontinued for more than two years or for the expansion of any existing use."

Vibalogics US, Inc ("Vibalogics") intends to occupy and use approximately 65,923± sf of the of the existing two-story facility at 1414 Massachusetts Avenue containing a total of 293,731± sf-gross floor area (GFA) between the first and second floors (value taken from current assessor records) to develop, manufacture and analyze small volume Pharmaceutical products in the facility. The Boxborough facility would also be established as the head office for the company. Vibalogics intends to grow the workforce on site progressively over the next 18 months to around 200, with 120 employed on dayshift and a further 80 employed on off shifts.

A request for Zoning Determination confirming that the proposed use of the existing building for Office Space, Research and Development (R&D), and Light Manufacturing is allowed within the Office Park (OP) Zoning District was submitted to the office of the Building Commissioner and Zoning Enforcement Officer on February 1st.

In prior communication, Vibalogics received a list of follow up questions from a prior meeting with the community "stakeholders" and a list of "Preliminary Questions" dated 12/29/20. Whereas, the first sentence in the list of "Preliminary Questions" states that the questions are separate from the Site Plan Approval process, and whereas the stakeholder questions pertained to a variety of



matters that are outside the scope of the Site Plan Approval process, the responses to such questions will be provided under separate cover to the office of the Town Administrator.

The Town of Boxborough Zoning Bylaws as amended through September 2018, Article II - 2100 Definitions provides definitions of the proposes uses detailed above for Professional or Business Office, Research & Development, and Light Manufacturing.

“2158 - Office shall mean a room or group of rooms used primarily for conducting the affairs of a business, profession, service, industry, or government.”

Vibalogics will use portions of the space for conducting the affairs of its business operations; as the location is intended to serve as the company’s headquarters, including operations related to human resources, bookkeeping, payroll, administration and supervision of the business.

“2168 - Research and Development shall mean an establishment or other facility for carrying on investigation in the natural, physical or social sciences, or engineering and development as an extension of investigation with the objective of creating end products.”

Vibalogics is a privately owned company focused on the process development, manufacturing, testing and final product formulation for pharmaceutical products. The core purpose of any company developing pharmaceuticals is to save or improve people’s lives. The oncolytic vaccines being developed have the potential to dramatically change the face of the treatment of cancer

“2146 - Light Manufacturing shall mean fabrication, processing, packaging, or assembly operations employing only electric or other substantially noiseless and inoffensive motor power, utilizing hand labor or quiet machinery and processes, and free from neighborhood disturbing agents such as odors, gas, fumes, smoke, cinders, refuse matter, electromagnetic radiation, heat, or vibration; provided that there is no outside storage of materials or finished goods.”

Vibalogics will also engage in the manufacturing of pharmaceutical products. The manufacturing processes are identical to those previously operated on Binney St in the center of Cambridge as Brammer Bio (now Thermo Fisher). As pharmaceutical products that will be injected into vulnerable people, they are required to be manufactured to the highest standards of control and cleanliness, therefore the resulting risk to employees, neighbors or the environment is very low. Manufacturing is completed in closed systems within clean rooms designed and approved by the FDA for that purpose. Commercial manufacturing in the facility cannot be undertaken without FDA approval. The manufacturing process employs only electric or other substantially noiseless and inoffensive motor power, utilizing hand labor or quiet machinery and processes, and free from neighborhood disturbing agents such as odors, gas, fumes, smoke, cinders, refuse matter, electromagnetic radiation, heat, or vibration; and there is no outside storage of materials or finished goods. A detailed description the proposed business operation demonstrating that it will comply with the requirements of Footnote #3 and Footnote #12 to the Zoning Use Table (Zoning Bylaw

Section 4003) is provided below along with information on anticipated hazardous materials usage and storage as part of the R&D and Light Manufacturing Uses proposed at the site.

Footnote #3 - *Provided that hazardous materials are not a primary part of the business.*

R&D activities are a normal part of biologics manufacturing and development of new therapies.

The use of hazardous materials is only incidental for this application. On a per experiment or per lab scale batch basis, mL quantities of concentrated hazardous materials, and up to ~ 1 0L quantities of diluted solutions are used. This represents a total % by volume of less than 2% that is used in any given process. These hazardous waste streams are then contained using specific safety cans or drums to ensure that no hazardous waste is put to drain. Hazardous materials are normally segregated by specific chemical, type or family class, and kept in small drums (1 00L or less) or safety cans (5L). Currently at the Vibalogics sister site in Germany these containers once filled are then shipped off site using a service provider licensed and specialized for the handling. In case of a very infrequent use of a specific chemical, the waste container is sealed and shipped off-site without being full if it has been in use for 90 days. Vibalogics intends to adopt a similar system for Boxborough, adapting as necessary to conform to the appropriate state and federal guidelines for MA and the USA. The intent is to contain and ship off-site any chemical meeting the definition of hazardous. All other substances which have been determined to be non hazardous (or Generally Regarded as Safe - GRAS- as defined by the FDA) that will be used in a Lab setting, like salts, media, and cell culture nutrients will be drained into our on-site waste treatment system which will be professionally designed to handle our waste. This system consists of the following 2 key components:

- 1- a "KillTank" where wastewater from the fermentors and/or downstream equipment is discharged and collected. The contents of the tank are then heat-sterilized with steam. The heat - treatment is designed to eliminate any living organism that was used during the biotech research activities. Following the heat-treatment the contents of the tank are cooled down prior to further waste treatment processing.
- 2- A pH neutralization step where the waste effluent pH is set to around 7 (neutral, pH of water). The purpose of this step is to ensure that any low or high pH solution used during the R&D activity are neutralized.

The net result of the waste water treatment is a discharge that is not harmful to the surrounding environment and meets all associated regulations. Waste water will be monitored routinely (real time monitoring of process parameters such as pH and temperature in addition to periodic sampling of the waste stream) to ensure that any risk to the surrounding environment is eliminated.

Footnote #12 - *Provided that these operations do not use hazardous materials except as an incidental part of their business nor in quantities greater than would normally be used in 90 days, and in accordance with the existing state and federal regulations and the Federal Resource Conservation & Recovery Act. The operation shall provide adequate facilities for storage, containment and safety precautions for the hazardous materials used. Hazardous materials shall be disposed of off-site by a state-registered hazardous waste disposal contractor.*

The overall approach for light manufacturing is identical to the one outlined above, but larger volumes are used. The use of hazardous materials in this application is much more limited than in laboratory operations and is therefore also an incidental part of operations. Materials like Ethanol are used to clean and disinfect our equipment and surfaces, so the majority of hazardous usage is for non-manufacturing activities. Some hazardous materials (weak acid like acetic acid [commonly known as vinegar] and sodium hydroxide [commonly known as caustic soda]) are used during the manufacturing process to control for pH or achieve separation of the product of interest during the purification process, but the amount is considered incidental due to the low % usage by volume (<1 %), and because they are used at intermediate steps and not part of the final product production. Again, all hazardous waste generated from the light manufacturing activities, whether for cleaning, or for production, will be collected, segregated and shipped off-site by a licensed vendor. Hazardous materials have specific EPA requirements for their storage conditions/durations, and allowable quantities. All these requirements will be met in the proposed facility (e.g in fact the intent is to have storage of hazardous waste for less than 90 days, even if longer time periods are allowed per federal regulations), and all the relevant permits and required inspections will be done in advance of manufacturing activities. For the other solutions, medias and salts (items defined as GRAS per FDA), the waste stream will follow the same path through the Killtank and the pH neutralization steps, as described above.

With regards to water usage, we expect an average daily consumption of~ 1300 gallons/day for all manufacturing and lab activities. Per EPA website-posted estimates, an average family consumes ~300 gallons of water a day. Based on this, our facility's water foot print would be the equivalent to 4-5 average US households.

Non-hazardous waste from the Labs and the light manufacturing (which we expect to be equivalent to the amount of water usage - ~ 1300 gallons/day) will share the same pathway through the internal waste treatment system. The design of this system is such that it will operate in cycles, so as waste flows from the facility on a per batch basis the Tank/amount of steam required/heat exchangers and pH neutralization capabilities will more than adequate to handle the expected waste produced from our facility. Current design is intended for peak flow of 68 gpm, and the anticipated use for peak Vibalogics production is approximately 34 gpm. Any incidental hazardous waste, or empty containers left over from regular cleaning activities will be disposed using a qualified vendor at the required frequency as outlined above.



Vibalogics has engaged Pare Corporation (Pare) to perform a thorough review of the existing on-site wastewater treatment facility and associated Groundwater Discharge Permit. Pare will be overseeing the design of the effluent pretreatment system and design of any required modifications and/or upgraded to the existing system required to adequately treat the proposed discharge from the Vibalogics facility. Pare has prepared a Memo detailing the condition of the existing on-site wastewater treatment facility, current MA DEP Groundwater Discharge Permit requirements, and an outline of the permitting and design process required to make the system operational.

SITE PLAN REVIEW APPLICATION REQUIREMENTS

The within application is being submitted in compliance with the sentence within Section 8002 of the Zoning Bylaw that reads: "Site plan approval shall also be required for the resumption of any use discontinued for more than two years or for the expansion of any existing use." However, the language of Section 8003 exempts certain projects from the requirements of Section 8002. In the underlying Office Park District, Section 8003 exempts "a proposed expansion of ten (10) percent of the existing gross floor area, including the basement, if applicable". The applicant's proposal is for a zero increase in the existing gross floor area. Notwithstanding the potential exception, the applicant has submitted the within materials.

Section 8005 refers to the Site Plan Regulations of the Planning Board for the application requirements. Such requirements are repeated below. In the case of certain of the requirements that apply to new construction or other exterior alterations, the applicant is requesting waivers of the submission requirements pursuant to Section 1.4 of the Rules and Regulations.

3.1 Site Plan Submission Requirements All Site Plans shall be prepared by a registered architect, landscape architect, or professional engineer. All Site Plans shall be on standard 24" by 36" sheets, be prepared at a maximum scale of 1" = 40', with continuation on 8 1/2" by 11" sheets as necessary for written information. Items required for submission include the following:

- 1) The project name, north arrow, date, scale, name and address of record owner and applicant, engineer, architect and their proper seals of registration. Names of all abutters within 300 feet of the site boundaries as determined from the latest tax records. If the property owner is not the applicant, a statement of consent from the property owner shall be included with the application.

Included within provided site plan.

- 2) Existing and proposed topography at a minimum contour interval of two feet, including all wetlands and the 100' buffer, streams, water bodies, drainage swales, areas subject to flooding, significant trees, historic features, and unique natural land features.



Included within provided site plan.

- 3) The dimensions of the lot, the frontage, location and footprint of all structures, existing and proposed, total area of buildings in square feet, parking areas, service areas, adjacent ways, streets and driveway openings within 300 feet of the site boundaries.

Included within provided site plan.

- 4) The location and description of all proposed septic systems, water supply, storm drainage systems, utilities, and refuse and other disposal methods.

To the degree that the plans submitted do not show certain features, waivers are requested whereas the applicant's construction will be limited to alterations to a portion of the interior of the existing building, and no changes are proposed to the exterior of the building, the parking lot, site lighting, access/egress driveways or any other impervious areas, storm water management features, landscaping or utilities; therefore, the existing conditions shall remain as they currently are.

- 5) Landscape Plan showing planting areas, signs, fences, walls, walks and lighting, both existing and proposed. Location, type, and screening details for all abutting properties and waste disposal containers.

To the degree that the plans submitted do not show certain features, waivers are requested whereas the applicant's construction will be limited to alterations to a portion of the interior of the existing building, and no changes are proposed to the exterior of the building, the parking lot, site lighting, access/egress driveways or any other impervious areas, storm water management features, landscaping or utilities; therefore, the existing conditions shall remain as they currently are.

- 6) The location, height, size, materials, and design of all proposed signage.

An application for changes to the signs will be submitted in the future as a separate application in accordance with all applicable zoning bylaw requirements.

- 7) The location, height, intensity, and bulb type of all external lighting fixtures, the direction of illumination, and methods to reduce glare onto adjoining properties, along with manufacturer lighting cut-sheets.

To the degree that the plans submitted do not show site lighting information, waivers are requested whereas the applicant's construction will be limited to alterations to a portion of the interior of the existing building, and no changes are proposed to the exterior of the building, the parking lot, site lighting, access/egress driveways or any



other impervious areas, storm water management features, landscaping or utilities; therefore, the existing conditions shall remain as they currently are.

- 8) Location and description of proposed open space and recreation areas.

To the degree that the plans submitted do not show proposed open space or recreation areas, waivers are requested whereas the applicant's construction will be limited to alterations to a portion of the interior of the existing building, and no changes are proposed to the exterior of the building, the parking lot, site lighting, access/egress driveways or any other impervious areas, storm water management features, landscaping or utilities; therefore, the existing conditions shall remain as they currently are.

- 9) A locus plan at the scale of 1" = 200'. A table of information showing how the plan conforms to the Zoning Bylaw.

A locus map is provided within the submitted site plan but due to the site of the parcel the scale of the locus map was increased to 1" = 1,200', a waiver is requested to allow for the increases scale of the locus map. The applicant's construction will be limited to alterations to a portion of the interior of the existing building, and no changes are proposed to the exterior of the building, the parking lot, site lighting, access/egress driveways or any other impervious areas, storm water management features, landscaping or utilities; therefore, the existing conditions shall remain as they currently are.

A Separate table of information showing how the plan conforms to the Zoning Bylaw has been submitted is included herein.

- 10) The location of zoning districts, and overlay zoning districts within the locus of the plan.

Included within provided site plan.

- 11) Building elevation plans at a scale of 1/4" = 1' showing elevations of all proposed buildings and structures and indicating the type and color of materials to be used on all facades.

To the degree that the plans submitted do not contain building elevation plans, waivers are requested whereas the applicant's construction is limited to alterations to a portion of the interior of the existing building, and no changes are proposed to the exterior of the building, the parking lot, site lighting, access/egress driveways or any other impervious areas, storm water management features, landscaping or utilities; therefore, the existing conditions shall remain as they currently are.

- 12) Evaluation of Impact on Water Resources. The applicant shall submit such materials on the measures proposed to prevent pollution of surface and ground water, erosion of soil, excessive runoff of precipitation, excessive raising or lowering of the water table, or flooding of other properties. The evaluation shall include the predicted impacts of the development on the aquifer, and if applicable, and compare the environmental impacts to the carrying capacity of the aquifer.

To the degree that the plans submitted do not show certain storm water management features, waivers are requested whereas the applicant's construction will be limited to alterations to a portion of the interior of the existing building, and no changes are proposed to the exterior of the building, the parking lot, site lighting, access/egress driveways or any other impervious areas, storm water management features, landscaping or utilities; therefore, the existing conditions shall remain as they currently are.

- 13) Evaluation of Impact on Landscape. The applicant shall submit an explanation, with sketches as needed, of design features intended to integrate the proposed new buildings, structures and plantings into the existing landscape to preserve and enhance existing aesthetic assets of the site, to screen objectionable features from neighbors and public areas.

To the degree that the plans submitted do not show certain landscaping features, waivers are requested whereas the applicant's construction will be limited to alterations to a portion of the interior of the existing building, and no changes are proposed to the exterior of the building, the parking lot, site lighting, access/egress driveways or any other impervious areas, storm water management features, landscaping or utilities; therefore, the existing conditions shall remain as they currently are.

- 14) Evaluation of Traffic Impacts. The applicant shall submit an evaluation of the development's impact on the existing traffic network. The evaluation shall include: a) The projected number of vehicle trips to enter and depart the site shall be estimated for an average day and peak hours; b) The projected traffic flow patterns for both vehicular and pedestrian access, including vehicular movements at all intersections likely to be affected by the proposed development; c) The impact of traffic upon existing streets in relation to levels of service and road capacities; and d) The proposed mitigating measures. The traffic study requirement may be waived by the Board if the proposed use will not generate more than 75 vehicle trips per day. 15) The proposed use or uses of the site, i.e. retail, office or storage, number of employees, and maximum seating capacity (where applicable).



To the degree that the materials do not contain a detailed traffic evaluation, waivers are requested whereas (a) the applicant's construction will be limited to alterations to a portion of the interior of the existing building, (b) no changes are proposed to the exterior of the building, the parking lot, site lighting, access/egress driveways or any other impervious areas, storm water management features, landscaping or utilities, (c) the applicant has gone on record as stating that the business operations will require highly qualified staff people, and over time the applicant intends to grow the workforce at the property progressively over the next 18 months to around 200 people, with 120 employed on dayshift and a further 80 employed on off shifts, and (d) the property was designed and constructed for a considerably larger workforce population.

Enclosed are the following:

- Original Signed Site Plan Application, with one copy of the Certified Abutters List
- One (1) copy of the Existing Conditions Site Plan
- One (1) copy of the Pare Corporation Memorandum dated February 8, 2021
- Site Plan Submission Filing Fee: \$480.80 (\$450.00 Application Fee + \$30.80 Notification Mailings Postage)

Should you have any questions, please do not hesitate to contact me.

Truly yours,

Level Design Group, L.L.C.

Nicola Facendola

Nicola Facendola, PE.
Principal

Cc: Iain Baird, Vibalogics
Paul F. Alphen, Esquire, Alphen & Santos, P.C.
File:

ZONING TABLE FOR VIBALOGICS SITE PLAN REVIEW APPLICATION

1414 & 1320 Massachusetts Avenue; 244A & 244B Adams Place; 984, 984A, 984B, 984C, 1451, 1497 & 1634 Hazard Lane; 328 & 1451 Rear Hazard Lane

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<u>Office Park (OP) Zoning District</u>	<u>Required</u>	<u>Provided</u>
Minimum lot area (sq. ft. x 1000)	160,000 sf. (3.763 Ac)	208.38± Ac.
Minimum upland lot area sq. ft. x 1000	N / A	N / A
Minimum upland lot area % of total lot area	20%	88%
Minimum lot frontage (ft.)	200	2,141'± (Total along Mass Ave. & Adams Place)
Minimum lot width (ft.) ⁷	125	1,390'±
Minimum front setback (ft.)	50	470'±
Minimum side setback (ft.)	50	780'± (Left) 202'± (Right)
Minimum rear setback (ft.)	50	1,916'±
Maximum stories	3	3
Maximum building height (ft.)	45	>45
Maximum lot coverage (%) by buildings, structures, and impervious surfaces	30%	7.5%
Floor area ratio	0.10	0.032
Minimum Open Space (%)	N / A	N / A