

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

**Amendment No. 1
To
FORM S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

BULLFROG AI HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of
incorporation or organization)

7374
(Primary Standard Industrial
Classification Code Number)

84-4786155
(I.R.S. Employer
Identification Number)

**325 Ellington Blvd., Unit 317
Gaithersburg, MD 20878
(240) 658-6710**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Vininder Singh
Chief Executive Officer
Bullfrog AI Holdings, Inc.
325 Ellington Blvd., Unit 317
Gaithersburg, MD 20878
(240) 658-6710**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to the public:

From time to time after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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 to Section 7(a)(2)(B) of the Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state or jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED NOVEMBER 25, 2024



1,565,000 Shares of Common Stock underlying Common Warrants
62,600 Shares of Common Stock underlying Placement Agent Warrants

This prospectus relates to the resale or other disposition from time to time by the selling stockholders identified herein (each, a “Selling Stockholder” and, together, the “Selling Stockholders”), in this prospectus of Bullfrog AI Holdings, Inc. (the “Company”) of: (i) up to 1,565,000 shares of common stock, par value \$0.00001 per share (“Common Stock”) issuable upon exercise of Common Stock purchase warrants (“Common Warrants”) with an exercise price of \$2.00 per share; and (ii) up to 62,600 shares of Common Stock issuable upon exercise of the placement agent Common Stock purchase warrants (“Placement Agent Warrants”) with an exercise price of \$2.00 per share. The Common Warrants were issued pursuant to that certain Securities Purchase Agreement dated October 18, 2024, in a private placement transaction. The Placement Agent Warrants were issued pursuant to that certain Placement Agency Agreement dated October 18, 2024, entered into for the sale of securities of the Company in a registered direct offering and concurrent private placement. The Common Warrants and Placement Agent Warrants are together referred to as the “Warrants”.

We are registering the offer and sale of Common Stock on behalf of the Selling Stockholders to satisfy certain registration rights that we have granted to the Selling Stockholders.

Each Selling Stockholder may, from time to time, sell, transfer, or otherwise dispose of any or all of the Common Stock on any stock exchange, market, or trading facility on which shares of our Common Stock are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The Selling Stockholders will bear all commissions and discounts, if any, attributable to the sales of Common Stock. We will bear all other costs, expenses, and fees in connection with the registration of the Common Stock. See “Plan of Distribution” which begins on page 22 of this prospectus.

This registration does not mean that the selling stockholders named herein will actually offer or sell any of these shares. We will not receive any proceeds from the resale of any of the shares of Common Stock being registered hereby sold by the Selling Stockholders. However, we may receive proceeds from the exercise of the Warrants held by the Selling Stockholders exercised other than pursuant to any applicable cashless exercise provisions of such Warrants.

Our Common Stock is listed on the Nasdaq Capital Market under the symbol “BFRG.” On November 7, 2024, the last reported sale price of our Common Stock on the Nasdaq Capital Market was \$2.63.

Investing in our securities is highly speculative and involves a high degree of risk. You should carefully consider the risks and uncertainties described under the heading “Risk Factors” beginning on page 5 of this prospectus before making a decision to purchase our securities.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

The date of this prospectus is , 2024.

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ABOUT THIS PROSPECTUS

You may only rely on the information contained in this prospectus or that we have referred you to. We have not authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than the common stock offered by this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any common stock in any circumstances in which such offer or solicitation is unlawful. Neither the delivery of this prospectus nor any sale made in connection with this prospectus shall, under any circumstances, create any implication that there has been no change in our affairs since the date of this prospectus. For investors outside the United States: Neither we nor the selling stockholders have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

Unless otherwise stated or the context requires otherwise, all references in this prospectus supplement to the “Company,” “we,” “us,” “our,” “BFRG” refer to Bullfrog AI Holdings, Inc., a Nevada corporation.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes and the information set forth under the headings “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in each case included elsewhere in this prospectus.

Overview of our Company

Bullfrog AI Holdings, Inc. was incorporated in the State of Nevada in February 2020. Bullfrog AI Holdings, Inc. is the parent company of Bullfrog AI, Inc. and Bullfrog AI Management, LLC, which were incorporated in Delaware and Maryland, in 2017 and 2021, respectively. Operations are currently conducted through Bullfrog AI Holdings, Inc., which began operations on February 6, 2020. We are a company focused specifically on advanced Artificial Intelligence / Machine Learning (AI/ML) analysis of complex data in the advancement of medicine. Our founding AI/ML platform (trade name: bfLEAP™) was created from technology originally developed at The Johns Hopkins University Applied Physics Laboratory (JHU-APL). Subsequently, we have developed new tools and capabilities composed of an ensemble of machine learning and artificial intelligence models.

In February 2018, Bullfrog AI Holdings secured the original exclusive, worldwide, royalty-bearing license from JHU-APL. The license covers three (3) issued patents, one (1) new provisional patent application, non-patent rights to proprietary libraries of algorithms and other trade secrets including modifications and improvements. Our objective is to utilize our AI/ML platform with a precision medicine approach toward drug development with biopharmaceutical collaborators, as well as for our own internal clinical development programs. We believe the bfLEAP™ platform is ideally suited for evaluating pre-clinical and clinical trial data generated in translational research and clinical trial settings that lead to faster, less expensive drug approvals.

Our aim is to improve the odds of success in each stage of developing medicine, ranging from early pre-clinical through late-stage clinical development. Our ultimate objective is to utilize bfLEAP™ to enable the success of ongoing clinical trials or rescue late-stage failed drugs (i.e., Phase 2 or Phase 3 clinical trial failures) for in-house development and divestiture; although, we also consider entering collaborations for earlier stage drugs.

In September 2020 and October 2021, the Company executed amendments to the original February 2018 license which represents improvements and new advanced analytics capabilities. In consideration of the rights granted to the Company under the original License Agreement, the Company granted JHU 178,571 warrants exercisable to purchase shares of Common Stock at \$2.10 per share.

In July 2022, the Company entered into an exclusive, worldwide, royalty-bearing license from JHU-APL that provides additional intellectual property rights including patents, copyrights, and knowhow to be utilized under the Company’s bfLEAP™ analytical AI/ML platform. In consideration of the new license, the Company issued to JHU-APL 39,879 shares of Common Stock. Under the terms of the new License Agreement, JHU will be entitled to eight (8%) percent of net sales for the services provided by the Company to other parties and three (3%) percent for internally developed drug projects in which the JHU license was utilized. The new license also contains tiered sub licensing fees that start at fifty (50%) percent and reduce to twenty-five (25%) percent based on revenues. The Company and JHU-APL entered into Amendment number 1 of the July 2022 License Agreement whereby the Company gained access to certain improvements including additional patents and knowhow in exchange for a series of payments totaling \$275,000. The first of these payments for \$75,000 was paid in July 2023 and the remaining payments of \$75,000, \$75,000 and \$50,000 are due in years 2025, 2026 and 2027, respectively. The amendment also reduced the 2023 minimum annual royalty payment to \$60,000, all other financial terms remain the same. As a result of this Amendment, the minimum annual payments were \$30,000 for 2022 and \$60,000 for 2023, and the minimum annual payments will be \$300,000 for 2024 and beyond, all of which are creditable by royalties. As of September 30, 2024, we have accrued \$225,000 of the 2024 minimum annual royalty payments.

We intend to continue to evolve and improve bfLEAP™, either in-house or with development partners like JHU-APL. We plan to leverage our proprietary AI/ML platform, developed over several years at one of the top innovation institutions in the world, which has already been successfully applied in multiple sectors.

Recent Developments

Registered Direct Offering and Concurrent Private Placement

On October 18, 2024, we entered into a securities purchase agreement (the “Purchase Agreement”) with certain institutional and accredited investors (the “Purchasers”) relating to the registered direct offering and sale of an aggregate of 862,602 shares of Common Stock and pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to 702,398 shares of Common Stock (the “Pre-funded Warrants Shares”) with an exercise price of \$0.0001 per share, at a purchase price of \$2.00 per share of Common Stock and a purchase price of \$1.9999 per Pre-Funded Warrant (the “October Offering”). The shares of Common Stock were offered by the Company pursuant to a prospectus supplement dated October 18, 2024 filed with the SEC on October 21, 2024, and the accompanying prospectus dated August 21, 2024, in connection with a takedown from the Company’s shelf registration statement on Form S-3 (File No. 333-281341), which was declared effective by the SEC on August 21, 2024.

Pursuant to the Purchase Agreement, in a concurrent private placement, the Company also agreed to sell to the Purchasers unregistered warrants (the “Common Warrants”) to purchase up to an aggregate of 1,565,000 shares of Common Stock. Each unregistered Common Warrant has an exercise price of \$2.00 per share, is exercisable at any time beginning six (6) months following their original issuance and will expire five years from the initial exercise date.

Pursuant to the terms of the Placement Agency Agreement dated October 18, 2024 (the “Placement Agency Agreement”), with Wallachbeth Capital, LLC (“Wallachbeth”), acting as the placement agent for the October Offering and the concurrent private placement, Wallachbeth (or its designees) were issued warrants (the

“Placement Agent Warrants”) to purchase an aggregate of 62,600 shares of Common Stock (the “Placement Agent Warrant Shares”), equal to 4% of the aggregate number of shares of Common Stock and/or Pre-Funded Warrants sold in the October Offering, at an exercise price per share equal to \$2.00, which is equal to the exercise price of the Common Warrants.

The shares of Common Stock underlying the Common Warrants and the Placement Agent Warrants are being registered on the registration statement of which this prospectus forms a part in accordance with the terms of the Purchase Agreement and the Placement Agency Agreement.

The gross proceeds to the Company from the October Offering were approximately \$3.13 million, before deducting offering expenses payable by the Company. The closing of the October Offering was announced on October 21, 2024.

Company Information

Bullfrog AI Holdings, Inc. was incorporated in the State of Nevada on February 6, 2020. Bullfrog AI Holdings, Inc. is the parent company of Bullfrog AI, Inc. and Bullfrog AI Management, LLC, which were incorporated in Delaware and Maryland, in 2017 and 2021, respectively. All of our operations are currently conducted through Bullfrog AI Holdings, Inc. The Company’s principal business address is 325 Ellington Blvd, Unit 317, Gaithersburg, MD 20878. Our website address is www.bullfrogai.com. The references to our website in this prospectus are inactive textual references only. The information on our website is neither incorporated by reference into this prospectus nor intended to be used in connection with this offering.

THE OFFERING

Securities Offered by the Selling Stockholders 1,627,600 shares of Common Stock comprising, (i) up to 1,565,000 shares of Common Stock issuable upon exercise of Common Warrants, with an exercise price of \$2.00 per share; and (ii) up to 62,600 shares of Common Stock issuable upon exercise of the Placement Agent Warrants, with an exercise price of \$2.00 per share.

Trading Market The Common Stock offered in this prospectus is listed on The Nasdaq Capital Market under the symbol “BFRG.”

Common Stock Outstanding Before this Offering 8,713,152 shares

Common Stock Outstanding After this Offering(1) 10,340,752 shares

Use of Proceeds We will not receive any of the proceeds from the sale of the shares of our Common Stock being offered for sale by the Selling Stockholders. Upon the exercise of the warrants for an aggregate of 1,627,600 shares of Common Stock by payment of cash however, we will receive the exercise price of the Warrants, or an aggregate of approximately \$3,255,200 from such exercise of Warrants.

Offering Price The Selling Stockholders may sell all or a portion of the shares of Common Stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. Registration of the Common Stock covered by this prospectus does not mean, however, that such shares necessarily will be offered or sold. See “Plan of Distribution.”

Risk Factors Please read “Risk Factors” and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in the securities offered in this prospectus.

(1) The number of shares of Common Stock expected to be outstanding after this offering is based on 8,713,152 shares outstanding as of November 4, 2024, and assumes the exercise of (i) the Common Warrants into 1,565,000 shares of Common Stock, and (ii) the Placement Agent Warrants into 62,600 shares of Common Stock; however, it excludes:

- Up to 5,581,728 shares of Common Stock issuable upon the exercise of outstanding warrants with a weighted-average exercise price of \$5.79 per share;
- Up to 849,427 shares of Common Stock issuable upon the exercise of outstanding stock options, which options have a weighted average exercise price of \$3.98 per share; and
- Up to an aggregate of 47,000 shares of Common Stock reserved for future issuance under our 2022 Equity Incentive Plan (the “2022 Plan”).

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully review the risks and uncertainties described below before deciding whether to purchase any of the securities being registered pursuant to the registration statement of which this prospectus is a part. Each of the risk factors described below could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities. The occurrence of any of these risks might cause you to lose all or part of your investment. Moreover, the risks described below are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business, financial condition, and results of operations. If any of these risks actually occur, our business, financial condition and results of operations could suffer. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment. Our business, affairs, prospects, assets, financial condition, results of operations and cash flows could be materially and adversely affected by these risks. For more information about our SEC filings, please see “Where You Can Find More Information”.

Risks Related to Liquidity, the Company’s Business and Industry

We have a limited operating history upon which you can evaluate our performance, and accordingly, our prospects must be considered in light of the risks that any new company encounters.

We were incorporated under the laws of Nevada on February 26, 2020. Accordingly, we have no significant history upon which an evaluation of our prospects and future performance can be made. Our proposed operations are subject to all of the business risks associated with a new enterprise. The likelihood of our creation of a viable business must be considered in light of the problems, expenses, difficulties, complications, and delays frequently encountered in connection with the inception of a business, operation in a competitive industry, and the continued development of our technology and the results of our clinical data. We anticipate that our operating expenses will increase for the near future. There can be no assurances that we will ever operate profitably. You should consider the Company’s business, operations and prospects in light of the risks,

expenses and challenges faced as an early-stage company.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in our Annual Report on Form 10-K for the Fiscal year ended December 31, 2023.

The report from our independent registered public accounting firm for the year ended December 31, 2023, includes an explanatory paragraph stating that we have incurred significant losses and need to raise additional funds to meet our obligations and sustain our operations. These conditions raise substantial doubt about our ability to continue as a going concern. As of September 30, 2024, we had approximately \$4.2 million in cash and an accumulated deficit of approximately \$15.1 million. We believe that our existing cash and cash equivalents as of September 30, 2024 are sufficient to fund planned operations into the fourth quarter of 2025. Our recurring losses from operations since inception and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern. These conditions could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. There is no assurance that sufficient financing will be available when needed, or at all, to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may also make it more difficult to operate our business due to concerns about our ability to meet our contractual obligations. Our ability to continue as a going concern is contingent upon, among other factors, the sale of our securities. There is no assurance that sufficient financing will be available when needed, or at all, to allow us to continue as a going concern.

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If we are unable to secure additional capital, we may be required to curtail our clinical and research and development initiatives and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our clinical and regulatory efforts, which is critical to the realization of our business plan. The consolidated financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern. It is not possible for us to predict at this time the potential success of our business. The revenue and income potential of our proposed business and operations are currently unknown. If we cannot continue as a viable entity, you may lose some or all of your investment.

If we are unable to attract and retain key management, scientific personnel and advisors, we may not achieve our business objectives.

Our success depends on the availability and contributions of members of our senior management team. The loss of services of any of these individuals could delay, reduce or prevent our drug development and other business objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform drug development work will be critical to our success. We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other public and private research institutions. We may be unable to attract and retain these individuals, and our failure to do so could materially adversely affect our business and financial condition.

The development of our technology, products, and services is highly competitive.

We face competition with respect to any products that we may seek to develop or commercialize in the future. Our competitors include major companies worldwide. Many of our competitors have significantly greater financial, technical and human resources than we have and superior expertise in research and development and marketing approved products/services and thus may be better equipped than us to develop and commercialize products/services. These competitors also compete with us in recruiting and retaining qualified personnel and acquiring technologies. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Accordingly, our competitors may commercialize products more rapidly or effectively than we are able to, which would adversely affect our competitive position, the likelihood that our products/services will achieve initial market acceptance and our ability to generate meaningful additional revenues from our products.

From time to time, third parties may claim that one or more of our products or services infringe their intellectual property rights.

Any dispute or litigation regarding patents or other intellectual property could be costly and time consuming due to the uncertainty of intellectual property litigation and could divert our management and key personnel from our business operations. A claim of intellectual property infringement could force us to enter into a costly or restrictive license agreement, which might not be available under acceptable terms or at all, could require us to redesign our products, which would be costly and time-consuming, and/or could subject us to an injunction against development and sale of certain of our products or services. We may have to pay substantial damages, including damages for past infringement if it is ultimately determined that our products infringe on a third party's proprietary rights. Even if these claims are without merit, defending a lawsuit takes significant time, may be expensive and may divert management's attention from other business concerns. Any public announcements related to litigation or interference proceedings initiated or threatened against us could cause our business to be harmed. Our intellectual property portfolio may not be useful in asserting a counterclaim, or negotiating a license, in response to a claim of intellectual property infringement. In certain of our businesses we rely on third party intellectual property licenses and we cannot ensure that these licenses will be available to us in the future on favorable terms or at all.

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Although dependent on certain key personnel, the Company does not have any key man life insurance policies on any such people.

The Company is dependent on Vininder Singh in order to conduct its operations and execute its business plan and the loss of Vininder Singh or any member of the board of directors or executive officer could harm the Company's business, financial condition, cash flow and results of operations; however, the Company has not purchased any insurance policies with respect to those individuals in the event of their death or disability. Therefore, if Vininder Singh or any member of the board of directors or an executive officer dies or become disabled, the Company will not receive any compensation to assist with such person's absence. The loss of such person could negatively affect the Company and its operations.

New product development involves a lengthy, expensive and complex process.

We may be unable to develop or commercialize any product candidates. Moreover, even if we develop such candidates, they may be subject to significant regulatory review, approval and other government regulations. There can be no assurance that our technologies will be capable of developing and commercializing products at all. New product development involves a lengthy, expensive and complex process and we currently have no fully validated diagnostic candidates. In addition, before we can commercialize any new product candidates, we will need to:

- conduct substantial research and development;
- conduct validation studies;
- expend significant funds;
- develop and scale-up our laboratory processes; and
- obtain regulatory approval and acceptance of our product candidates.

This process involves a high degree of risk and takes several years. Our product development efforts may fail for many reasons, including:

- failure of the product at the research or development stage; and
- lack of clinical validation data to support the effectiveness of the product.

Few research and development projects result in commercial products, and perceived viability in early clinical trials often is not replicated in later studies. At any point, we may abandon development of a product candidate or we may be required to expend considerable resources repeating clinical trials, which would adversely impact the timing for generating potential revenues from those product candidates. In addition, as we develop product candidates, we will have to make significant investments in product development, marketing and sales resources.

We may not be able to conduct clinical trials necessary to increase the value of our proposed products and formulations.

In order to conduct clinical trials that are necessary to obtain approval of a product by the FDA, it is necessary to receive clearance from the FDA to conduct such clinical trials. The FDA can halt clinical trials at any time for safety reasons or because we or our clinical investigators do not follow the FDA's requirements for conducting clinical trials. If we are unable to receive clearance to conduct clinical trials or the trials are halted by the FDA, the likelihood of our ability to sell or license our products would be greatly reduced as it is the FDA approval which will enhance the value of our products.

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Our ability to resell and/or license our products will depend upon successful clinical trials.

Only a small number of research and development programs result in the development of a product that obtains FDA approval. Success in preclinical work or early stage clinical trials does not ensure that later stage or larger scale clinical trials will be successful. Conducting clinical trials is a complex, time-consuming and expensive process. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors including protocol design, regulatory and institutional review board approval, the rate of patient enrollment in clinical trials, and compliance with extensive current Good Clinical Practices. If we fail to adequately manage the design, execution and regulatory aspects of our clinical trials, our studies and ultimately our regulatory approvals may be delayed, or we may fail to gain approval for our product candidates. Clinical trials may indicate that our product candidates have harmful side effects or raise other safety concerns that may significantly reduce the likelihood of regulatory approval, result in significant restrictions on use and safety warnings in any approved label, adversely affect placement within the treatment paradigm, or otherwise significantly diminish the commercial potential of the product candidate. Also, positive results in a registrational trial may not be replicated in any subsequent confirmatory trials. Even if later stage clinical trials are successful, regulatory authorities may disagree with our view of the data or require additional studies, and may fail to approve or delay approval of our product candidates or may grant marketing approval that is more restricted than anticipated, including indications for a narrower patient population than expected and the imposition of safety monitoring or educational requirements or risk evaluation and mitigation strategies. In addition, if another Company is the first to file for marketing approval of a competing drug candidate, that Company may ultimately receive marketing exclusivity for its drug candidate, thereby reducing the value of our product.

We face significant competition from other biotechnology and pharmaceutical companies.

While we believe that our technology, development experience and scientific knowledge provide competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical, and biotechnology companies, academic institutions and governmental agencies, and public and private research institutions. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the development of drug candidates as well as in obtaining regulatory approvals of those drug candidates in the United States and in foreign countries.

Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drug candidates that are more effective or less costly than any drug candidate that we may develop.

Our ability to compete successfully will depend largely on our ability to:

- identify drugs that have suffered set backs in the clinical development and regulatory process which we believe can be assisted by our platform's ability to design a better study group;
- attract qualified scientific, product development and commercial personnel;
- obtain patent or other proprietary protection for our drugs and technologies;
- obtain required regulatory approvals; successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new drugs; and
- negotiate competitive pricing and reimbursement with third party payors.

The availability of our competitors' technologies could limit the demand, and the price we are able to charge for our services and for any drug candidate we develop. The inability to compete with existing or subsequently introduced drug development technologies would have a material adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies and research institutions may invest heavily to accelerate discovery and development of novel compounds or to license novel compounds that could make bLEAP™ less competitive, which would have a material adverse impact on our business.

We may not be able to acquire the rights to any failed drugs or we may not be able to rescue failed drugs through analysis due to our technology or the lack of clinical data.

Our business model is based on the use of AI/ML technology, which technology may not uncover actionable insights or we may not be able to access sufficient clinical data to uncover such insights that lead to a successful project, clinical trial, or product. The failure of such projects, clinical trials or products would result in a loss of revenue from one of our three sources, which could have a material adverse impact on our business as a whole.

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We may not succeed in acquiring the rights to failed drugs, which could limit one of our main sources of revenue.

Our business model is partly based on our ability to acquire drugs that have failed to pass Phase 2 or Phase 3 of the FDA approval process; however, there is no guarantee that we will be able to acquire the rights to such drugs, which would significantly impact our ability to generate revenue and as a result would have a material adverse impact on our business.

We intend to invest in early stage experimental technologies which have a high risk of failure.

To continue supporting our business model, we intend to invest in early stage and experimental technologies, some or all of which may not be useful to us. There is a risk that we will invest in technology that will not ultimately contribute to the success of our projects, which could have a material adverse impact on our business.

We are dependent on our collaborative agreements for the development of products and business development, which exposes us to the risk of reliance on the viability of third parties.

In conducting our research and development activities, we currently rely, and will in the future rely, on collaborative agreements with third parties such as manufacturers, contract research organizations, commercial partners, universities, governmental agencies and not-for-profit organizations for both strategic and financial resources. The loss of, or failure to perform by us or our partners under, any applicable agreements or arrangements, or our failure to secure additional agreements for other products in development, would substantially disrupt or delay our research and development and commercialization activities. Any such loss would likely increase our expenses and materially harm our business, financial condition and results of operation.

We extensively outsource our clinical trial activities and usually perform only a small portion of the start-up activities in-house.

We rely on independent third-party contract research organizations (CROs) to perform most of our clinical studies, including document preparation, site identification, screening and preparation, pre-study visits, training, program management and bioanalytical analysis. Many important aspects of the services performed for us by the CROs are out of our direct control. If there is any dispute or disruption in our relationship with our CROs, our clinical trials may be delayed. Moreover, in our regulatory submissions, we rely on the quality and validity of the clinical work performed by third-party CROs. If any of our CROs' processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals could be adversely impacted.

We are a biotechnology company with no significant revenue. We have incurred operating losses since our inception, and we expect to incur losses for the foreseeable future and may never achieve profitability.

We have incurred significant operating losses since our inception. To date, we have not generated any revenue and we may not generate any revenue from sales of our clinical analytics services or drug candidates for the foreseeable future. We expect to continue to incur significant operating losses and we anticipate that our losses may increase substantially as we expand our drug development programs.

To achieve profitability, we must successfully develop and obtain regulatory approval for one or more of drugs and effectively commercialize any drugs we develop. Even if we succeed in developing and commercializing one or more drug candidates, we may not be able to generate sufficient revenue and we may never be able to achieve or sustain profitability.

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We will continue to require additional capital for the foreseeable future. If we are unable to raise additional capital when needed, we may be forced to delay, reduce or eliminate our drug acquisition efforts.

We expect to continue to incur significant operating expenses in connection with our ongoing activities, including conducting clinical trials and seeking regulatory approval of drug candidates. Our ongoing future capital requirements will depend on numerous factors, including:

- the rate of progress, results and costs of completion of clinical trials of drug candidates;
- the size, scope, rate of progress, results and costs of completion of any potential future clinical trials and preclinical tests of our drug candidates that we may initiate;
- the costs of obtaining regulatory approval of drug candidates;
- the scope, prioritization and number of drug development programs we pursue;
- the costs for preparing, filing, prosecuting, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other products and technologies and the costs to be able to obtain regulatory approval of such products;
- our ability to establish strategic collaborations and licensing or other arrangements on terms favorable to us; and
- competing technological and market developments.

Any additional fundraising efforts may divert our management from their day to day activities, which may adversely affect our ability to identify and acquire new drug candidates and to further the regulatory process of such products. Our ability to raise additional funds will depend, in part, on the success of our product development activities and other factors related to financial, economic and market conditions, many of which are beyond our control. There can be no assurance that we will be able to raise additional capital when needed or on terms that are favorable to us, if at all. If adequate funds are not available on a timely basis, we may be forced to:

- delay, reduce the scope of or eliminate one or more of our drug development programs;
- limit the amount of new products that we acquire or relinquish, license or otherwise dispose of rights on terms that are less favorable than if we were able to further the regulatory approval process; or
- liquidate and dissolve the Company.

If our operating plans change, we may require additional capital sooner than planned. Such additional financing may not be available when needed or on terms favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current and future operating plan.

We are increasingly dependent on information technology systems to operate our business and a cyber-attack or other breach of our systems, or those of third parties on whom we may rely, could subject us to liability or interrupt the operation of our business.

We are increasingly dependent on information technology systems to operate our business. A breakdown, invasion, corruption, destruction or interruption of critical information technology systems by employees, others with authorized access to our systems or unauthorized persons could negatively impact operations. In the ordinary course of business, we collect, store and transmit confidential information and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information. Additionally, we outsource certain elements of our information technology systems to third parties. As a result of this outsourcing, our third party vendors may or could have access to our confidential information making such systems vulnerable. Data breaches of our information technology systems, or those of our third party vendors, may pose a risk that sensitive data may be exposed to unauthorized persons or to the public. For example, the loss of clinical trial data from completed or ongoing clinical trials or preclinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. While we believe that we have taken appropriate security measures to protect our data and information technology systems, and have been informed by our third party vendors that they have as well, there can be no assurance that our efforts will prevent breakdowns or breaches in our systems, or those of our third party vendors, that could materially adversely affect our business and financial condition.

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We must complete extensive clinical trials to demonstrate the safety and efficacy of our drug candidates. If we are unable to demonstrate the safety and efficacy of our drug candidates, we will not be successful.

The success of our business depends primarily on our ability to further the regulatory approval process to increase the value of our drug candidates. Drug candidates must satisfy rigorous standards of safety and efficacy before they can be approved for sale which greatly enhances their value. To satisfy these standards, we must engage in expensive and lengthy testing of drug candidates.

We may not be able to obtain authority from the FDA or other equivalent foreign regulatory agencies to move on to further efficacy segments of the Phase 2 or Phase 3 clinical trials or commence and complete any clinical trials for any of our drug candidates. Positive results in preclinical studies of a drug candidate may not be predictive of similar results in human clinical trials, and promising results from early clinical trials of a drug candidate may not be replicated in later clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from the preclinical tests or clinical trials for our drug candidates may not be predictive of the results we may obtain in later stage trials. The failure of clinical trials to demonstrate safety and efficacy of one or more of our drug candidates will have a material adverse effect on our business and financial condition.

Delays in the commencement of clinical trials of our drug candidates could result in increased costs to us and delay our ability to successfully license or sell such products.

Our drug candidates will require continued extensive clinical trials to increase the value and desirability of the products. Because of the nature of clinical trials, we do not know whether future planned clinical trials will begin on time, if at all. Delays in the commencement of clinical trials could significantly increase our drug development costs and delay our ability to successfully sell or license our drug candidates. In addition, many of the factors that may cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to denial of regulatory approval of a drug candidate. The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy in past clinical trials to obtain regulatory approval to commence a further clinical trial;
- convincing the FDA that we have selected valid endpoints for use in proposed clinical trials; and
- obtaining institutional review board approval to conduct a clinical trial at a prospective site.

In addition, the commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

If we are unable to obtain U.S. and/or foreign regulatory approval, we will be unable to resell or license our drug candidates.

Our drug candidates will be subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, record keeping, labelling, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required in the U.S. and in many foreign jurisdictions prior to the commercial sale of drug candidates. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that no drug candidate that we present to the FDA will obtain marketing approval which will significantly diminish the value and desirability of our product candidates. In connection with the clinical trials for our drug candidates, we face risks that:

- the drug candidate may not prove to be efficacious;
- the drug candidate may not prove to be safe;
- the drug candidate may not be readily co-administered or combined with other drugs or drug candidates;
- the results may not confirm the positive results from earlier preclinical studies or clinical trials;

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- the results may not meet the level of statistical significance required by the FDA or other regulatory agencies; and
- the FDA or other regulatory agencies may require us to carry out additional studies.

We have limited experience in conducting and managing later stage clinical trials necessary to obtain regulatory approvals, including approval by the FDA. However, this risk would be mitigated in the event the Company is successful entering into a co-development agreement with a pharma partner for late stage clinical development. The time required to complete clinical trials and for the FDA and other countries' regulatory review processes is uncertain and typically takes many years. Our analysis of data obtained from preclinical and clinical trials is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unanticipated delays or increased costs due to government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials, and FDA regulatory review.

We will rely on third parties for manufacturing of our clinical drug supplies; our dependence on these manufacturers may impair the development of our drug candidates.

We have no ability to internally manufacture the drug candidates that we need to conduct our clinical trials for the products that we acquire. For the foreseeable future, we expect to continue to rely on third-party manufacturers and other third parties to produce, package and store sufficient quantities of our drug candidates and any future drug candidates for use in our clinical trials. We may face various risks and uncertainties in connection with our reliance on third-party manufacturers, including:

- reliance on third-party manufactures for regulatory compliance and quality assurance;
- the possibility of breach of the manufacturing agreement by the third-party manufacturer because of factors beyond our control;
- the possibility of termination or nonrenewal of our manufacturing agreement by the third-party manufacturer at a time that is costly or inconvenient for us;
- the potential that third-party manufacturers will develop know-how owned by such third-party manufacturers in connection with the production of our drug candidates that is necessary for the manufacture of our drug candidates; and
- reliance on third-party manufacturers to assist us in preventing inadvertent disclosure or theft of our proprietary knowledge.

Our drug candidates may be complicated and expensive to manufacture. If our third-party manufacturers fail to deliver our drug candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, we may be required to delay or suspend clinical trials or otherwise discontinue development of our drug candidates. While we may be able to identify replacement third-party manufacturers or develop our own manufacturing capabilities for these drug candidates, this process would likely cause a delay in the availability of our drug candidates and an increase in costs. In addition, third-party manufacturers may have a limited number of facilities in which our drug candidates can be manufactured, and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available drug candidates.

We may rely on technology solution partners for the development and deployment of our AI technology

Our partners may experience technical, financial, operational, or security issues that reduce or eliminate their ability to support the Company. This could prevent the Company from generating revenue and eliminate our ability to operate.

In addition to the risks listed above, businesses are often subject to risks not foreseen or fully appreciated by the management. It is not possible to foresee all risks that may affect us. Moreover, the Company cannot predict whether the Company will successfully effectuate the Company's current business plan. Each prospective Purchaser is encouraged to carefully analyze the risks and merits of an investment in the Securities and should take into consideration when making such analysis, among other, the Risk Factors discussed above.

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RISKS RELATED TO INTELLECTUAL PROPERTY RIGHTS

We rely on various intellectual property rights, including patents and licenses in order to operate our business.

Our intellectual property rights, may not be sufficiently broad or otherwise may not provide us a significant competitive advantage. In addition, the steps that we have taken to maintain and protect our intellectual property may not prevent it from being challenged, invalidated, circumvented or designed-around, particularly in countries where intellectual property rights are not highly developed or protected. In some circumstances, enforcement may not be available to us because an infringer has a dominant intellectual property position or for other business reasons, or countries may require compulsory licensing of our intellectual property. Our failure to obtain or maintain intellectual property rights that convey competitive advantage, adequately protect our intellectual property or detect or prevent circumvention or unauthorized use of such property, could adversely impact our competitive position and results of operations. We also rely on nondisclosure and noncompetition agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary rights. There can be no assurance that these agreements will adequately protect our trade secrets and other proprietary rights and will not be breached, that we will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets or other proprietary rights.

As we expand our business, protecting our intellectual property will become increasingly important. The protective steps we have taken may be inadequate to deter our competitors from using our proprietary information. In order to protect or enforce our patent rights, we may be required to initiate litigation against third parties, such as infringement lawsuits. Also, these third parties may assert claims against us with or without provocation. These lawsuits could be expensive, take significant time and could divert management's attention from other business concerns. The law relating to the scope and validity of claims in the technology field in which we operate is still evolving and, consequently, intellectual property positions in our industry are generally uncertain. We cannot assure you that we will prevail in any of these potential suits or that the damages or other remedies awarded, if any, would be commercially valuable.

The Company could be negatively impacted if found to have infringed on intellectual property rights.

Technology companies, including many of the Company's competitors, frequently enter into litigation based on allegations of patent infringement or other violations of intellectual property rights. In addition, patent holding companies seek to monetize patents they have purchased or otherwise obtained. As the Company grows, the intellectual property rights claims against it will likely increase. The Company intends to vigorously defend infringement actions in court and before the U.S. International Trade Commission. The plaintiffs in these actions frequently seek injunctions and substantial damages. Regardless of the scope or validity of such patents or other intellectual property rights, or the merits of any claims by potential or actual litigants, the Company may have to engage in protracted litigation. If the Company is found to infringe one or more patents or other intellectual property rights, regardless of whether it can develop non-infringing technology, it may be required to pay substantial damages or royalties to a third-party, or it may be subject to a temporary or permanent injunction prohibiting the Company from marketing or selling certain products. In certain cases, the Company may consider the desirability of entering into licensing agreements, although no assurance can be given that such licenses can be obtained on acceptable terms or that litigation will not occur. These licenses may also significantly increase the Company's operating expenses. Regardless of the merit of particular claims, litigation may be expensive, time-consuming, disruptive to the Company's operations and distracting to management. In recognition of these considerations, the Company may enter into arrangements to settle litigation. If one or more legal matters were resolved against the Company's consolidated financial statements for that reporting period could be materially adversely affected. Further, such an outcome could result in significant compensatory, punitive or trebled monetary damages, disgorgement of revenue or profits, remedial corporate measures or injunctive relief against the Company that could adversely affect its financial condition and results of operations.

We rely heavily on our technology and intellectual property, but we may be unable to adequately or cost-effectively protect or enforce our intellectual property rights, thereby weakening our competitive position and increasing operating costs.

To protect our rights in our services and technology, we rely on a combination of copyright and trademark laws, patents, trade secrets, confidentiality agreements and protective contractual provisions. We also rely on laws pertaining to trademarks and domain names to protect the value of our corporate brands and reputation. Despite our efforts to protect our proprietary rights, unauthorized parties may copy aspects of our services or technology, obtain and use information, marks, or technology that we regard as proprietary, or otherwise violate or infringe our intellectual property rights. In addition, it is possible that others could independently develop substantially equivalent intellectual property. If we do not effectively protect our intellectual property, or if others independently develop substantially equivalent intellectual property, our competitive position could be weakened.

Effectively policing the unauthorized use of our services and technology is time-consuming and costly, and the steps taken by us may not prevent misappropriation of our technology or other proprietary assets. The efforts we have taken to protect our proprietary rights may not be sufficient or effective, and unauthorized parties may copy aspects of our services, use similar marks or domain names, or obtain and use information, marks, or technology that we regard as proprietary. We may have to litigate to enforce our intellectual property rights, to protect our trade secrets, or to determine the validity and scope of others' proprietary rights, which are sometimes not clear or may change. Litigation can be time consuming and expensive, and the outcome can be difficult to predict.

We rely on agreements with third parties to provide certain services, goods, technology, and intellectual property rights necessary to enable us to implement some of our applications.

Our ability to implement and provide our applications and services to our clients depends, in part, on services, goods, technology, and intellectual property rights owned or controlled by third parties. These third parties may become unable to or refuse to continue to provide these services, goods, technology, or intellectual property rights on commercially reasonable terms consistent with our business practices, or otherwise discontinue a service important for us to continue to operate our applications. If we fail to replace these services, goods, technologies, or intellectual property rights in a timely manner or on commercially reasonable terms, our operating results and financial condition could be harmed. In addition, we exercise limited control over our third-party vendors, which increases our vulnerability to problems with technology and services those vendors provide. If the services, technology, or intellectual property of third parties were to fail to perform as expected, it could subject us to potential liability, adversely affect our renewal rates, and have an adverse effect on our financial condition and results of operations.

If any third-party owners of intellectual property we may license in the future do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.

We may enter into licenses for third-party intellectual property in the future. Our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights.

If applicable, our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents issue in respect of any such patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. In addition, our licensors may terminate their agreements with us in the event we breach the applicable license agreement and fail to cure the breach within a specified period of time. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could materially adversely affect our competitive business position, business prospects and financial condition.

Because our research and development of drug candidates often incorporates compounds and other information that is the intellectual property of third parties, we depend on continued access to such intellectual property to conduct and complete our preclinical and clinical research and commercialize the drug candidates that result from this research. We expect that future licenses would impose, numerous obligations on us. For example, under our existing and future license agreements, we may be required to pay (i) annual maintenance fees until a drug candidate is sold for the first time, (ii) running royalties on net sales of drug candidates, (iii) minimum annual royalties after a drug

candidate is sold for the first time, and (iv) one-time payments upon the achievement of specified milestones. We may also be required to reimburse patent costs incurred by the licensor, or we may be obligated to pay additional royalties, at specified rates, based on net sales of our drug candidates that incorporate the licensed intellectual property rights. We may also be obligated under some of these agreements to pay a percentage of any future sublicensing revenues that we may receive. Future license agreements may also include payment obligations such as milestone payments or minimum expenditures for research and development. We expect that any future licenses would contain reporting, insurance and indemnification requirements. We are actively reviewing and preparing additional patent applications to expand our patent portfolio, but there can be no assurances that patents related to our existing patent applications or any applications we may file in the future will be issued or that any issued patents will provide meaningful protection for our drug candidates, which could materially adversely affect our competitive business position, business prospects and financial condition.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.

We rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could materially adversely affect our business and financial condition.

RISKS RELATED TO OUR COMMON STOCK

Due to the low price and volume of our stock, a shareholder may be unable to sell shares, or may lose money on their investment.

The trading price of our common stock may be subject to wide fluctuations in response to quarter-to-quarter fluctuations in operating results, announcements of material adverse events, general conditions in our industry or the public marketplace and other events or factors, including the thin trading of our common stock. In addition, stock markets have experienced extreme price and trading volume volatility in recent years. This volatility has had a substantial effect on the market prices of securities of many technology-related companies for reasons frequently unrelated to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our common stock. In addition, if our operating results differ from our announced guidance or the expectations of equity research analysts or investors, the price of our common stock could decrease significantly.

Because Vininder Singh, our Chief Executive Officer and director, controls a significant number of shares of our voting capital stock, he has effective control over actions requiring stockholder approval.

Mr. Vininder Singh, our Chief Executive Officer and a director, beneficially owns approximately 28% of the Company's common stock. As a result, Mr. Singh possesses significant influence on the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. Accordingly, any investors who purchase shares will be minority stockholders and as such will have little to no say in the direction of us and the election of directors. Additionally, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

We will indemnify and hold harmless our officers and directors to the maximum extent permitted by Nevada law.

Our bylaws provide that we will indemnify and hold harmless our officers and directors against claims arising from our activities, to the fullest extent not prohibited by Nevada law. If we were called upon to perform under our indemnification agreement, then the portion of our assets expended for such purpose would reduce the amount otherwise available for our business.

The price of our common stock may fluctuate substantially.

You should consider an investment in our common stock to be risky, and you should invest in our common stock only if you can withstand a significant loss and wide fluctuations in the market value of your investment. Some factors that may cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this "Risk Factors" section and elsewhere in this prospectus, are:

- sales of our common stock by our stockholders, executives, and directors;
- volatility and limitations in trading volumes of our shares of common stock;
- our ability to obtain financing to conduct and complete research and development activities;
- our ability to attract new customers;
- changes in the development status of the drugs we acquire;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy or future issuances of securities;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- reputational issues;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new products, capital commitments, or other events by us or our competitors;
- changes in general economic, political and market conditions in or any of the regions in which we conduct our business;
- changes in industry conditions or perceptions;
- changes in valuations of similar companies or groups of companies;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigations related to intellectual property rights, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the

trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

We have never paid dividends on our capital stock and we do not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.

We have not paid dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any future indebtedness we may incur could preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain from an investment in our common stock for the foreseeable future. Consequently, in the foreseeable future, you will likely only experience a gain from your investment in our common stock if the price of our common stock increases.

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If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock may be affected by the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline if one or more equity analysts downgrade our common stock or if analysts issue other unfavorable commentary or cease publishing reports about us or our business.

Provisions of our charter documents or Nevada law could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our stockholders, and could make it more difficult to change management.

Provisions of our articles of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders might otherwise consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or remove our current management by making it more difficult to replace or remove our board of directors. These provisions include:

- limitations on our stockholders' ability to call special meetings of stockholders;
- an advance notice requirement for stockholder proposals and nominations for members of our Board;
- the authority of our Board to determine the number of director seats on our Board;
- the authority of our Board to fill vacancies occurring on the Board; and
- the authority of our Board to issue preferred stock with such terms as our Board may determine.

Our articles of incorporation grants our Board of Directors the power to designate and issue additional shares of common and/or preferred stock.

Our authorized capital consists of 100,000,000 shares of common stock and 10,000,000 shares of preferred stock. Our preferred stock may be designated into series pursuant to authority granted by our articles of incorporation, and on approval from our Board of Directors. The Board of Directors, without any action by our stockholders, may designate and issue shares in such classes or series as the Board of Directors deems appropriate and establish the rights, preferences and privileges of such shares, including dividends, liquidation and voting rights. The rights of holders of other classes or series of stock that may be issued could be superior to the rights of holders of our common stock. The designation and issuance of shares of capital stock having preferential rights could adversely affect other rights appurtenant to shares of our common stock.

We are an "emerging growth company" under the JOBS Act of 2012 and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and we may take advantage of certain exemptions from various reporting requirements that are not applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933 (the "Securities Act") for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are choosing to take advantage of the extended transition period for complying with new or revised accounting standards.

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We will remain an "emerging growth company" until the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act, although we will lose that status sooner if our revenues exceed \$1.07 billion, if we issue more than \$1 billion in non-convertible debt in a three year period, or if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last day of our most recently completed second fiscal quarter.

Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

Our common stock may be delisted from The Nasdaq Capital Market if we cannot maintain compliance with Nasdaq Capital Market's continued listing requirements.

Our common stock is listed on the Nasdaq Capital Market. There are a number of continued listing requirements that we must satisfy in order to maintain our listing on the Nasdaq Capital Market.

We cannot assure you our securities will meet the continued listing requirements to be listed on Nasdaq Capital Market in the future. If the Nasdaq Capital Market delists our common stock from trading on its exchange, we could face significant material adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly resulting in a reduced level of trading activity in the secondary trading market for our common stock;
- a limited amount of news and analyst coverage for our company; and

- a decreased ability to issue additional securities or obtain additional financing in the future.

If we fail to maintain compliance with all applicable continued listing requirements for the Nasdaq Capital Market and Nasdaq Capital Market determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock, our ability to obtain financing to repay debt and fund our operations.

We will continue to incur significant costs to ensure compliance with United States corporate governance and accounting requirements.

We will continue to incur significant costs associated with our public company reporting requirements, including costs associated with applicable corporate governance requirements such as those required by the Sarbanes-Oxley Act of 2002, and with other rules issued or implemented by the SEC. We expect all of these applicable rules and regulations will result in significant legal and financial compliance costs and to make some activities more time consuming and costly. We are currently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

If we fail to successfully maintain an effective internal control over financial reporting, the integrity of our financial reporting could be compromised, which could result in a material adverse effect on our reported financial results.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement the required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Trading of our Common Stock is limited, and trading restrictions imposed on us by applicable regulations may further reduce trading in our Common Stock, making it difficult for our stockholders to sell their shares; and future sales of Common Stock could reduce our stock price.

Trading of our Common Stock is currently conducted on the Nasdaq Capital Market. The liquidity of our Common Stock is limited, including in terms of the number of shares that can be bought and sold at a given price and reduction in security analysts' and the media's coverage of us, if any. These factors may result in different prices for our Common Stock than might otherwise be obtained in a more liquid market and could also result in a larger spread between the bid and asked prices for our Common Stock. In addition, in the absence of a large market capitalization, our Common Stock is less liquid than the stock of companies with broader public ownership, and, as a result, the trading prices of our Common Stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate his or her investment in our Common Stock. Trading of a relatively small volume of our Common Stock may have a greater impact on the trading price of our stock. We cannot predict the prices at which our Common Stock will trade in the future, if at all.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may in the future offer additional shares of our Common Stock or other securities convertible into or exchangeable for our Common Stock at prices that may not be the same as the price per share paid by any investor in this offering. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by any investor in this offering, and investors purchasing shares or other securities in the future could have rights superior to you. The price per share at which we sell additional shares of our Common Stock, or securities convertible or exchangeable into shares of Common Stock, in future transactions may be higher or lower than the price per share paid by any investor in this offering.

Management will have broad discretion as to the use of any proceeds received pursuant to the exercise of the Warrants for cash and we may not use the proceeds effectively.

Our management will have broad discretion as to the application of any proceeds received from the Selling Stockholders on the exercise of the Warrants and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our Common Stock.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements.

In some cases, you can identify forward-looking statements by terminology, such as "expects", "anticipates", "intends", "estimates", "plans", "potential", "possible", "probable", "believes", "seeks", "may", "will", "should", "could" or the negative of such terms or other similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus.

You should read this prospectus and the documents that we reference herein and have filed as exhibits to the registration statement, of which this prospectus is part, completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this prospectus is accurate as of the date on the front cover of this prospectus only. Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of the information presented in this prospectus, and particularly our forward-looking statements, by these cautionary statements.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our Common Stock for the foreseeable future. We expect to retain future earnings, if any, to fund the development and growth of our business. Any future determination to pay dividends on our Common Stock will be at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements and any contractual restrictions.

USE OF PROCEEDS

This prospectus relates to the resale by the Selling Stockholders of up to 1,627,600 shares of Common Stock. The Selling Stockholders will receive all of the proceeds from this offering. We will not receive any of the proceeds from the sale or other disposition of our Common Stock by the Selling Stockholders pursuant to this prospectus. However, we may receive proceeds in the aggregate of up to approximately \$3.26 million if all of the Warrants are exercised for cash, based on the exercise price of the Warrants. We cannot predict when, or if, the Warrants will be exercised. It is possible that the Warrants may expire and may never be exercised for cash.

We intend to use any proceeds from the exercise of the Warrants for general corporate purposes and working capital. We may temporarily invest the net proceeds, if any, in short-term, interest-bearing instruments or other investment-grade securities. We have not determined the amount of net proceeds, if any, to be used specifically for such purposes. As a result, management will retain broad discretion over the allocation of any net proceeds it receives as a result of the exercise of the Warrants.

THE SELLING STOCKHOLDERS

The shares of Common Stock being offered by the Selling Stockholders are those unregistered shares of Common Stock purchased in the October Private Placement and shares of Common Stock issuable to the Selling Stockholders upon exercise of the Warrants. For additional information regarding the issuance of the shares of unregistered Common Stock and the Warrants, see “Recent Developments – Registered Direct Offering and Concurrent Private Placement” above. We are registering the shares of Common Stock issuable upon exercise of the Warrants in order to permit the Selling Stockholders to offer the Common Stock for resale from time to time.

Except for ownership of warrants and the Placement Agency Agreement and engagement by the Company as a financial advisor in connection with prior capital raising efforts, the Selling Stockholders have not had any material relationship with us within the past three years.

The table below lists the Selling Stockholders and other information regarding the beneficial ownership (as determined under Section 13(d) of the Exchange Act of 1934, as amended, and the rules and regulations thereunder) of the shares of Common Stock held by each of the Selling Stockholders. The second column lists the number of shares of Common Stock beneficially owned by each Selling Stockholder, based on its beneficial ownership of the Warrants and our Common Stock, as of November 4, 2024, assuming exercise of all Warrants held by each such Selling Stockholder on that date, without regard to any limitations on exercise. The third column lists the shares of Common Stock being offered under this prospectus by the Selling Stockholders.

In accordance with the terms of the Purchase Agreement, this prospectus generally covers the resale of the number of shares of Common Stock issuable upon exercise of the Warrants issued under both the October Offering and the Placement Agency Agreement, determined as if the outstanding Warrants were exercised in full as of the trading day immediately preceding the date of the registration statement of which this prospectus forms a part was initially filed with the SEC, without regard to any limitations on the exercise of the Warrants. The fourth column assumes the sale of all of the shares of Common Stock offered by the Selling Stockholders pursuant to this prospectus.

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Under the terms of the Warrants, a Selling Stockholder may not exercise any portion of the Common Warrants or the Placement Agent Warrants to the extent such exercise would cause the Selling Stockholder (together with the Selling Stockholder’s affiliates, and any other persons acting as a group together with the Selling Stockholder or the Selling Stockholder’s affiliates) to own more than 4.99% (or, upon election by the Selling Stockholder prior to the issuance of any Warrants, 9.99%) of the Company’s outstanding Common Stock after giving effect to the issuance of shares of Common Stock issuable upon exercise of each such Warrants, respectively. A Selling Stockholder may decrease, or upon at least 61 days’ prior notice to the Company, increase such limitation, but, in no event shall such beneficial ownership limitation exceed 9.99%. The percentages set forth in the fifth column give effect to all beneficial ownership blockers set forth in the warrants held by the applicable selling stockholders.

The Selling Stockholders may sell all, some or none of their shares of Common Stock in this offering. See “Plan of Distribution.”

Selling Stockholder	Number of Shares Beneficially Owned Prior to Offering	Maximum Number of Shares Offered	Number of Shares Beneficially Owned After Offering (1)	Percentage of Shares Owned After Offering
Empery Asset Master, LTD(2)	2,236,181	801,002	1,435,179	8.58%
Empery Tax Efficient, LP(3)	756,389	265,621	490,768	4.99%
Empery Tax Efficient III, LP(4)	1,283,885	498,377	785,508	5.42%
Douglas Bantum(5)	8,581	24,100	32,681	0.30%
David Beth(6)	6,129	14,085	20,214	0.18%
Michael Wallach(7)	6,129	14,085	20,214	0.18%
Gene McNeil(8)	1,838	5,165	7,003	0.06%
Kenneth Bantum(9)	1,838	5,165	7,003	0.06%

- (1) Assumes that all of the Purchase Shares held by the selling stockholder before this offering and covered by this prospectus are sold and that the selling stockholder acquires no additional shares of common stock before the completion of this offering. However, as the selling stockholder can offer all, some, or none of their Purchase Shares, no definitive estimate can be given as to the number of shares of Common Stock that the selling stockholders will ultimately offer or sell under this prospectus.
- (2) These shares are comprised of 419,223 shares of Common Stock issued in connection with the October Offering, 359,503 shares of Common Stock issuable upon the exercise of Pre-Funded Warrants issued in connection with the October Offering, 801,002 shares of Common Stock issuable upon the exercise of the Common Warrants and 656,453 shares of Common Stock issuable upon exercise of warrants issued prior to the October Offering. Empery Asset Management LP, the authorized agent of Empery Asset Master Ltd (“EAM”), has discretionary authority to vote and dispose of the shares held by EAM and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by EAM. EAM, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.
- (3) These shares are comprised of 139,020 shares of Common Stock issued in connection with the October Offering, 119,215 shares of Common Stock issuable upon the exercise of Pre-Funded Warrants issued in connection with the October Offering, 265,621 shares of Common Stock issuable upon the exercise of the Common Warrants and 232,533 shares of Common Stock issuable upon exercise of warrants issued prior to the October Offering. Empery Asset Management LP, the authorized agent of Empery Tax Efficient, LP (“ETE”), has discretionary authority to vote and dispose of the shares held by ETE and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by ETE. ETE, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.
- (4) These shares are comprised of 260,840 shares of Common Stock issued in connection with the October Offering, 223,680 shares of Common Stock issuable upon the exercise of Pre-Funded Warrants issued in connection with the October Offering, 498,377 shares of Common Stock issuable upon the exercise of the Common Warrants and 300,988 shares of Common Stock issuable upon exercise of warrants issued prior to the October Offering. Empery Asset Management LP, the authorized agent of Empery Tax Efficient III, LP (“ETE III”), has discretionary authority to vote and dispose of the shares held by ETE III and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by ETE III. ETE III, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.
- (5) These shares are comprised of 8,581 shares of Common Stock issuable upon the exercise of Placement Agent Warrants received as compensation in connection with prior offerings and 24,100 shares of Common Stock issuable upon the exercise of the Placement Agent Warrants, received as compensation in connection with the October Offering and concurrent private placement. The Selling Stockholder is a designee of the Placement Agent. The Placement Agent is a registered broker dealer with a registered address at 1001 Yamato Rd., Suite 404, Boca Raton, FL 33431 USA.

- (6) These shares are comprised of 6,129 shares of Common Stock issuable upon the exercise of Placement Agent Warrants received as compensation in connection with prior offerings and 14,085 shares of Common Stock issuable upon the exercise of the Placement Agent Warrants, received as compensation in connection with the October Offering and concurrent private placement. The Selling Stockholder is a designee of the Placement Agent. The Placement Agent is a registered broker dealer with a registered address at 1001 Yamato Rd., Suite 404, Boca Raton, FL 33431 USA.
- (7) These shares are comprised of 6,129 shares of Common Stock issuable upon the exercise of Placement Agent Warrants received as compensation in connection with prior offerings and 14,085 shares of Common Stock issuable upon the exercise of the Placement Agent Warrants, received as compensation in connection with the October Offering and concurrent private placement. The Selling Stockholder is a designee of the Placement Agent. The Placement Agent is a registered broker dealer with a registered address at 1001 Yamato Rd., Suite 404, Boca Raton, FL 33431 USA.
- (8) These shares are comprised of 1,838 shares of Common Stock issuable upon the exercise of Placement Agent Warrants received as compensation in connection with prior offerings and 5,165 shares of Common Stock issuable upon the exercise of the Placement Agent Warrants, received as compensation in connection with the October Offering and concurrent private placement. The Selling Stockholder is a designee of the Placement Agent. The Placement Agent is a registered broker dealer with a registered address at 1001 Yamato Rd., Suite 404, Boca Raton, FL 33431 USA.
- (9) These shares are comprised of 1,838 shares of Common Stock issuable upon the exercise of Placement Agent Warrants received as compensation in connection with prior offerings and 5,165 shares of Common Stock issuable upon the exercise of the Placement Agent Warrants, received as compensation in connection with the October Offering and concurrent private placement. The Selling Stockholder is a designee of the Placement Agent. The Placement Agent is a registered broker dealer with a registered address at 1001 Yamato Rd., Suite 404, Boca Raton, FL 33431 USA.

PLAN OF DISTRIBUTION

Each Selling Stockholder (together the “Selling Stockholders”) of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the Nasdaq or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act of 1933, as amended (the “Securities Act”), if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company has agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

The Selling Stockholders will pay any underwriting discounts and commissions and expenses incurred by the Selling Stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the Selling Stockholders in disposing of the securities covered by this prospectus. We will bear the costs, fees and expenses incurred in effecting the registration of the securities covered by this prospectus, including all registration and filing fees, and fees and expenses of our counsel and our independent registered public accountants.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the Selling Stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

Once sold under the registration statement, of which this prospectus forms a part, the shares of Common Stock will be freely tradable in the hands of persons other than our affiliates.

DESCRIPTION OF SECURITIES

General

The following description of our capital stock, together with any additional information we include in any applicable prospectus supplement or any related free writing prospectus, summarizes the material terms and provisions of our common stock and the preferred stock that we may offer under this prospectus. While the terms we have summarized below will apply generally to any future common stock or preferred stock that we may offer, we will describe the particular terms of any class or series of these securities in more detail in the applicable prospectus supplement. For the complete terms of our common stock and preferred stock, please refer to our articles of incorporation and our bylaws that are incorporated by reference into the registration statement of which this prospectus is a part. The summary below and that contained in any applicable prospectus supplement or any related free writing prospectus are qualified in their entirety by reference to our articles of incorporation and our bylaws.

Common Stock

We are authorized to issue 100,000,000 shares of common stock, \$0.00001 par value per share. As of the date of this prospectus, there are 8,713,152 shares of common stock issued and outstanding. The outstanding shares of common stock are validly issued, fully paid and nonassessable.

Voting rights

Each share of common stock entitles the holder to one vote, either in person or by proxy, at meetings of stockholders. The holders are not permitted to vote their shares cumulatively.

Dividend rights

Holders of common stock are entitled to receive ratably such dividends, if any, as may be declared by the Board of Directors out of funds legally available.

Rights upon liquidation

Upon our liquidation, dissolution or winding up, the holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities.

Other rights

Holders of our common stock do not have any pre-emptive rights or other subscription rights, conversion rights, redemption or sinking fund provisions.

Preferred Stock

We are authorized to issue up to 5,500,000 shares of our Series A Preferred Stock, par value \$0.00001 per share, from time to time in one or more series. As of the date of this prospectus, there were 73,449 shares of our Series A Preferred Stock issued and outstanding.

Conversion rights

Each holder of Series A Preferred Stock may, from time to time, convert any or all of such holder's shares of Series A Preferred Stock into fully paid and nonassessable shares of common stock in an amount equal to ten shares of common stock for each one share of Series A Preferred Stock surrendered.

A holder of shares of Series A Preferred Stock is not entitled to convert shares of Series A Preferred Stock if upon such conversion the number of shares of common stock to be received, together with the number of shares of common stock beneficially owned by the holder and its affiliates on the conversion date, would result in beneficial ownership by the holder and its affiliates of more than 4.99% of the outstanding shares of common stock of the Company on such conversion date.

Voting rights

Each holder of Series A Preferred Stock has no voting rights.

Rights upon liquidation

Upon our liquidation, dissolution or winding up, the holders of our Series A Preferred Stock shall not be entitled to any liquidation preference and are to receive any liquidation as if they were converted to common stock.

Issuance of Preferred Stock

A prospectus supplement relating to the issuance of preferred stock being offered will include specific terms relating to the offering. Such prospectus supplement will include:

- the title and stated or par value of the preferred stock;
- the number of shares of the preferred stock offered, the liquidation preference per share and the offering price of the preferred stock;
- the dividend rate(s), period(s) and/or payment date(s) or method(s) of calculation thereof applicable to the preferred stock;
- whether dividends shall be cumulative or non-cumulative and, if cumulative, the date from which dividends on the preferred stock shall accumulate;
- the provisions for a sinking fund, if any, for the preferred stock;
- any voting rights of the preferred stock;
- the provisions for redemption, if applicable, of the preferred stock;
- any listing of the preferred stock on any securities exchange;
- the terms and conditions, if applicable, upon which the preferred stock will be convertible into our common stock, including the conversion price or the manner of calculating the conversion price and conversion period;
- if appropriate, a discussion of Federal income tax consequences applicable to the preferred stock; and
- any other specific terms, preferences, rights, limitations or restrictions of the preferred stock.

The terms, if any, on which the preferred stock may be convertible into or exchangeable for our common stock will also be stated in the preferred stock prospectus supplement. The terms will include provisions as to whether conversion or exchange is mandatory, at the option of the holder or at our option, and may include provisions pursuant to which the number of shares of our common stock to be received by the holders of preferred stock would be subject to adjustment.

Transfer Agent and Registrar

The transfer agent for our common stock is VStock Transfer, LLC. The transfer agent's address is 18 Lafayette Place, Woodmere, New York 11598.

Listing

Our common stock is currently traded on The Nasdaq Capital Market under the symbol "BFRG".

OUR BUSINESS

Our Corporate History and Background

Bullfrog AI Holdings, Inc. was incorporated in the State of Nevada on February 6, 2020. Bullfrog AI Holdings, Inc. is the parent company of Bullfrog AI, Inc. and Bullfrog AI Management, LLC which were incorporated in Delaware and Maryland, in 2017 and 2021, respectively. All of our operations are currently conducted through Bullfrog AI Holdings, Inc. The Company's principal business address is 325 Ellington Blvd, Unit 317, Gaithersburg, MD 20878. Our website address is www.bullfrogai.com. The references to our website in this Prospectus are inactive textual references only. The information on our website is neither incorporated by reference into this Prospectus.

Acquisition of Bullfrog AI, Inc.

In March 2020, Bullfrog AI, Inc. received an investment from TEDCO - the Technology Development Corporation of Maryland, a State of Maryland Investment Fund – pursuant to the issuance of a \$200,000 convertible note with an 18-month term, 6% annual interest rate, and a 20% discount. In June 2020, Bullfrog AI Holdings, Inc. acquired Bullfrog AI, Inc. pursuant to an exchange agreement under which each share of Bullfrog AI, Inc. common stock was exchanged for a share of common stock of Bullfrog AI Holdings, Inc. Immediately prior to the share exchange, each outstanding common share of Bullfrog AI, Inc. was split into 25 shares of common stock. Pursuant to the agreement, 24,223,975 shares of the Company's common stock were issued to the shareholders of Bullfrog AI, Inc. in exchange for 100% of the outstanding stock of Bullfrog AI, Inc. Upon completion of the exchange, Bullfrog AI, Inc. became the Company's wholly-owned subsidiary and the shareholders of Bullfrog AI, Inc. held 100% of the common stock of the Company. As a result, Bullfrog AI Holdings, Inc. assumed a total of \$330,442 in net liabilities of Bullfrog AI, Inc. Both of the entities were controlled before and after the transactions by the same controlling shareholder.

Bullfrog AI Corporate History

Bullfrog AI, Inc. was incorporated in the State of Delaware on August 25, 2017. Vininder Singh is the founder, CEO and chairman of Bullfrog AI.

Business Overview

Most new therapeutics will fail at some point in preclinical or clinical development. This is the primary driver of the high cost of developing new therapeutics. A major part of the difficulty in developing new therapeutics is efficient integration of complex and highly dimensional data generated at each stage of development to de-risk subsequent stages of the development process. Artificial Intelligence and Machine Learning (AI/ML) has emerged as a digital solution to help address this problem.

We use artificial intelligence and machine learning to advance medicines for both internal and external projects. We are committed to increasing the probability of success and decreasing the time and cost involved in developing therapeutics. Most current AI/ML platforms still fall short in their ability to synthesize disparate, high-dimensional data for actionable insight. Our platform technology, named, bfLEAP™, is an analytical AI/ML platform derived from technology developed at The Johns Hopkins University Applied Physics Laboratory (JHU-APL), which is able to surmount the challenges of scalability and flexibility currently hindering researchers and clinicians by providing a more precise¹, multi-dimensional understanding of their data. We are deploying bfLEAP™ for use at several critical stages of development for internal programs and through strategic partnerships and collaborations with the intention of streamlining data analytics in therapeutics development, decreasing the overall development costs by decreasing failure rates for new therapeutics, and impacting the lives of countless patients that may otherwise not receive the therapies they need.

¹ In an August 2021 publication in DeepAI.org (<https://deepai.org/publication/random-subspace-mixture-models-for-interpretable-anomaly-detection>), the algorithms used in bfLEAP were compared to 10 of the most popular clustering algorithms in the world using 12 data sets. The end result showed that the algorithms used in bfLEAP had the highest average score when measuring speed and accuracy of prediction. The bfLEAP platform currently has more advanced versions of these algorithms and is applying them in multiple data analytics projects.

Our Strategy

We plan to achieve our business objectives by enabling the successful development of drugs and biologics using a precision medicine approach via our proprietary artificial intelligence platform bfLEAP. The bfLEAP™ platform utilizes both supervised and unsupervised machine learning - as such, it is able to reveal real/meaningful connections in the data without the need for a prior hypothesis. Supervised machine learning uses labeled input and output data, while an unsupervised learning algorithm does not. In supervised learning, the algorithm "learns" from the training dataset by iteratively making predictions on the data and adjusting for the correct answer. Unsupervised learning, also known as unsupervised machine learning, uses machine learning algorithms to analyze and cluster unlabeled datasets. These algorithms discover hidden patterns or data groupings without the need for human intervention. Algorithms used in the bfLEAP™ platform are designed to handle highly imbalanced data sets to successfully identify combinations of factors that are associated with outcomes of interest.

Together with our strategic partners and collaborators, our primary goal is to improve the odds of success at any stage of pre-clinical and clinical therapeutics development. Our primary business model is improving the success and efficiency of drug development which is accomplished either through acquisition of drugs or partnerships and collaborations with companies that are developing drugs. We hope to accomplish this through strategic acquisitions of current clinical stage and failed drugs for in-house development, or through strategic partnerships with biopharmaceutical industry companies. We are able to pursue our drug asset enhancement business by leveraging a powerful and proven AI/ML platform (trade name: bfLEAP™) initially derived from technology developed at JHU-APL. We believe the bfLEAP™ analytics platform is a potentially disruptive tool for analysis of pre-clinical and/or clinical data sets, such as the robust pre-clinical and clinical trial data sets being generated in translational R&D and clinical trial settings. In November 2021, we amended the agreement with JHU-APL to include additional advanced AI technology. On July 8, 2022, the Company entered into an exclusive, world-wide, royalty-bearing license from JHU-APL for the additional technology developed to enhance the bfLEAP™ platform. The July 8, 2022 JHU-APL license provides the Company with new intellectual property and also encompasses most of the intellectual property from the February 2018 license.

We believe bfLEAP™ will inform/enable decision making throughout the development cycle:

- Discovery Phase - Analyze and categorize discovery phase data to better define highest-value leads from groups of candidates, for advancement to preclinical phase of development. Integrate data from high-throughput screening, pharmacodynamics assays, pharmacokinetics assays, and other key data sets to create the most accurate profile of a pool of therapeutic candidates. There is often a high degree of similarity among closely related therapeutics in a candidate pool - bfLEAP™ is able to harmonize disparate data streams for a more nuanced understanding of each candidate's characteristics/potency.
- Pre-Clinical Data - Large-scale/multivariate analysis of pre-clinical and/or early-stage clinical data sets. In these settings, bfLEAP could be used to find novel drug targets, elucidate mechanism of action (MOA), predict potential off-target effects/side effects, uncover specific genetic/phenotypic background(s) with highest correlation to therapeutic response, etc. These insights from bfLEAP™ analysis can be used to inform decision making/study design at the subsequent step(s) of therapeutic/diagnostic development, including first-inhuman/Phase I RCTs.
- Clinical Development - Advanced/multivariate analysis of PhI and/or PhII clinical trials data, to find niche populations of highly responsive patients and/or inform patient selection for later-stage CT(s). This can be used to decrease overall study risk for larger clinical trials - including Phase II trials, and any Phase III Registration Clinical Trials. The bfLEAP™ platform analysis can also be used to more precisely understand complex correlations between therapeutic treatment and adverse events, side effects, and other undesirable responses which could jeopardize clinical trial success.

Our platform is agnostic to the disease indication or treatment modality and therefore we believe that it is of value in the development of biologics or small molecules.

The process for our drug asset enhancement program is to:

- acquire the rights to a drug from a biopharmaceutical industry company or academia;
- use the proprietary bfLEAP™ AI/ML platform to determine a multi-factorial profile for a patient that would best respond to the drug;
- rapidly conduct a clinical trial to validate the drug's use for the defined "high-responder" population; and;
- divest/sell the rescued drug asset with the new information back to a large player in the pharma industry, following positive results of the clinical trial.

As part of our strategy, we will continue evolving our intellectual property, analytical platform and technologies, build a large portfolio of drug candidates, and implement a model that reduces risk and increases the frequency of cash flow from rescued drugs. This strategy will include strategic partnerships, collaborations, and relationships along the entire drug development value chain, as well as acquisitions of the rights to developing failed drugs and possibly the underlying companies.

To date, we have not conducted clinical trials on any pharmaceutical drugs and our platform has not been used to identify a drug candidate that has received regulatory approval for commercialization. However, we currently have a strategic relationship with a leading rare disease non-profit organization for artificial intelligence/machine learning ("AI/ML") analysis of late-stage clinical data. We have acquired the rights to a series of preclinical and early clinical drug assets from universities and entered into a strategic collaboration with a world-renowned research institution to create a HSV1 viral therapeutic platform to engineer immunotherapies for colorectal cancer. We have signed exclusive worldwide license agreements with Johns Hopkins University for a cancer drug that targets glioblastoma (brain cancer), pancreatic cancer, and other cancers. We have also signed an exclusive worldwide license with George Washington University for another cancer drug that targets hepatocellular carcinoma (liver cancer), and other liver diseases.

Our platform was originally developed by The Johns Hopkins University Applied Physics Laboratory ("JHU-APL"). JHU-APL uses the same technology for applications related to national defense. Over several years, the software and algorithms have been used to identify relationships, patterns, and anomalies, and make predictions that otherwise may not be found. These discoveries and insights provide an advantage when predicting a target of interest, regardless of industry or sector. We have applied the technology to various clinical data sets and have identified novel relationships that may provide new intellectual property, new drug targets, and other valuable information that may help with patient stratification for a clinical trial thereby improving the odds for success. The platform has not yet aided in the development of a drug that has reached commercialization. However, we have licensed one drug candidate that has completed a Phase I trial and a second candidate that is in the preclinical stages. Our aim is to use our technology on current and future available data to help us better determine the optimal path for development.

While we have not generated significant revenues from our AI/ML operations, we anticipate generating revenue in the future from the following three sources:

Contract Services

Our fee for service partnership offering model is designed for biopharmaceutical companies, as well as other organizations, of all sizes that have challenges analyzing data throughout the drug development process. We provide the customer with an analysis of large complex data sets using our proprietary Artificial Intelligence / Machine Learning platform called bfLEAP™. This platform is designed to predict targets of interest, patterns, relationships, and anomalies. Our service model involves a cash fee plus the potential for rights to new intellectual property generated from the analysis, which can be performed at the discovery, preclinical, or clinical stages of drug development.

Collaborative Arrangements

We plan to enter into collaborative arrangements with biotechnology and pharmaceutical companies who have drugs that are in development or have failed late Phase 2 or Phase 3 trials. The collaborations may also be at the discovery or preclinical stages of drug development. Our revenue will be a combination of fee for service cash payments and success fees based on achieving certain milestones as determined by each specific arrangement. There may also be fees or legal rights associated with the development of new intellectual property.

Acquisition of Rights to Certain Drugs

We may acquire the rights to drugs that have failed late Phase 2 or Phase 3 trials and generate revenues by using our platform to accurately determine the profile of patients that would respond to the drugs, conduct a clinical trial to test our findings either independently or with a clinical partner, and finally sell the drug back to pharmaceutical companies. We have and may continue acquiring the rights to drugs that have not yet failed any trials. We will use our technology to improve the chances for success, conduct a trial, and divest the asset. When divesting assets, the transaction may involve a combination of upfront payments, milestone payments based on clinical success, and royalties on sales of the product.

Our Products

Product/Platform	Description	Target Market/Indications
bfLEAP™ – AI/ML platform for analysis of preclinical and/or clinical data	AI/ML analytics platform derived from technology developed at JHU-APL and licensed by the Company.	Biotechnology and pharmaceutical companies and other organizations.
siRNA	siRNA targeting Beta2-spectrin in the treatment of human diseases developed at George Washington University licensed by the Company	Hepatocellular carcinoma (HCC), treatment of obesity, non-alcoholic fatty liver disease, and non-alcoholic steatohepatitis. Has not yet initiated clinical testing.

On January 14, 2022, the Company entered into an exclusive, worldwide, royalty-bearing license from George Washington University (GWU) for rights to use siRNA targeting Beta2-spectrin in the treatment of human diseases, including hepatocellular carcinoma (HCC). The license covers methods claimed in three U.S. and worldwide patent applications, and also includes use of this approach for treatment of obesity, non-alcoholic fatty liver disease, and non-alcoholic steatohepatitis. This program is currently in the preclinical stage of development. The Company recently initiated proof-of-concept studies on this asset and will use the outcome of these studies to inform a clinical development plan that would include initiation of IND-enabling studies.

Metabolic dysfunction-associated steatotic liver disease (MASLD, which until recently was called non-alcoholic fatty liver disease, or NAFLD) is a condition in which excess lipids, or fat, build up in the liver. This condition, which is more common in people who have obesity and related metabolic diseases including type 2 diabetes, affects as many as 24% of adults in the US and is associated with risk of progression to more serious conditions, including metabolic dysfunction-associated steatohepatitis (MASH), with associated liver inflammation and fibrosis, and HCC. Evidence in animal models of obesity suggest that a protein called β 2-spectrin may play a key role in lipid accumulation, tissue fibrosis, and liver damage, and targeting expression or activity of this protein may be a useful approach in treating MASH and liver cancer (Rao et al., 2021).

In February 2022, the Company entered into an exclusive, worldwide, royalty-bearing license from Johns Hopkins University (JHU) for the use of an improved formulation of Mebendazole for the treatment of any human cancer or neoplastic disease. This formulation shows potent activity in animal models of different types of cancer and has been evaluated in a Phase I clinical trial in patients with high-grade glioma (NCT01729260). The trial, an open-label dose-escalation study, assessed the safety of the improved formulation with adjuvant temozolomide in 24 patients with newly diagnosed gliomas. Investigators observed no dose-limiting toxicity in patients receiving all but the highest tested dose (200mg/kg/day). Four of the 15 patients receiving the maximum tested dose of 200mg/kg/day experienced dose-limiting toxicity, all of which were reversed by decreasing or eliminating the dose given. There were no serious adverse events attributed to mebendazole at any dose during the trial. The Company is currently formulating a strategy to find a partner to conduct additional clinical trials with this asset to enable evaluation of safety in humans.

In October 2022, the Company entered into an exclusive, world-wide, royalty-bearing license from Johns Hopkins University (JHU) and the Institute of Organic Chemistry and Biochemistry (IOCB) of the Czech Academy of Sciences for rights to commercialize N-substituted prodrugs of mebendazole that demonstrate improved solubility and bioavailability. The license covers prodrug compositions and use for treating disease as claimed in multiple US and worldwide patent applications. Patents have since been issued in the United States and Australia and are still in the prosecution phase in other territories. In September 2023 the Company announced results from a preclinical study demonstrating the effectiveness of BF-223, a compound chosen from this class, in an animal model for glioblastoma. The Company is currently formulating a strategy for initiating IND-enabling studies on BF-223 and is conducting outreach to identify partners that may want to license or partner in the development of BF-223.

Our bfLEAP™ Analytics Platform

We are able to pursue our drug rescue business by leveraging a powerful and proven AI/ML platform (trade name: bfLEAP™) derived from technology developed at The Johns Hopkins University Applied Physics Laboratory (JHU-APL). The bfLEAP™ platform is based on an exclusive, world-wide license granted by Johns Hopkins University Applied Physics Laboratory. The license covers three (3) issued patents, as well as a new provisional patent application, non-patent rights to proprietary libraries of algorithms and other trade secrets, which also includes modifications and improvements. On July 8, 2022, the Company entered into an exclusive, world-wide, royalty-bearing license from JHU-APL for the additional technology developed to enhance the bfLEAP™ platform. The new license provides additional intellectual property rights including patents, copyrights and knowhow to be utilized under the Company's bfLEAP™ analytical AI/ML platform. Under the terms of the new License Agreement, JHU will be entitled to eight (8%) percent of net sales for the services provided by the Company to other parties and 3% for internally development drug projects in which the JHU license was utilized. The new license also contains tiered sub licensing fees that start at 50% and reduce to 25% based on revenues.

We believe the bfLEAP™ analytics platform is a potentially disruptive tool for analysis of pre-clinical and/or clinical data sets, such as the robust pre-clinical and clinical trial data sets being generated in translational R&D and clinical trial settings. The input data for bfLEAP™ can include raw data (preclinical and/or clinical readouts), categorical data, sociodemographic data of patients, and various other inputs. Thus, the bfLEAP™ platform is capable of capturing the particular genetic and physical characteristics of patients in an unbiased manner, and contextualizing it against other disparate data sources from patients (e.g. molecular data, physiological data, etc.) for less biased and more meaningful conclusions. It is also uniquely scalable - the bfLEAP™ platform is able to perform analysis on large, high-volume data sets (i.e. 'big data') and also able to analyze highly disparate "short and wide" data as well. In terms of visualization, bfLEAP™ is able to integrate with most commonly used visualization tools for graph analytics.

We believe that the combination of a) scalable analytics (i.e., large data or short/wide data), b) state-of-the-art proprietary algorithms, c) unsupervised machine learning, and d) streamlined data ingestion/visualization makes bfLEAP™ one of the most flexible and powerful new platforms available on the market.

The Company will continue to evolve and improve bfLEAP™, and some of the proceeds from this offering may be used toward that effort either in-house or with development partners like The Johns Hopkins University Applied Physics Lab.

Lieber Institute for Brain Development

On September 8, 2023, the Company entered a data use and technology partnership agreement (the "Partnership Agreement") with the Lieber Institute for Brain Development (LIBD). The Partnership Agreement covers the right of BullFrog AI to leverage its bfLEAP™ platform to mine LIBD's comprehensive brain data, including transcriptomic, genomic, DNA methylation, cell-line, clinical, and imaging data to identify previously unrecognized relationships. The goal of the partnership is to identify previously unrecognized relationships between genes and pathways in the brain and the development of neurologic and psychiatric disorders, thereby facilitating the development of more effective treatments for diseases of the human brain. The collaboration will proceed in two stages, with the first involving unsupervised construction of graphical models to reveal relationships between brain diseases and genomic/biologic attributes, with the goal of identifying new biomarkers and drug targets across disorders. The second stage will involve creating disease-specific models that will enable identification of genes and pathways within these respective disorders. The Partnership Agreement has a one-year term of data exclusivity to complete the first stages of analyses, with a two-year extension option as performance milestones are met.

As contemplated in the Partnership Agreement, on October 16, 2023, the Company and LIBD entered into a commercial agreement (the "Commercial Agreement") that sets forth the key terms for commercialization of products and services developed under the Partnership Agreement. Pursuant to the Commercial Agreement, LIBD granted the Company a worldwide, royalty-bearing exclusive license so long as the Company receives net sales or income from the licensing of "Licensed Products" (as defined in the Commercial Agreement) in the application of machine learning and/or artificial intelligence for research and development in drug development, and specifically includes therapeutic products, patient selection strategies, and target identification, but excludes diagnostics and incidental uses of machine learning and/or artificial intelligence on data derived from research. Generally, "Licensed products" are any product or service which incorporates, results from, or is derived from LIBD's Data (meaning finished brain-related data, including but not limited to DNA methylation, RNAseq, genomic, DNA methylation, cell-line, clinical, and imaging data, and the specified data set forth in the Partnership Agreement) and that the Company or its affiliate develops during the term of the Partnership Agreement, and any improvements thereof after the term of the Partnership Agreement, and all Licensed Products or services derived therefrom by the Company or its affiliates. Licensed Products may include, but are not limited to, biomarker and target identification, target validation, mapping unmet needs, identifying genetic risk factors and predictive modeling.

The Company was also granted the right to sublicense, to use the deliverables under the Partnership Agreement, and LIBD's intellectual property rights in the data, to (i) use, sell, distribute for sale, have distributed for sale, offer for sale, have sold, import and have imported Licensed Products and (ii) to develop, have developed, make, have made Licensed Products that are derived from Licensed Products developed during the term of the Partnership Agreement, and any improvements made following the term. The Company is prohibited from sublicensing LIBD Data. The Company shall pay LIBD a royalty based on net sales of all Licensed Products sold by the Company and/or its affiliates.

The Commercial Agreement, generally, may be terminated at any time by either the Company or LIBD if either party defaults or breaches any material term of the agreement or files for protection under bankruptcy laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver, trustee, or similar agent over its property.

Summary for CATIE Schizophrenia Case Study

The Company worked with the Lieber Institute for Brain Development to analyze data from the landmark CATIE trials. The CATIE trials were the largest trials ever conducted for anti-psychotic medications. Bullfrog analyzed CATIE data from ~200 schizophrenia patients, with a library of almost 1 million genetic data points for each patient, more than 200 non-genetic attributes per patient, and 4 different medications used in the trial. For each of the four medications used, bfLEAP™ analysis revealed new, previously unknown relationships between individual genetic variants and negative patient symptoms. The genetic loci identified represent potential druggable targets, as well as potential stratifying criteria for future clinical trials in schizophrenia.

We performed another analysis on the data using our new advanced clustering algorithms bfLEAP 2.0 but focused on one particular drug named Olanzapine. Our bfLEAP™ 2.0 analytical results identified previously unknown, multi-dimensional associations among newly identified genetic variants, drug clearance, clinical trial sites, and clinical outcome variables in schizophrenia patients.

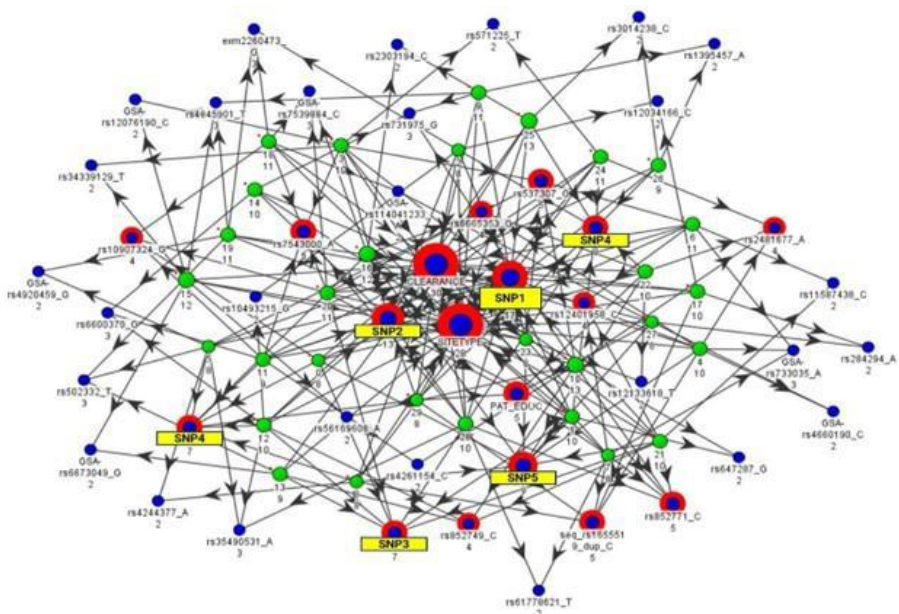


FIGURE 1 - bfLEAP™ Analytical Map

Each green node represents a different sampling of the data, and arrows point to attributes (blue nodes) which were found to be key indicators according to that sampling. Attribute importance is determined by how many samplings identify that attribute as an indicator (i.e., number of incoming arrows to each blue node).



Identification of clustered multi-variate associations (e.g., novel genetic variants, drug clearance, substance abuse) could help us 1) identify novel drug targets, 2) predict which patients are most likely to respond, and 3) identify modifiable factors that could contribute to better outcomes.

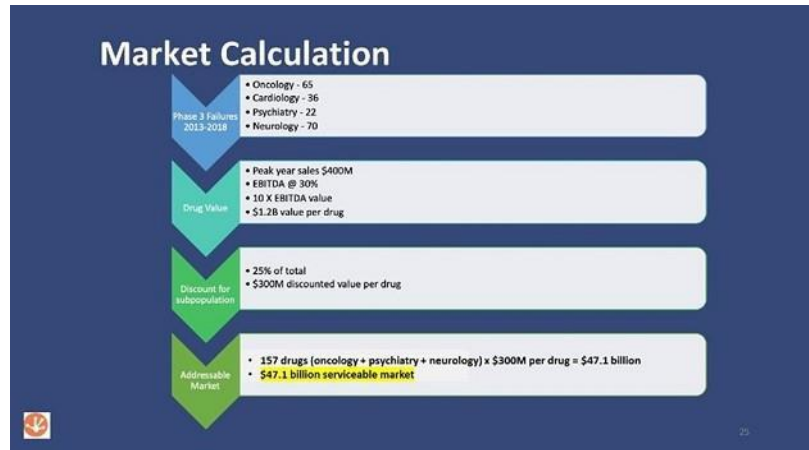
The Company worked with an international collaborator in cardiovascular devices to analyze data from an ongoing clinical trial for a new device. Bullfrog analyzed data from ~55 patients, with a library of almost 15,000 unique attributes of data for each patient. The data also included adverse events, and key demographic information. For this collaborator, bLEAP™ analysis was able to provide ground truth for the company - confirming multiple correlations and non-correlations within the data. In terms of actionable output, the analytical results confirmed at least two demographic co-variables for the ongoing trial, and also provided a starting point for deeper physiological and molecular studies.

Our Supply Chain and Customer Base

We have launched our businesses using funds from our initial public offering and through our partnerships and relationships. We have a strategic relationship with FSHD Society, a leading non-governmental organization, for AI/ML analysis of clinical trial data for patients with a rare neuromuscular disorder. We also have several other developing strategic relationships in the project design phase. The Company has executed a joint development deal for a biologics discovery phase opportunity that is directed toward targeted cancer therapeutics. The Company has also obtained exclusive worldwide rights to a Phase 2 ready glioblastoma drug and a discovery phase hepatocellular carcinoma drug from universities. Since we intend to conduct late-stage clinical trials with partners on rescued therapeutic assets, there will be a requirement of drug product or other significant services to plan and execute our clinical development programs. The success of our partnered clinical development programs will require adequate availability of raw materials and/or drug product for our R&D and clinical trials, and, in some cases, may also require establishment of third-party arrangements to obtain finished drug product that is manufactured appropriately under industry-standard guidelines, and packaged for clinical use or sale. Since we are a digital biopharmaceutical company, our clinical development programs will also require, in some cases, the establishment of third-party relationships for execution and completion of clinical trials.

Our Market Opportunity

One aim of our business is to “rescue” drugs that have failed in phase 3 clinical trials by using our technology to analyze all available data with the goal of designing a precision medicine clinical trial that will have a better chance of being successful. The graphic below illustrates the estimated market opportunity for these failed drugs. The top arrow shows the number of failed phase 3 trials for several disease categories over a 5-year period. The arrows below provide our assumptions for narrowing or discounting certain parameters associated with the market size calculation. The final arrow shows the math behind the \$47.1B. To date, we have not penetrated the failed drug market, however; we are actively searching for failed drug opportunities.

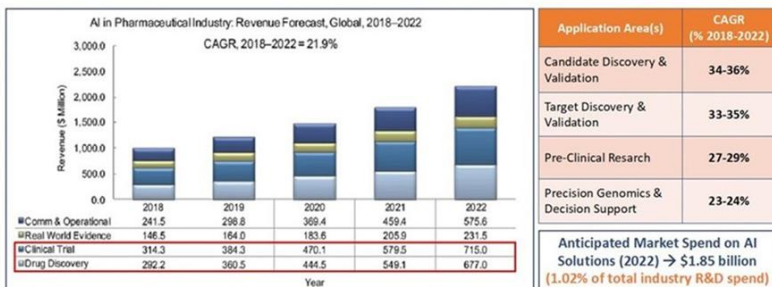


Identification of candidates with potential for rescue may be challenging and require significant resources, and once these assets are identified the Company may find it challenging to license them under favorable terms in order to create value for shareholders. Subsequent development of these assets for clinical testing may require significant effort and resources. Ultimately, these assets must undergo rigorous clinical testing and approval by FDA or comparable regulatory authorities in other countries in order to be marketed. A key part of our strategy is to partner our R&D programs. In addition, we do not intend on commercializing drugs and instead will seek to divest each drug asset to a company that will commercialize the drug. The Company may receive future royalties in come transactions.

The following graphic illustrates the global revenue forecast for applying AI in the pharmaceutical industry, as well as the increase in anticipated market spend and annual growth rate for AI solutions per certain application areas.

Market – AI in the Pharmaceutical Industry

BullFrog is poised to impact multiple high-growth application areas



Source: Frost & Sullivan – “Growth Insight – Role of AI in the Pharmaceutical Industry” (Sept. 2019)

Intellectual Property

Patents

We have exclusive worldwide rights to the following patents related to our intellectual property:

Mebendazole Polymorph For Treatment And Prevention Of Tumors

Serial Number	Country	Status	Issue Date	Expiration Date
62/112,706	United States	Converted	N/A	N/A
PCT/US2016/016968	PCT	Nationalized	N/A	N/A
11,110,079	United States	Granted	9/7/2021	2/8/2036
17/402,131	United States	Abandoned	N/A	N/A
18/525,209	United States	Pending	N/A	N/A
16747414.7	Europe	Granted	12/15/2021	2/8/2036
16747414.7	Czech Republic	Granted	12/15/2021	2/8/2036
16747414.7	France	Granted	12/15/2021	2/8/2036
60 2016 067 384.3	Germany	Granted	12/15/2021	2/8/2036
16747414.7	Ireland	Granted	12/15/2021	2/8/2036
502022000018341	Italy	Granted	12/15/2021	2/8/2036
16747414.7	Spain	Granted	12/15/2021	2/8/2036
16747414.7	Switzerland	Granted	12/15/2021	2/8/2036
16747414.7	United Kingdom	Granted	12/15/2021	2/8/2036
253854	Israel	Granted	6/26/2021	2/8/2036
2016800144274	China	Granted	6/25/2021	2/8/2036
201717028684	India	Granted	12/1/2020	2/8/2036
2017-541687	Japan	Granted	11/18/2020	2/8/2036

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Mebendazole Prodrugs with Enhanced Solubility and Oral Bioavailability

Serial Number	Country	Status	Issue Date	Expiration Date
62/627,810	United States	Converted	N/A	N/A
PCT/US2019/017291	PCT	Nationalized	N/A	N/A
11,712,435	United States	Granted	8/1/2023	2/8/2039
2019216757	Australia	Granted	1/4/2024	2/8/2039
19751700.6	Europe	Pending	N/A	N/A
3,090,691	Canada	Pending	N/A	N/A

Inhibition of SPTBN1 to treat Obesity/NASH and Obesity/NASH-driven cancer

Serial Number	Country	Status	Filing Date	Expiration Date
63/113,745	United States	Converted	11/13/2020	N/A
63/147,141	United States	Converted	2/8/2021	N/A
PCT/US2021/059245	United States	Nationalized	11/12/2021	N/A
2023-528428	Japan	Filed	11/12/2021	N/A
18/252,771	United States	Filed	5/12/2023	N/A
21892928.9	Europe	Filed	6/13/2023	N/A
2021800763877	Canada	Filed	11/12/2021	N/A

John Hopkins University Applied Physics Lab Licensed Intellectual Property:

Title	Serial Number	File Date	Country	Status	Expiration Date	Assignee
Apparatus and Method for Distributed Graph Processing	U.S. Patent 10,146,801	7/13/2015	US	Granted	3/2/2037	The Johns Hopkins University
Method and Apparatus for Analysis and Classification of High Dimensional Data Sets	U.S. Patent 10,936,965	10/5/2017	US	Granted	9/25/2038	The Johns Hopkins University
Generalized Low Entropy Mixture Model	U.S. Patent 10,839,256	4/2/2018	US	Granted	12/15/2038	The Johns Hopkins University

Licenses

We hold the following licenses related to our intellectual property:

Licensor	Licensee	Description of Rights Granted
Johns Hopkins University Applied Physics Lab	Bullfrog AI, Inc.	Worldwide, exclusive rights for therapeutics development and analytical services
George Washington University	Bullfrog AI Holdings	Worldwide, exclusive rights for therapeutics development
Johns Hopkins University	Bullfrog AI Holdings	Worldwide, exclusive rights for therapeutics development

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JHU-APL Technology License

On February 7, 2018, the Company entered into an exclusive, world-wide, royalty-bearing license from JHU-APL for the technology. The license covers three (3) issued patents, one (1) new provisional patent application, non-patent rights to proprietary libraries of algorithms and other trade secrets, the license also includes modifications and improvements. In October of 2021, the Company executed an amendment to the original license which represents improvements and new advanced analytics capabilities. In consideration of the rights granted to the Company under the License Agreement JHU received a warrant equal to five percent (5%) of the then fully diluted equity base of the Company, which shall be diluted following the closing of the IPO. Under the terms of the License Agreement, JHU will be entitled to eight percent (8%) royalty on net sales for the services provided by the Company in which the JHU licensed technology was utilized, as well as fifty percent (50%) of all sublicense revenues received by the Company. In addition, the Company is required to pay JHU an annual maintenance fee of \$1,500. Minimum annual royalty payments are \$20,000 for 2022, \$80,000 for 2023, and \$300,000 for 2024 and beyond. If cumulative annual royalty payments do not reach these levels, the amount due to JHU to reach the annual minimum is due by January 31st of the following year. Failure to make annual royalty payments is considered a material breach under the agreement and upon notice from JHU of a material breach, the Company shall have 60 days to cure the material breach.

On July 8, 2022, the company entered into an exclusive, world-wide, royalty-bearing license from JHU-APL for the additional technology developed to enhance the bfLEAP™ platform. The new license provides additional intellectual property rights including patents, copyrights, and knowhow to be utilized under the Company's bfLEAP™ analytical AI/ML platform. This license supersedes the previous license. In consideration of the new license, the Company issued 39,879 shares of common stock. Under the terms of the new License Agreement, JHU will be entitled to eight percent (8%) of net sales for the services provided by the Company to other parties and three percent (3%) for internally development drug projects in which the JHU license was utilized. The new license also contains tiered sub licensing fees that start at 50% and reduce to 25% based on revenues. In addition, the Company is required to pay JHU an annual maintenance fee of \$1,500. Minimum annual payments are set to be \$30,000 for 2022, \$80,000 for 2023, and \$300,000 for 2024 and beyond, all of which are creditable by royalties. The financial terms of the new license agreement replace the original terms and are not duplicative.

On May 31, 2023, the Company and JHU-APL entered into Amendment number 1 of the July 8, 2022 License Agreement whereby the Company gained access to certain improvements including additional patents and knowhow in exchange for a series of payments totaling \$275,000. The first of these payments for \$75,000 was due in July 2023 followed by payments of \$75,000, \$75,000, and \$50,000 in years 2025, 2026 and 2027, respectively. The amendment also reduced the 2023 minimum annual royalty payment to \$60,000, all other financial terms remain the same. As of September 30, 2024, we have accrued \$225,000 of the 2024 minimum annual royalty payments.

George Washington University - Beta2-spectrin siRNA License

On January 14, 2022, the Company entered into an exclusive, world-wide, royalty-bearing license from GWU for rights to use siRNA targeting Beta2-spectrin in the treatment of human diseases, including HCC. The license covers methods claimed in three US and worldwide patent applications, and also includes use of this approach for treatment of obesity, non-alcoholic fatty liver disease, and non-alcoholic steatohepatitis. This program is currently in the preclinical stage of development. The Company has not yet initiated development activities or IND-enabling studies on this asset; however, the plan is to conduct this work over the next 24 months. All R&D to date on this candidate has been conducted by the licensor of the technology, George Washington University. The term of the agreement began on January 14, 2022 and ends on the expiration date of the last patent to expire or 10 years after the first sale of a licensed product if no patents have been issued. The license can be terminated by the licensee upon 60 days' written notice, or by the licensor if the Company is more than 30 days late in paying amounts owed to the licensor and does not make payment upon demand, or in the event of any material breach of the license that is not cured within 45 days.

Non-alcoholic fatty liver disease (NAFLD) is a condition in which excess lipids, or fat, build up in the liver. This condition, which is more common in people who have obesity and related metabolic diseases including type 2 diabetes, affects as many as 24% of adults in the US and is associated with risk of progression to more serious conditions, including non-alcoholic steatohepatitis (NASH), with associated liver inflammation and fibrosis, and hepatocellular carcinoma (HCC). Evidence in animal models of obesity suggest that a protein called β 2-spectrin may play a key role in lipid accumulation, tissue fibrosis, and liver damage, and targeting expression or activity of this protein may be a useful approach in treating NASH and liver cancer (Rao et al., 2021).

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In consideration of the rights granted to the Company under the license agreement, GWU received a \$20,000 License Initiation Fee. Under the terms of the License Agreement, GWU will be entitled to a three percent (3%) royalty on net sales subject to quarterly minimums once the first sale has occurred subsequent to regulatory approval, as well sublicense or assignment fees in the event the Company sublicenses or assigns their rights to use the technology. The Company will also reimburse GWU for previously incurred and ongoing patent costs. The Sublicense and Assignment fee amounts decline as the Company advances the clinical development of the licensed technology. The license agreement also contains milestone payments for clinical development through the approval of a New Drug Application (NDA) and commercialization.

Aggregate payments made to GWU to date include the \$20,000 License Initiation Fee and an additional \$6,550 to reimburse the licensor for past patent costs. Aggregate future milestone costs could reach \$860,000 if the drug successfully completes clinical trials and is the subject of an NDA to the U.S. FDA. Future milestones on sales revenue are limited to \$1 million on the first \$20 million in net sales.

As of September 30, 2024, there has been no accrual for royalties since we have not begun to generate applicable revenue. The Company assessed whether the license should be capitalized and determined that the licensed program is in the early stage and therefore may not be recoverable; the Company expensed the license fee and will expense development costs until commercial viability is likely.

Johns Hopkins University – Mebendazole License

On February 22, 2022, the Company entered into an exclusive, worldwide, royalty-bearing license from JHU for the use of an improved formulation of Mebendazole for the treatment of any human cancer or neoplastic disease. This formulation shows potent activity in animal models of different types of cancer, and has been evaluated in a Phase I clinical trial in patients with high-grade glioma (NCT01729260). The trial, an open-label dose-escalation study, assessed the safety of the improved formulation with adjuvant temozolomide in 24 patients with newly diagnosed gliomas. Investigators observed no dose-limiting toxicity in patients receiving all but the highest tested dose (200mg/kg/day). Four of the 15 patients receiving the maximum tested dose of 200mg/kg/day experienced dose-limiting toxicity, all of which were reversed by decreasing or eliminating the dose given. There were no serious adverse events attributed to mebendazole at any dose during the trial. The Company is currently formulating a strategy to conduct additional clinical trials with this asset to enable evaluation of safety in humans.

The license covers six (6) issued patents and one (1) pending application, with the term of the agreement beginning on February 22, 2022 and ending on the date of expiration of the last to expire patent. The license can be terminated by the licensee upon 90 days' written notice, or by the licensor in the event of any material breach of the license that is not cured within 30 days. In consideration of the rights granted to the Company under the license agreement, JHU will receive a staggered Upfront License Fee of \$250,000, with the first \$50,000 payment due within 30 days of the effective date. The Company will also reimburse JHU for previously incurred and ongoing patent costs. Under the terms of the license agreement, JHU will be entitled to three- and one-half percent (3.5%) royalty on net sales by the Company. In addition, the Company is required to pay JHU minimum annual royalty payments of \$5,000 for 2022, \$10,000 for 2023, \$20,000 for 2024, \$30,000 for 2025, and \$50,000 for 2026 and each year after until the first commercial sale, after which, the annual minimum royalty shall be \$250,000. The license agreement also contains milestone payments for clinical development steps through the approval of an NDA and commercialization. Aggregate payments made to date include the initial \$50,000 upfront fee and an additional \$79,232 to reimburse the licensor for past patent costs. Aggregate future milestone costs could reach \$1,500,000 if the drug successfully completes Phase II and III clinical trials and is approved for sale and marketing by the US FDA. Future milestones on sales revenue are \$1 million on the first \$20 million in sales revenue, \$2 million in the first-year cumulative sales revenue exceeds \$100 million, \$10 million in the first-year cumulative sales revenue exceeds \$500 million, and \$20 million in the first-year cumulative sales revenue exceeds \$1 billion. As of September 30, 2024 and December 31, 2023, the balance of accrued expense related to this license agreement was \$15,000 and \$10,000, respectively. The Company assessed whether the license should be capitalized and determined that the licensed program is in the early stage and therefore may not be recoverable; the Company expensed the license fee and will expense development costs until commercial viability is likely.

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Johns Hopkins University – Mebendazole Prodrug License

On October 13, 2022, the Company entered into an exclusive, worldwide, royalty-bearing license from JHU and the Institute of Organic Chemistry and Biochemistry (IOCB) of the Czech Academy of Sciences for rights to commercialize N-substituted prodrugs of mebendazole that demonstrate improved solubility and bioavailability. The license covers prodrug compositions and use for treating disease as claimed in multiple US and worldwide patent applications. The term of the agreement began on October 13, 2022 and continues until the date of expiration of the last to expire patent, or for 20 years from the effective date of the agreement if no patents are issued. The license can be terminated by the Company upon 90 days' written notice, or by the licensor in the event of any material breach of the license that is not cured by the Company within 30 days.

In consideration for the rights granted to the Company under the License Agreement JHU and IOCB will receive a staggered upfront license fee of \$100,000. The Company will also reimburse JHU and IOCB for previously incurred patent costs totaling \$33,265 and will be responsible for reimbursing licensors for future patent costs. Under the terms of the License Agreement, the licensors will be entitled to a four percent (4%) royalty on net sales subject to annual minimums upon first commercial sale of a licensed product, as well sublicense or assignment fees in the event the Company sublicenses or assigns their rights to use the technology. The Sublicense fee amount declines as the Company advances the clinical development of licensed technology. In addition, the Company is required to pay JHU and IOCB minimum annual royalty payments of \$5,000 for 2026, \$10,000 for 2027, \$20,000 for 2028, \$30,000 for 2029, and \$50,000 for 2030 and each year after until the first commercial sale, after which, the annual minimum royalty shall be \$150,000. The Company will be responsible for milestone payments for patent issuance of up to \$50,000 and clinical development milestones up to and including approval of an NDA totaling up to \$2.3 million. The Company will be required to pay a commercial milestone of \$1 million once sales reach \$20 million in the US, \$2 million when sales in the US reach \$100 million, \$10 million when US sales reach \$500 million, and \$20 million when US sales exceed \$1 billion.

As of September 30, 2024 and December 31, 2023, no expenses have been accrued. The Company assessed whether the license should be capitalized and determined that the licensed program is in the early stage and therefore may not be recoverable; the Company expensed the license fee and will expense development costs until commercial viability is likely.

On September 26, 2023, the Company announced positive data in a preclinical study investigating the anti-cancer activity of a novel prodrug of mebendazole for the treatment of glioblastoma. The study assessed the relative efficacy of BF-222, a novel formulation of mebendazole that has been evaluated in clinical trials, and BF-223, a novel prodrug of mebendazole with improved solubility and bioavailability relative to BF-222, compared with placebo in mice that had been implanted with tumor cells as a model for human glioblastoma. Animals treated with BF-223 had an average survival time of 27.9 days compared with 27.3 days for mice treated with BF-222 and 23.4 days for mice given placebo. Mice treated with BF-223 were administered 80% of the dose that mice treated with BF-222 received, and improved outcomes for both treatment groups were statistically significant compared to placebo. In addition, animals treated with equivalent doses of BF-222 and BF-223 showed comparable and significant reduction in tumor growth compared to control animals during the study.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. The immuno-oncology, neuroscience, and rare disease segments of the industry in particular are highly competitive. While we believe that our technology, development experience and scientific knowledge provide competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical, and biotechnology companies, academic institutions and governmental agencies, and public and private research institutions.

Many of our competitors may have significantly greater financial resources, and expertise in research and development, manufacturing, preclinical studies, conducting clinical trials, obtaining regulatory approvals, and marketing approved medicines than we do. Mergers and acquisitions in the pharmaceutical, biotechnology, and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to or necessary for our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

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The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, if any, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize medicines that are safer, are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any medicines we may develop. Our competitors also may obtain FDA or other regulatory approval for their medicines more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic medicines. There are many generic medicines currently on the market for certain of the indications that we are pursuing, and additional generics are expected to become available over the coming years. If our therapeutic product candidates are approved, we expect that they will be priced at a significant premium over competitive generic medicines.

Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. If the product candidates of our priority programs are approved for the indications for which we are currently planning clinical trials, they will compete with the drugs discussed below and will likely compete with other drugs currently in development.

bfLEAP

The analytics industry and application of AI in healthcare is growing rapidly. Competition exists along the entire continuum of the drug development process from discovery to commercialization and beyond. We believe the weakness of the industry is the quality of the data and we believe bfLEAP provides several competitive advantages, that will position the Company for success. First, bfLEAP is highly scalable and can process data from small to extremely large complex data sets without the need for additional code being developed. Second, it is adept at processing and analyzing incomplete data and making predictions that we do not believe other technologies are capable of doing. Finally, bfLEAP has the ability to extract the most important features for analysis out of extremely large complex data sets using unsupervised machine learning algorithms, thereby greatly simplifying complex problems. Since data quality is a problem that exists in the healthcare industry, we see these as major differentiators. The ability to make predictions, find relationships and patterns and anomalies in extremely large complex data sets has been demonstrated by the Applied Physics Lab in other applications and sectors. Finally, the algorithms used by bfLEAP are proprietary and protected, having been developed at Johns Hopkins University Applied Physics Lab. We believe most of the competitors rely on open-source algorithms and we also believe that we have already demonstrated our superiority via the August 2021 publication in DeepAI.org.

Government Regulation

The FDA does not currently require approval of AI technologies used to aid in therapeutics, but that could change in the future. The FDA will regulate any clinical trials conducted by the Company.

Our clinical development programs will, in some cases, require regulatory review of preclinical and/or clinical data by the FDA or other governing agencies, and subsequent compliance with applicable federal, state, local, and foreign statutes and regulations. The results of the clinical trials that we conduct will be evaluated by the FDA and other regulatory bodies. The comments and approvals that are obtained are expected to lead to milestone payments under the collaborative agreement. Accordingly, our ability to navigate the regulatory process is extremely important to the success of the Company. We believe that we have a competitive advantage in this process due to primarily focusing on drug candidates that already have some level of success in clinical trials. Previous success of a particular candidate in trials combined with our precision medicine approach to clinical trial design using our bfLEAP platform, will de-risk the development process and improve the chances for success.

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Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act (FD&C Act) and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications (NDAs), warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves preclinical laboratory and animal tests, the submission to FDA of an investigational new drug application (IND) which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to FDA as part of the IND.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances, such as where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the applicant under an approved NDA is also subject to an annual program fee for each prescription product. These fees are typically increased annually. Sponsors of applications for drugs granted Orphan Drug Designation are exempt from these user fees.

FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an outside advisory committee – typically a panel that includes clinicians and other experts – for review, evaluation, and a recommendation as to whether the application should be approved. FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practices (cGMPs) is satisfactory and the NDA contains data that provides substantial evidence that the drug is safe and effective in the indication studied.

Fast Track Designation

FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the Fast Track program, the sponsor of a new drug candidate may request that FDA designate the drug candidate for a specific indication as a Fast Track drug concurrent with, or after, the filing of the IND for the drug candidate. FDA must determine if the drug candidate qualifies for Fast Track Designation within 60 days of receipt of the sponsor's request.

If a submission is granted Fast Track Designation, the sponsor may engage in more frequent interactions with FDA, and FDA may review sections of the NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. While we may seek Fast Track Designation, there is no guarantee that we will be successful in obtaining any such designation. Even if we do obtain such designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A Fast Track Designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. Additionally, Fast Track Designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA. FDA also may require post-marketing testing, known as Phase 4 testing, REMS and surveillance to monitor the effects of an approved product, or FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with FDA subjects entities to periodic unannounced

inspections by FDA, during which the Agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Generic Competition

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application (ANDA). An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product (a Paragraph IV certification). The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carve out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents or certifies that the listed patents will not be infringed by the new product, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification, the NDA and patent holders may then initiate a patent infringement lawsuit in response. The filing of a patent infringement lawsuit within 45 days of the receipt of such a certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

Exclusivity

Upon NDA approval of a new chemical entity (NCE) that drug receives five years of marketing exclusivity during which FDA cannot receive any ANDA seeking approval of a generic version of that drug. An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period. Certain changes to a drug, such as the addition of a new indication to the package insert, can be the subject of a three-year period of exclusivity if the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the application. FDA cannot approve an ANDA for a generic drug that includes the change during the period of exclusivity.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase (the time between IND application and NDA submission) and all of the review phase (the time between NDA submission and approval up to a maximum of five years). The time can be shortened if FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years, and only one patent can be extended. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the United States Patent and Trademark Office must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Other Healthcare Laws

In the United States, biotechnology company activities are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services (CMS), other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General and the Office for Civil Rights), the U.S. Department of Justice (DOJ) and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, research, sales, marketing, and scientific/educational grant programs have to comply with the anti-fraud and abuse provisions of the Social Security Act, the federal false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act (HIPAA) and similar state laws, each as amended, as applicable.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Data privacy and security regulations by both the federal government and the states in which business is conducted may also be applicable. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. HIPAA requires covered entities to limit the use and disclosure of protected health information to specifically authorized situations and requires covered entities to implement security measures to protect health information that they maintain in electronic form. Among other things, HITECH made HIPAA's security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Insurance Coverage and Reimbursement

Significant uncertainty exists as to the insurance coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any product candidates for which regulatory approval for commercial sale is obtained will depend in part on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities and health programs in the United States such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of FDA-approved drugs for a particular indication. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will

be applied consistently or obtained in the first instance.

Human Capital Resources

As of November 4, 2024, the Company has 13 full-time employees and consultants, including its Chief Executive Officer Vininder Singh and its Chief Financial Officer, Dane Saglio and 4 part-time employees, advisors, and consultants. None of these employees are covered by a collective bargaining agreement, and we believe our relationship with our employees is good. We also engage consultants on an as-needed basis to supplement existing staff.

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Properties

Currently, the Company does not own any real property. All of the Company's employees work virtually.

Legal Proceedings

The Company is not a party to any legal proceedings.

Corporate Information

Bullfrog AI Holdings, Inc. was incorporated in the State of Nevada on February 6, 2020. Our principal business address is 325 Ellington Blvd, Unit 317, Gaithersburg, MD 20878. Our website address is www.bullfrogai.com. The references to our website in this Prospectus are inactive textual references only. The information on our website is neither incorporated by reference into this Prospectus nor intended to be used in connection with this Prospectus. All of our operations are currently conducted through Bullfrog AI Holdings, Inc.

Available Information

We file annual, quarterly, and current reports, proxy statements and other information with the U.S. Securities Exchange Commission (the "SEC"). These filings are available to the public through the SEC's website at <http://www.sec.gov>. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included unless otherwise specified, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market for Common Stock

Our Common Stock and tradeable warrants are listed on the Nasdaq Capital Market under the symbol "BFRG" and "BFRGW," respectively.

Holders

As of November 4, 2024, there were approximately 15 holders of the Company's Common Stock, not including shares held in "street name" in brokerage accounts, which are unknown.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis should be read in conjunction with our consolidated financial statements and the related notes thereto included elsewhere herein. The Management's Discussion and Analysis contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Any statements that are not statements of historical fact are forward-looking statements. When used, the words "believe," "plan," "intend," "anticipate," "target," "estimate," "expect," and the like, and/or future-tense or conditional constructions ("will," "may," "could," "should," etc.), or similar expressions, identify certain of these forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements in this prospectus. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors including, but not limited to, those noted under "Risk Factors." We do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this prospectus, except as may be required under applicable law.

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Overview

Bullfrog AI Holdings, Inc. was incorporated in the State of Nevada in February 2020. Bullfrog AI Holdings, Inc. is the parent company of Bullfrog AI, Inc. and Bullfrog AI Management, LLC, which were incorporated in Delaware and Maryland, in 2017 and 2021, respectively. Operations are currently conducted through Bullfrog AI Holdings, Inc., which began operations on February 6, 2020. We are a company focused specifically on advanced Artificial Intelligence / Machine Learning (AI/ML) analysis of complex data in the advancement of medicine. Our founding AI/ML platform (trade name: bfLEAP™) was created from technology originally developed at The Johns Hopkins University Applied Physics Laboratory (JHU-APL). Subsequently, we have developed new tools and capabilities composed of an ensemble of machine learning and artificial intelligence models.

In February 2018, Bullfrog AI Holdings secured the original exclusive, worldwide, royalty-bearing license from JHU-APL. The license covers three (3) issued patents, one (1) new provisional patent application, non-patent rights to proprietary libraries of algorithms and other trade secrets including modifications and improvements. Our objective is to utilize our AI/ML platform with a precision medicine approach toward drug development with biopharmaceutical collaborators, as well as for our own internal clinical development programs. We believe the bfLEAP™ platform is ideally suited for evaluating pre-clinical and clinical trial data generated in translational research and clinical trial settings that lead to faster, less expensive drug approvals.

Our aim is to improve the odds of success in each stage of developing medicine, ranging from early pre-clinical through late-stage clinical development. Our ultimate objective is to utilize bfLEAP™ to enable the success of ongoing clinical trials or rescue late-stage failed drugs (i.e., Phase 2 or Phase 3 clinical trial failures) for in-house development and divestiture; although, we also consider entering collaborations for earlier stage drugs.

In September 2020 and October 2021, the Company executed amendments to the original February 2018 license which represents improvements and new advanced analytics capabilities. In consideration of the rights granted to the Company under the original License Agreement, the Company granted JHU 178,571 warrants exercisable to purchase shares of common stock at \$2.10 per share.

In July 2022, the Company entered into an exclusive, worldwide, royalty-bearing license from JHU-APL that provides additional intellectual property rights including patents,

copyrights, and knowhow to be utilized under the Company's bfLEAP™ analytical AI/ML platform. In consideration for the new license, the Company issued to JHU-APL 39,879 shares of common stock. Under the terms of the new License Agreement, JHU will be entitled to eight (8%) percent of net sales for the services provided by the Company to other parties and three (3%) percent for internally developed drug projects in which the JHU license was utilized. The new license also contains tiered sub licensing fees that start at fifty (50%) percent and reduce to twenty-five (25%) percent based on revenues. The Company and JHU-APL entered into Amendment number 1 of the July 2022 License Agreement whereby the Company gained access to certain improvements including additional patents and knowhow in exchange for a series of payments totaling \$275,000. The first of these payments for \$75,000 was paid in July 2023 and the remaining payments of \$75,000, \$75,000 and \$50,000 are due in years 2025, 2026 and 2027, respectively. The amendment also reduced the 2023 minimum annual royalty payment to \$60,000, all other financial terms remain the same. As a result of this Amendment, the minimum annual payments were \$30,000 for 2022 and \$60,000 for 2023, and the minimum annual payments will be \$300,000 for 2024 and beyond, all of which are creditable by royalties. As of September 30, 2024, we have accrued \$225,000 of the 2024 minimum annual royalty payments.

We intend to continue to evolve and improve bfLEAP™, either in-house or with development partners like JHU-APL. We plan to leverage our proprietary AI/ML platform, developed over several years at one of the top innovation institutions in the world which has already been successfully applied in multiple sectors.

We have staffed our business using funds from our initial public offering and have entered into partnerships and relationships and recently completed our first commercial service contract with a leading rare disease non-profit organization for AI/ML analysis of late-stage clinical data. We have also acquired the rights to a series of preclinical and early clinical drug assets from universities, as well as a strategic collaboration with a world-renowned research institution to create a HSV1 viral therapeutic platform to engineer immunotherapies for a variety of diseases. We have signed exclusive worldwide License Agreements with JHU for a cancer drug that targets glioblastoma (brain cancer), pancreatic cancer, and others. We have also signed an exclusive worldwide license from George Washington University for another cancer drug that targets hepatocellular carcinoma (liver cancer) and other liver diseases. In addition, we have signed three-year strategic data and commercialization agreements with the Lieber Institute for Brain Development ("LIBD") whom we believe has a repository of the largest collection of postmortem brains in the world including molecular, clinical, and other data. The objective of this partnership is for the Company to analyze these rich data sets using its proprietary AI/ML tools and models and then go to market with the discoveries with the ultimate goal of securing revenue generating strategic partnership deals with biopharmaceutical companies. We intend to secure the rights to other proprietary data sets and repeat this strategy. Additionally, we intend to gain access to later-stage clinical assets through partnerships or the acquisition of rights to failed therapeutic candidates for drug rescue. In certain circumstances, we intend to conduct late-stage clinical trials in an effort to rescue therapeutic assets that previously failed. In these cases, there will be a requirement for drug supply and regulatory services to conduct clinical trials. The success of our clinical development programs will require finding partners to support the clinical development, adequate availability of raw materials and/or drug product for our R&D and clinical trials, and, in some cases, may also require establishment of third-party arrangements to obtain finished drug product that is manufactured appropriately under Good Manufacturing Practices, and packaged for clinical use or sale. Since we are a company focused on using our AI technology to advance medicines, any clinical development programs will also require, in all cases, partners and the establishment of third-party relationships for execution and completion of clinical trials.

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Since completing our IPO in February 2023, aided by the receipt of the IPO proceeds in addition to the proceeds from our February 2024 and October 2024 offerings, we have implemented several initiatives: investor relations and marketing to promote and raise awareness of the company in the financial and business sectors, research and development, collaboration with the J Craig Venter Institute and initiated preclinical studies with our in-licensed drug programs. The Company is actively engaged in developing and pursuing new intellectual property as it strives to continuously evolve its AI/ML platform.

Internally, the Company has added incremental staff to accelerate execution, and the development of processes and custom scripts for use in performing new drug target discovery and analytical services for customers, while also launching initiatives targeting large public health data sources and seeking access to proprietary health data sources, such as our agreement with the Lieber Institute for Brain Development. We also transitioned our accounting and financial reporting systems and processes to enhance our internal control environment as a public company. Capital from the IPO was also used to retire two notes that were sold to fund the Company through the IPO that did not convert into common stock as well as other debts accrued over time to our staff, employees and consultants as well as obligations related to the acquisition of our licensed drug programs.

The Company has had negative cash flows from operations and operated at a net loss since inception. In the first quarter of 2023, we completed our initial public offering ("IPO"). In February 2024, we received net proceeds of approximately \$5.7 million from an underwritten secondary public offering of common stock and warrants. As of September 30, 2024, the Company has a cash balance of approximately \$4.2 million. In October 2024, we received net proceeds of approximately \$2.7 million from a registered direct offering of common stock and pre-funded warrants, and concurrent private placement of common stock warrants. In the absence of significant revenues in 2024 and 2025, the Company believes that its capital resources are sufficient to fund planned operations into the fourth quarter of 2025.

Accordingly, we will require additional capital to continue to execute our strategy. We anticipate raising this additional capital through various avenues including sales of equity securities, debt transactions, licensing agreements and collaborative arrangements. Although management believes that such funding sources will be available, there can be no assurance that any such arrangements will be consummated to provide sufficient capital when needed to allow us to continue our operations, or if available, on terms acceptable to us. If we do not raise sufficient funds in a timely manner, among other things, we may be forced to delay, scale back or eliminate some or all our research and product development programs and/or our capital expenditures or to enter into arrangements on unfavorable terms. We currently do not have commitments for future funding from any source.

Our Strategy

The Company has a unique strategy designed to reduce risk and increase the frequency of cash flow. The first part of the strategy is to generate revenues through strategic relationships with biopharma companies. These relationships will be structured as a combination of fees and intellectual property based on the specific scope of the engagement. The objective of these engagements will be to uncover valuable insights to reduce the risk and/or increase the speed of the drug development process which can be achieved through manual or automated integration into the client's workflow or analysis of discrete data sets.

In the future, the second part of our strategy involves acquiring the rights to drugs at various stages of development, using our proprietary AI/ML technology to advance the development and make discoveries, with the objective of creating near term value and then exiting and monetizing as quickly as possible, preferably within approximately 30 months.

Critical Accounting Policies and Estimates

Our financial statements are prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, as well as related disclosures. We evaluate our estimates and assumptions on an ongoing basis. Our estimates are based on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Our actual results could differ from these estimates. There have been no material changes to our critical accounting policies and estimates as those described in our Form 10-K for the fiscal year ended December 31, 2023.

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Financial Operations Overview

Revenue

While we generated our first revenues in late 2022 from our services provided to a pharmaceutical customer, we completed our first commercial service contract and recognized revenue in the amount of \$65,000 in the third quarter of 2023. We did not generate any revenue during the nine months ended September 30, 2024.

Research and Development Costs and Expenses

Research and development expenses consist primarily of costs related to the acquisition of licensed technology, annual minimum royalty fees payable until commercialization, fees paid to external service providers and internal costs for personnel working on research and development activities, including work on our proprietary platform which utilizes bLEAP™ and an ensemble of AI/ML tools and models.

Research and development costs are expensed as incurred. Estimates are used in determining the expense liability of certain costs where services have been performed but not yet invoiced.

We anticipate our research and development costs continuing to increase as we execute on our business plan and begin conducting preclinical research and development activities directed at securing development partners and filing an Investigational New Drug application for our licensed drug development programs described in this filing, as well as under strategic partnerships and for other drug development programs we may pursue. Further, we anticipate our research and development costs will increase as we add additional staff and perform analytical work aimed at target discovery on proprietary data sets through our partnering efforts as well as with prospective customers.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel related costs, including non-cash stock-based compensation, as well as accounting and consulting services, insurance expense, and legal fees relating to corporate matters. We anticipate that our general and administrative expenses will increase in the future to support our target discovery efforts, service offerings, and clinical and pre-clinical research and development activities associated with strategic partnering and collaborations.

Results of Operations - Comparison of Three Months Ended September 30, 2024 and 2023

	September 30,		Net Change
	2024	2023	
Operating expenses:			
Research and development	\$ 566,584	\$ 380,015	\$ 186,569
General and administrative	1,253,357	983,929	269,428
Total operating expenses	<u>\$ 1,819,941</u>	<u>\$ 1,363,944</u>	<u>\$ 455,997</u>

Research and Development

Our research and development expenses for the three months ended September 30, 2024 increased, compared to the same period ended September 30, 2023, primarily due to increased personnel costs related to the hiring of several additional technical staff as well as our Chief Science Officer. In addition, in the first quarter of 2024, we engaged disease experts as area consultants, we expanded our target discovery efforts, and we also initiated a preclinical obesity study related to siRNA program. We expect our R&D expenses to increase as we begin the validation process on potential targets identified in our target discovery program.

General and Administrative

Our general and administrative expenses for the three months ended September 30, 2024 increased, compared to the same period ended September 30, 2023, primarily due to increased personnel costs related to the hiring of several additional staff, as well as associated increases in equity compensation costs and recruiting fees as we work to expand our technical staff and capabilities.

Other Income (Expense), Net

Interest income generated from cash held in an overnight sweep account increased by \$4,531 for the three months ended September 30, 2024, compared to the same period ended September 30, 2023.

Results of Operations - Comparison of Nine Months Ended September 30, 2024 and 2023

	September 30,		Net Change
	2024	2023	
Operating expenses:			
Research and development	\$ 1,632,409	\$ 1,023,619	\$ 608,790
General and administrative	3,835,213	3,067,940	767,273
Total operating expenses	<u>\$ 5,467,622</u>	<u>\$ 4,091,559</u>	<u>\$ 1,376,063</u>

Research and Development

Our research and development expenses for the nine months ended September 30, 2024 increased, compared to the same period ended September 30, 2023, primarily due to increased personnel costs related to the hiring of several additional technical staff as well as our Chief Science Officer. In addition, in the first quarter of 2024, we engaged disease experts as area consultants, we expanded our target discovery efforts, and we also initiated a preclinical obesity study related to siRNA program. We expect our R&D expenses to increase as we begin the validation process on potential targets identified in our target discovery program.

General and Administrative

Our general and administrative expenses for the nine months ended September 30, 2024 increased, compared to the same period ended September 30, 2023, primarily due to increased personnel costs related to the hiring of several additional staff, as well as associated increases in equity compensation costs and recruiting fees as we work to expand our technical staff and capabilities.

Other Income (Expense), Net

Interest expense decreased \$60,730 for the nine months ended September 30, 2024, compared to the same period ended September 30, 2023, due to the majority of our debt converting or being paid off in the first quarter of 2023. Interest income generated from cash held in an overnight sweep account increased by \$62,193 for the nine months ended September 30, 2024, compared to the same period ended September 30, 2023, due to an increase in our average cash balances.

Results of Operations

Liquidity and Capital Resources

In 2022, the Company received net proceeds from the sale of Convertible Bridge Notes of approximately \$1,016,000 and repaid unsecured promissory notes sold in 2021 in the amount of \$49,000. The Company sold one additional promissory note and received net proceeds of \$100,000 in January 2023.

Through September 30, 2024, the Company has an accumulated deficit of approximately \$15.1 million and has funded its operations through the sale of common stock and debt. We anticipate that our expenses will increase in the future to support our target discovery activities, service offerings, clinical and pre-clinical research and development activities associated with strategic partnering and collaborations, as well as acquired product candidates and the increased costs of operating as a public company.

The Company's current entities include Bullfrog AI, Inc. and Bullfrog Management, LLC, which are wholly owned subsidiaries of Bullfrog AI Holdings, Inc., which is a holding company that depends upon the sale of its securities and cash generated through its subsidiaries to fund consolidated operations.

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On February 16, 2023, the Company completed its IPO of 1,297,318 units (each, a "Unit," collectively, the "Units") at a price of \$6.50 per unit for a total of approximately \$8.4 million of gross proceeds to the Company. Each Unit consists of one share of the Company's common stock, one tradeable warrant (each, a "Tradeable Warrant," collectively, the "Tradeable Warrants") to purchase one share of common stock at an exercise price of \$7.80 per share, and one non-tradeable warrant (each, a "Non-tradeable Warrant," collectively, the "Non-tradeable Warrants"; together with the Tradeable Warrants, each, a "Warrant," collectively, the "Warrants") to purchase one share of the Company's common stock at an exercise price of \$8.125. In connection with the IPO, the Company also completed a 1-for-7 reverse stock split of our common stock.

In connection with the IPO, a SAFE and convertible loan agreement held by a related party converted into 55,787 shares of common stock. Additionally, all outstanding convertible bridge notes and accrued interest through November 30, 2022 were converted into 276,289 shares of common stock and 276,289 warrants to purchase common stock and were issued to the Convertible Bridge Note holders at conversion. The convertible bridge note conversions and the warrant exercise pricing were determined using a \$25 million company valuation immediately before the IPO.

In April 2023, the holders of warrants exercised 436,533 warrants for common stock at various exercise prices and the Company received proceeds of approximately \$1,495,000.

In February 2024, we completed an underwritten secondary offering of common stock and warrants generating approximately \$5.7 million of net proceeds.

In the first quarter of 2024, holders exercised warrants (including prefunded warrants from the secondary offering) to purchase 508,814 shares of common stock generating proceeds of approximately \$106,000.

In October 2024, we completed a registered direct offering of common stock and pre-funded warrants, and concurrent private placement of common stock warrants generating approximately \$2.7 million of net proceeds.

In the absence of significant revenues in 2024 and 2025, management believes the Company's capital resources are sufficient to fund planned operations into the fourth quarter of 2025. Accordingly, we will seek additional capital to continue to execute our strategy as discussed above.

Consolidated Cash Flow Data

	Nine Months Ended September 30,		Change
	2024	2023	
Net cash (used in) provided by			
Operating activities	\$ (4,338,214)	\$ (4,983,282)	\$ 645,068
Investing activities	-	-	-
Financing activities	5,952,472	8,781,649	(2,829,177)
Net increase in cash and cash equivalents	\$ 1,614,258	\$ 3,798,367	\$ (2,184,109)

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Cash Flows Used in Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2024 decreased compared to the same period ended September 30, 2023 primarily due to paying down payables and accrued expenses for technology access, consultants, and compensation in 2023, partially offset by increased operating costs in 2024.

Cash Flows Used in Investing Activities

There was no cash used in investing activities during the nine months ended September 30, 2024 or 2023.

Cash Flows Provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2024 decreased compared to the same period ended September 30, 2023 primarily due to proceeds from our Initial Public Offering in February 2023 exceeding the proceeds from our secondary offering in February 2024.

Results of Operations

For the years ended December 31, 2023 and 2022

Revenue and Costs of Goods Sold

We recognized \$65,000 and \$10,000 in revenue and \$5,200 and \$800 in costs of goods sold during the years ended December 31, 2023 and 2022, respectively.

	Year ended December 31,		Net Change
	2023	2022	
Operating expenses:			
Research and development	\$ 1,432,614	\$ 609,270	\$ 823,344
General and administrative	3,994,710	1,855,731	2,138,979
Total operating expenses	\$ 5,427,324	\$ 2,465,001	\$ 2,962,323

Research and Development

Our research and development expenses for the year ended December 31, 2023 increased by \$823,344 compared to the same period ended December 31, 2022, primarily due to the inclusion of the cost of salaries and consulting fees in 2023 as we initiated our collaboration with J Craig Venter Institute and completion of a preclinical study for our Mebendazole prodrug program, as well as the cost of acquiring access to additional technology from JHU-APL related to bFLEAP™ pursuant to Amendment 1 of the July 2022 License Agreement. In 2022, the majority of the research and development expenses were directly related to the acquisition of two drug development product candidates including Mebendazole.

General and Administrative

Our general and administrative expenses for the year ended December 31, 2023 increased by \$2,138,979, compared to the same period ended December 31, 2022, primarily due to higher salary and consulting costs reflecting an increased level of service as well the initiation of investor relations and marketing efforts and the transition of our accounting and financial reporting process to support a public company. The 2023 period also reflects approximately \$120,000 in recruiting fees related to staff additions.

Other Income (Expense), Net

Interest expense decreased \$268,056 for the year ended December 31, 2023, compared to the same period ended December 31, 2022 due to the majority of our debt converting or being paid off in the first quarter of 2023. The loss on the conversion of notes of \$92,959 for the year ended December 31, 2023 was due to the conversion of the convertible notes. Other income increased by \$183,244 due to interest earned on our IPO proceeds which we hold in an overnight sweep account.

Liquidity and Capital Resources

In 2022, the Company received net proceeds from the sale of Convertible Bridge Notes of approximately \$1,016,000 and repaid the unsecured promissory notes sold in 2021 in the amount of \$49,000. The Company sold one additional promissory note and received net proceeds of \$100,000 in January 2023.

For the year ended December 31, 2022, the Company used approximately \$911,000 on operating activities versus approximately \$382,000 for the same period in 2021. The 2022 cash use included approximately \$548,000 in salaries, approximately \$634,000 in consulting and professional fees including legal, accounting and auditing fees, as well as consulting fees for operational activities and approximately \$609,000 in technology license fees, patent cost reimbursements and minimum annual royalties which has been recorded as a research & development expense.

Through December 31, 2023, the Company has an accumulated deficit of approximately \$9,755,000 and funded its operations through the sale of common stock and debt. We anticipate that our expenses will increase in the future to support our service offerings, clinical and pre-clinical research and development activities associated with strategic partnering and collaborations, as well as acquired product candidates and the increased costs of operating as a public company. These increases could include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company including expenses related to services associated with maintaining compliance with exchange listing and Securities and Exchange Commission requirements, insurance, and investor relations costs.

The Company's current operations include BullFrog AI, Inc. and BullFrog Management, LLC, which are wholly owned subsidiaries of BullFrog AI Holdings, Inc., which is a holding company that depends upon the sale of its securities and cash generated through its subsidiaries to fund consolidated operations.

On February 16, 2023, the Company completed its IPO of 1,297,318 units (each, a "Unit," collectively, the "Units") at a price of \$6.50 per unit for a total of approximately \$8.4 million of gross proceeds to the Company. Each Unit consists of one share of the Company's common stock, one tradeable warrant (each, a "Tradeable Warrant," collectively, the "Tradeable Warrants") to purchase one share of common stock at an exercise price of \$7.80 per share, and one non-tradeable warrant (each, a "Non-tradeable Warrant," collectively, the "Non-tradeable Warrants"; together with the Tradeable Warrants, each, a "Warrant," collectively, the "Warrants") to purchase one share of the Company's common stock at an exercise price of \$8.125. In connection with the IPO, the Company also completed a 1-for-7 reverse stock split of our common stock.

In connection with the IPO, a SAFE and convertible loan agreement held by a related party converted into 55,787 shares of post reverse split common stock. Additionally, all outstanding convertible bridge notes and accrued interest through November 30, 2022 were converted into 276,289 shares of common stock and 276,289 warrants to purchase common stock were issued to the Convertible Bridge Note holders at conversion. The convertible bridge note conversions and the warrant exercise pricing were determined using a \$25 million dollar company valuation immediately before the IPO.

Between April 5 and April 13, 2023, the holders of warrants exercised 436,533 warrants for common stock at various exercise prices and the Company received proceeds of approximately \$1,495,000.

In the absence of revenues in 2024 management believes the company's capital resources are sufficient to fund planned operations for substantially longer than 12 months from the date of this filing.

Consolidated Cash Flow Data

	Year ended December 31,		Net Change
	2023	2022	
Net cash (used in) provided by			
Research and development Operating activities	\$ (6,001,299)	\$ (910,890)	\$ (5,090,409)
General and administrative Investing activities	-	(8,744)	8,744
Financing activities	8,568,359	967,290	7,601,069
Net increase in cash and cash equivalents	<u>\$ 2,567,060</u>	<u>\$ 47,656</u>	<u>\$ 2,519,404</u>

Cash Flows Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2023 increased by \$5,090,409 compared to the same period ended December 31, 2022 primarily due to paying down accrued expenses for technology access, consultants, and compensation in 2023, coupled with increased operating costs, including D&O insurance premiums.

Cash Flows Used in Investing Activities

There was no cash used in investing activities during the year ended December 31, 2023.

Net cash provided by financing activities for the year ended December 31, 2023 increased by \$7,601,069, compared to the same period ended December 31, 2022 primarily due to the completion of our Initial Public Offering in February 2023 and proceeds received pursuant to warrant exercises.

Critical Accounting Policies

In Footnote 2 of our Audited Financial Statements for the year ended December 31, 2023 found elsewhere in this filing, we included a discussion of the most critical accounting policies used in the preparation of our financial statements. There has been no material change in the policies and estimates used in the preparation of our financial statements since the completion of the 2023 audit.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements, as such term is defined in Item 303(a)(4) of Regulation S-K.

Financial Operations Overview

Revenue

While we generated our first revenues in late 2022 from our services provided to a pharmaceutical customer, in the third quarter of 2023 we completed our first commercial service contract and recognized revenue in the amount of \$65,000. We have service contracts with two organizations and currently have multiple discussions underway, although there can be no assurance of entering into additional service agreements and business relationships in 2024.

Operating Expenses

We classify our operating expenses into two categories: research and development and general and administrative. Prior to 2022, most of our activities were related to: technology evaluation, acquisition and validation, capital acquisition and business development activities in general, which we believe have readied the Company for contract services while exploring strategic partnering and asset acquisition. These activities and related expenditures have been recorded and reported as General and Administrative in our Financial Statements. In 2022, we licensed two drug development programs from universities and also entered into a new license with JHU-APL for new IP and other enhancements used with our bfLEAP™ platform. In 2022, we expended appropriately \$608,000 on license related payments for our bfLEAP™ AI/ML platform and our two drug development programs from universities. We expect that our research and development expenses will increase in 2024 as we initiate activities directed towards the development of service offering products, collaborations (JCVI) and preclinical studies aimed at generating the data to enable the filing of an Investigational New Drug (IND) application.

Research and Development Costs and Expenses

Research and development costs and expenses in 2022 consisted primarily of costs related to the acquisition of licensed technology. In 2023 we have initiated development activities on our licensed drug candidates and our discovery collaboration with JCVI. In addition to fees paid to external service providers, we are also allocating internal costs for personnel working on these efforts in addition to personnel costs related to our internal efforts to develop our product and service offerings using bfLEAP™. We anticipate our research and development costs could become significant as we execute on our business plan and begin conducting preclinical research and development activities directed at securing development partners and filing an IND for our licensed drug development programs described in this filing, as well as under strategic partnerships and for other drug development programs we may acquire. Research and development expenses are recorded in operating expenses in the period in which they are incurred. Estimates will be used in determining the expense liability of certain costs where services have been performed but not yet invoiced. We will monitor levels of performance under each significant contract for external services through communications with the service providers to reflect the actual amount expended.

General and Administrative Expenses

In anticipation of the IPO, a management team with deep industry experience was identified and engaged as employees and consultants to assist the Company in preparing for the IPO and subsequently, to operate and function as a public company. Through 2022, the primary activities included: technology evaluation, acquisition, and validation, capital acquisition and business development activities which in general, have readied the Company for contract services while exploring strategic partnering and asset acquisition as noted above. In February 2023, the Company achieved its objective of completing an IPO and listing on NASDAQ. Our 2023 general and administrative expenses are significantly higher than our 2022 general and administrative expenses due to several factors. The primary increases in 2023 relate to new costs associated with being a public company such as D&O insurance, professional services engaged to support SEC compliance as well as higher salary and consulting expenses as we have hired additional staff and consultants. We have also increased our business development, investor relations and marketing efforts. We anticipate that our general and administrative expenses may increase in the future to support our service offerings, clinical and pre-clinical research and development activities associated with strategic partnering and collaborations.

Emerging Growth Company Status

We are an “emerging-growth company”, as defined in the JOBS Act, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies, including, but not limited to, not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As an emerging growth company we can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We intend to avail ourselves of these options. Once adopted, we must continue to report on that basis until we no longer qualify as an emerging growth company.

We will cease to be an emerging growth company upon the earliest of: (i) the end of the fiscal year following the fifth anniversary of the initial public offering; (ii) the first fiscal year after our annual gross revenue are \$1.235 billion or more; (iii) the date on which we have, during the previous three-year period, issued more than \$1.0 billion in non-convertible debt securities; or (iv) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded \$700 million as of the end of the second quarter of that fiscal year. We cannot predict if investors will find our Common Stock less attractive if we choose to rely on these exemptions. If, as a result of our decision to reduce future disclosure, investors find our common shares less attractive, there may be a less active trading market for our common shares and the price of our common shares may be more volatile.

We are also a “smaller reporting company”, meaning that the market value of our stock held by non-affiliates plus the aggregate amount of gross proceeds to us as a result of the IPO is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the

most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation

MANAGEMENT

The following table lists the executive officers and directors of the Company:

Name	Age	Position(s)
Executive Officers:		
Vin Singh	55	Chief Executive Officer and Chair of the Board of Directors
Dane Saglio	66	Chief Financial Officer
Non-Executive Directors:		
R. Donald Elsey	70	Director and Chair of Audit Committee
William Enright	61	Director and Chair of Compensation Committee
Jason D. Hanson	55	Director and Chair of Nominating and Corporate Governance Committee

Vininder (Vin) Singh is the Founder, Chairman, and CEO of Bullfrog AI Holdings, Inc. since its inception in August 2017. Over the past five years, he has built the Company from scratch and during that time he led strategy, built a highly experienced team of leaders, spear headed the acquisition and development of Bullfrog's core AI technology and drug assets, secured the first revenue, and raised approximately \$2M in financing prior to the Company's IPO in February 2023. In February of 2020, he formed Bullfrog AI Holdings, Inc., and Bullfrog AI Inc. became a wholly owned subsidiary designated as the holder of core intellectual property. Vin is a serial entrepreneur and experienced executive with 25 years of experience in the life sciences and biotechnology industries. He has extensive start-up experience having founded and built several pioneering investor-backed companies including Bullfrog AI, which uses machine learning/AI to enable drug development, Next Healthcare Inc., a personalized diagnostics and adult cell banking service, and MaxCyte Inc. (NASDAQ: MXCT), a cell therapy company. He was also an executive at GlobalStem Inc. and ThermoFisher Scientific, leading their global cell therapy services business. Vin has a B.S. in Electrical Engineering from Rutgers University, an M.S. in Biomedical Engineering from Rensselaer Polytechnic Institute, and an M.B.A. from Johns Hopkins University. We believe that Mr. Singh is qualified to serve as a member of our board of directors due to the perspective and experience that he brings as our Founder and Chief Executive Officer, his extensive experience in the science and biotechnology industries and in the management of startup companies.

Dane Saglio, joined Bullfrog Holdings AI, Inc. as Chief Financial Officer in September 2021. Mr. Saglio brings more than 40 years of financial management experience in both public and private companies across a number of business sectors. Previously, Mr. Saglio has served as CFO at Seneca Biopharma, RegeneRx Biopharmaceuticals since 2011, New Generation Biofuels 2010 until 2011, and EntreMed from 2000 until 2008, all public companies in the biotechnology arena. Prior to joining the Company, Mr. Saglio was the CFO of Seneca Biopharma, initially as a consultant in August 2019 and then as an employee in April 2020 until the Company merged with Leading Bio Sciences, forming Palisades Bio, Inc. in April 2021. He previously served as CFO at Celios Corporation from October 2017 until July 2019 and Helomics Corporation, a personalized medicine company in cancer from October 2014 through July 2017. He began his career at Informatics Corp, now Computer Associates International and then at Bressler & Reiner, a DC-based real estate developer and homebuilder. Dane has a B.S. from the University of Maryland and is a licensed CPA in Maryland (inactive).

R. Donald Elsey has been a director and chair of the Audit Committee of our board since February 14, 2023. Mr. Elsey was the CFO of Lyra until his retirement in December 2020. Previously, from February 2015 to February 2019, Mr. Elsey served as Chief Financial Officer at Senseonics, Inc., a medical device company. From May 2014 until February 2015, Mr. Elsey served as Chief Financial Officer of Regado Biosciences, Inc., a biopharmaceutical company. From December 2012 to February 2014, Mr. Elsey served as Chief Financial Officer of LifeCell Corporation, a privately held regenerative medicine company. Mr. Elsey holds a B.A. in economics and an M.B.A. in finance from Michigan State University. We believe that Mr. Elsey is qualified to serve as a member of our board of directors because of his extensive professional experience in science and biotechnology companies.

William "Bill" Enright has been a director and chair of the Compensation Committee of our board since February 14, 2023. He is a seasoned biotech executive with more than thirty-four years of experience in building and financing both privately held and publicly held companies and he is currently the CEO and a Director of Barinthus Biotherapeutics plc (NASDAQ: BRNS), which he helped to take public in April 2021. Prior to Barinthus, Bill spent more than ten years at Altimimmune (NASDAQ: ALT) as a Director, President & CEO, moving multiple programs into clinical testing, completing several acquisitions, and eventually taking the company public. Prior to joining Altimimmune, Bill spent six years with GenVec, Inc. (acquired by Precigen) with increasing responsibilities, culminating as Head of Business Development. Bill brings a breadth of experiences in a variety of positions within the life science/biotech industry, including time as a consultant, a bench scientist and 12 years with Life Technologies, Inc. (acquired by Thermo-Fisher), working in various senior level licensing, business management, manufacturing and research roles. Bill received a Master of Arts in Molecular Biology from SUNY at Buffalo and a Master of Science in Business Management from Johns Hopkins University. We believe that Mr. Enright is qualified to serve as a member of our board of directors because of his extensive professional experience in life science/biotech companies and in the management of public companies.

Jason D. Hanson has served as a director and chair of the Nominating and Corporate Governance Committee since February 14, 2023. Mr. Hanson served as Chief Executive Officer and as a Director of enGene Inc. from July 2018 to July 2024. He also served as President of enGene Inc. from July 2018 to December 2022. Mr. Hanson effectively re-launched enGene from a small private company working in the GI discovery space into a clinical stage gene therapy oncology company trading on Nasdaq, implementing a new scientific, technical and strategic vision for the Company. From August 2016 to November 2017, Mr. Hanson served as President and Chief Executive Officer of Ohana Biosciences, a biotechnology company based in Cambridge, MA, and as member of the Ohana Board of Directors and consultant to Ohana from November 2017 to June 2018. Mr. Hanson previously served as Executive Vice President and Chief Strategy Officer for NuVasive, Inc. from November 2015 to August 2016. Mr. Hanson served as Corporate Vice President of General Electric Company and member of the senior executive team of GE Healthcare, a global pharmaceutical, medical device and healthcare services business from May 2014 to October 2015. In January 2013, Mr. Hanson served as Company Group Chairman and Executive Vice President of Valeant Pharmaceuticals International, Inc. (now Bausch Health Companies Inc.). Previously, he served in various roles at Medicis Pharmaceutical Corporation, including as Executive Vice President and Chief Operating Officer between July 2006 and December 2012. Mr. Hanson also served in numerous roles at GE Healthcare, including General Counsel roles, from April 1999 to July 2006. Mr. Hanson holds a B.S. from Cornell University and a J.D. from Duke University School of Law.

Family Relationships

There are no family relationships among our executive officers and directors.

Involvement in Certain Legal Proceedings

During the past ten years, none of our directors, executive officers, promoters, control persons, or nominees has been:

- the subject of any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
- convicted in a criminal proceeding or is subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
- subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or any Federal or State authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities;
- found by a court of competent jurisdiction (in a civil action), the Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law;

- the subject of, or a party to, any Federal or State judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of (a) any Federal or State securities or commodities law or regulation; (b) any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order; or (c) any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or
- the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act (15 U.S.C. 78c(a)(26))), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act (7 U.S.C. 1(a)(29))), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Board of Directors Diversity

Our Board seeks members from diverse professional backgrounds who combine a solid professional reputation and knowledge of our business and industry with a reputation for integrity. Our Board does not have a formal policy concerning diversity and inclusion but is in the process of establishing a policy on diversity. Diversity of experience, expertise, and viewpoints is one of many factors the Nominating and Corporate Governance Committee considers when recommending director nominees to our Board. Further, our Board is committed to actively seeking highly qualified women and individuals from minority groups and the LGBTQ+ community to include in the pool from which new candidates are selected. Our Board also seeks members that have experience in positions with a high degree of responsibility or are, or have been, leaders in the companies or institutions with which they are, or were, affiliated, but may seek other members with different backgrounds, based upon the contributions they can make to our Company. While the Board has continued its efforts to identify candidates that have such experience, they have currently been unable to identify any such candidates which fulfill the diversity requirement with the requisite professional experience.

The table below provides certain information regarding the diversity of our board of directors as the date of this prospectus:

Board Diversity Matrix <i>(As of November 4, 2024)</i>				
Total Number of Directors	#			
	Female	Male	Non-binary	Did not disclose Gender
Part I: Gender Identity				
Directors	0	4	0	0
Part II: Demographic Background				
African American or Black				
Alaskan Native or Native American				
Asian		1		
Hispanic or Latinx				
Native Hawaiian or Pacific Islander				
White		3		
Two or More Races or Ethnicities				
LGBTQ+			0	
Did not Disclose Demographic Background			N/A	

Director Independence

Messrs. Eley, Enright and Hanson, three members of our Board of Directors, are independent using the definition of independence under Nasdaq Listing Rule 5605(a)(2) and the standards established by the SEC.

Board Leadership Structure

The Board does not have a policy regarding the separation of the roles of the Chief Executive Officer and Chair of the Board, as the Board believes it is in the best interest of the Company and its stockholders to make that determination based on the position and direction of the Company and the membership of the Board, from time to time. Currently, Mr. Singh serves as both the Chief Executive Officer and as Chair of the Board. At this time, the Board believes that these combined roles are beneficial to both the daily operations of the Company and the strategic perspective of the Board.

Committees of our Board

Audit Committee

Our audit committee consists of R. Donald Eley, William Enright and Jason D. Hanson, with Mr. Eley serving as chair. Our board of directors has affirmatively determined that each meets the definition of “independent director” under the rules of The Nasdaq Capital Market, and that they meet the independence standards under Rule 10A-3. Each member of our audit committee meets the financial literacy requirements of Nasdaq rules, and qualifies as a financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the pertinent listing standards of Nasdaq, as in effect from time to time. In making this determination, our board of directors has considered the members’ formal education and previous and current experience in financial roles. Our board of directors has adopted a written charter for the audit committee, which can be found on our website at <https://ir.bullfrogai.com/corporate-governance/governance-documents>.

The audit committee is appointed by the board of directors to assist the board of directors in its duty to oversee the Company’s accounting, financial reporting, and

internal control functions and the audit of the Company's financial statements. The role of the audit committee is to oversee management in the performance of its responsibility for the integrity of the Company's accounting and financial reporting and its systems of internal controls, the performance and qualifications of the Company's independent auditor, including the independent auditor's independence, the performance of the Company's internal audit function; and the Company's compliance with legal and regulatory requirements.

Compensation Committee

Our compensation committee consists of William Enright, R. Donald Elsey and Jason D. Hanson, with Mr. Enright serving as chair. Our board of directors has adopted a written charter for the compensation committee, which can be found on our website at <https://ir.bullfrogai.com/corporate-governance/governance-documents>.

The compensation committee is responsible for reviewing and recommending, among other things:

- the adequacy and form of compensation of the board;
- the compensation of Chief Executive Officer, including base salary, incentive bonus, stock options and other grants, awards and benefits upon hiring and on an annual basis;
- the compensation of other senior management upon hiring and on an annual basis; and
- the Company's incentive compensation and other equity-based plans and recommending changes to such plans to our board of directors, when necessary.

Nominating & Corporate Governance Committee

Our nominating and corporate governance committee consists of Jason D. Hanson, William Enright and R. Donald Elsey, with Mr. Hanson serving as chair. Our board of directors has adopted a written charter for the nominating and corporate governance committee, which can be found on our website at <https://ir.bullfrogai.com/corporate-governance/governance-documents>.

The nominating committee is responsible for, among other things:

- developing criteria for membership on the board of directors and committees;

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- identifying individuals qualified to become members of the board of directors;
- recommending persons to be nominated for election as directors and to each committee of the board of directors;
- annually reviewing our corporate governance guidelines; and
- monitoring and evaluating the performance of the board of directors and leading the board in an annual self-assessment of its practices and effectiveness.

Term of office

All directors hold office until the next annual meeting of the stockholders of the company and until their successors have been duly elected and qualified. Officers are elected by and serve at the discretion of our Board.

Role of Board of Directors in Risk Oversight Process

The board of directors has extensive involvement in the oversight of risk management related to us and our business and accomplishes this oversight through the regular reporting by the Audit Committee. We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

We conduct periodic risk assessments to identify cybersecurity threats, as well as assessments in the event of a material change in our business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.

Following these risk assessments, we re-design, implement, and maintain reasonable safeguards to minimize identified risks; reasonably address any identified gaps in existing safeguards; and regularly monitor the effectiveness of our safeguards. Primary responsibility for assessing, monitoring and managing our cybersecurity risks rests with our Chief Information Officer who reports to our Chief Commercial Officer, to manage the risk assessment and mitigation process.

We engage consultants, or other third parties in connection with our risk assessment processes. These service providers assist us to design and implement our cybersecurity policies and procedures, as well as to monitor and test our safeguards. We require each third-party service provider to certify that it has the ability to implement and maintain appropriate security measures, consistent with all applicable laws, to implement and maintain reasonable security measures in connection with their work with us, and to promptly report any suspected breach of its security measures that may affect our company.

We have not encountered cybersecurity challenges that have materially impaired our operations or financial standing.

Governance

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The board of directors' audit committee is responsible for overseeing Company's cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including the information technology team at the direction of our Chief Information Officer. Our executive team including our Chief Executive Officer, and Chief Financial Officer are responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel. This executive team is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

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Our cybersecurity incident response and vulnerability management policies are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including our Chief Executive Officer, and Chief Financial Officer. In addition, the Company's incident response and vulnerability management policies include reporting to the audit committee of the board of directors for certain cybersecurity incidents including significant breaches to the Company's networks or systems. The audit committee receives regular reports from the information technology team concerning the Company's significant cybersecurity threats and risk

and the processes the Company has implemented to address them. The audit committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, employees or persons performing similar functions. Our code of ethics can be found at <https://ir.bullfrogai.com/corporate-governance/governance-documents>.

Clawback Policy

On December 1, 2023, the Board adopted the BullFrog AI Clawback Policy (the “Clawback Policy”), effective December 1, 2023, providing for the recovery of certain incentive-based compensation from current and former executive officers of the Company in the event the Company is required to restate any of its financial statements filed with the SEC under the Exchange Act in order to correct an error that is material to the previously-issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period. Adoption of the Clawback Policy was mandated by new Nasdaq listing standards introduced pursuant to Exchange Act Rule 10D-1. The Clawback Policy is in addition to Section 304 of the Sarbanes-Oxley Act of 2002 which permits the SEC to order the disgorgement of bonuses and incentive-based compensation earned by a registrant issuer’s chief executive officer and chief financial officer in the year following the filing of any financial statement that the issuer is required to restate because of misconduct, and the reimbursement of those funds to the issuer. A copy of the Clawback Policy has been filed herewith, and can also be found at www.bullfrogai.com.

Insider Trading Policies

We have adopted an insider trading policy governing the purchase, sale, and other dispositions of our securities by directors, senior management, and employees.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information as of November 4, 2024, with respect to the beneficial ownership of our common stock, the sole outstanding class of our voting securities, by:

- each of our named executive officers;
- each of our directors;
- all of our current directors and named executive officers as a group; and
- each stockholder known by us to own beneficially more than 5% of our common stock.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Shares of common stock that may be acquired by an individual or group within 60 days of November 4, 2024, pursuant to the exercise of options or warrants, vesting of common stock or conversion of convertible debt, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Percentage of ownership is based on 8,713,152 shares of Common Stock issued and outstanding as of November 4, 2024.

Except as otherwise indicated, all shares are owned directly. Unless otherwise indicated, the address of each of the persons shown is c/o Bullfrog AI Holdings, Inc., 325 Ellington Blvd., Unit 317, Gaithersburg, MD 20878.

Title of Class	Name and Address of Beneficial Owners	Amount and Nature of Beneficial Ownership	Percent of Class
	Directors and Executive Officers		
Common Stock	Vininder Singh (1) Chief Executive Officer and Director	2,469,306	28.25%
Common Stock	Dane Saglio (2) Chief Financial Officer	127,634	1.45%
Common Stock	R. Donald Elsey (3) Director	31,109	*%
Common Stock	William Enright (4) Director	31,109	*%
Common Stock	Jason D. Hanson (5) Director	31,109	*%
	All executive officers and directors as a group (5 persons)	2,690,267	30.22%
	Beneficial owners of more than 5%		
Common Stock	Tivoli Trust (6)	904,391	9.46%

* Represents a percentage that is less than 1%.

(1) Comprised of 2,442,446 shares of Common Stock and 26,860 Stock Options exercisable within 60 days.

(2) Comprised of 47,142 shares of Common Stock and 80,492 Stock Options exercisable within 60 days.

(3) Comprised of 0 shares of Common Stock and 31,109 Stock Options exercisable within 60 days.

(4) Comprised of 0 shares of Common Stock and 31,109 Stock Options exercisable within 60 days.

(5) Comprised of 0 shares of Common Stock and 31,109 Stock Options exercisable within 60 days.

(6) Comprised of 73,449 shares of non-voting Series A Preferred Stock, 115,185 warrants exercisable at \$2.50 per share and 54,714 shares of Common Stock. Assumes the conversion of all Series A Preferred Stock into common stock in an amount equal to ten shares of common stock for each one share of Series A Preferred Stock.

DIRECTOR AND EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth all plan and non-plan compensation for the last two fiscal years paid to individuals who served as the Company’s principal executive officers and the Company’s two other most highly compensated executive officers serving as executive officers at the end of the last completed fiscal year, as required by Item 402(m)(2) of Regulation S-K of the Securities Act. We refer to these individuals collectively as our “named executive officers.”

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards	All Other Compensation	Nonequity Incentive Plan Compensation	Nonqualified Deferred Compensation Earnings	Total Compensation
Vininder Singh	2023	\$ 707,666(1)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 707,666
<i>Chief Executive Officer and Director</i>	2022	\$ 179,000(2)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 179,000
Dane Saglio	2023	\$ 310,000(3)	\$ 50,000	\$ -	\$ 147,000	\$ -	\$ -	\$ -	\$ 507,000
<i>Chief Financial Officer</i>	2022	\$ 30,000	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 30,000

- (1) Comprised of \$380,000 related to Mr. Singh's 2023 salary, and salary amounts of \$240,000 and \$87,666 deferred in 2022 and years prior to 2022, respectively, and paid in 2023.
- (2) Comprised of Mr. Singh's salary amounts of \$179,000 deferred in years prior to 2022 and paid in 2022.
- (3) Comprised of \$220,000 related to Mr. Saglio's 2023 consulting fees, and consulting fees of \$90,000 deferred in 2022 and paid in 2023.

Narrative Disclosure to Summary Compensation Table

Employment Agreements

On May 16, 2022, we entered into an employment agreement with Vininder Singh, pursuant to which he will receive an annual base salary of \$400,000, which is subject to bi-annual review by the Company. Mr. Singh will also be eligible for an annual bonus based on the achievement of certain goals and performance criteria established by the Board. Mr. Singh's target annual bonus for the fiscal years ended 2022 through 2025 will be a minimum of twenty (20%) percent of the current base salary, with a maximum payout of up to one-hundred (100%) percent based on target achievement. For 2023, the criteria to determine Mr. Singh's bonus will include the following: (i) the Company achieves \$500,000 in sales; (ii) the filing of an Investigational New Drug (IND) Application with the FDA for mebendazole; (iii) the Company enters into two (2) strategic partnerships; and (iv) the Company commences partner negotiations with a third party for HSV-1, bf-114 or bf-222. Mr. Singh will also be eligible to participate in the Company's stock incentive plan, subject to Board approval. The agreement with Mr. Singh shall continue until either his resignation, termination for cause by the Company, or death or disability of Mr. Singh.

Director Compensation

The following table summarizes the compensation paid to our executive and non-executive directors during the year ended December 31, 2023.

Name	Fees Earned or Paid in Cash (1)	Stock Awards	Option Awards (2)	All Other Compensation	Nonequity Incentive Plan Compensation	Nonqualified Deferred Compensation Earnings	Total Compensation
Vininder Singh ⁽³⁾	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
R. Donald Elsey	\$ 39,375	\$ -	\$ 197,200	\$ -	\$ -	\$ -	\$ 236,575
William Enright	\$ 39,375	\$ -	\$ 197,200	\$ -	\$ -	\$ -	\$ 236,575
Jason D. Hanson	\$ 39,375	\$ -	\$ 197,200	\$ -	\$ -	\$ -	\$ 236,575

- (1) Represents cash compensation for service as a director and as chair of a board committee during the fiscal year 2023.
- (2) Represents annual value of stock options issued during fiscal year 2023 under our 2022 Equity Incentive Plan.
- (3) Mr. Singh did not receive additional compensation for his service as a director of our Company during the fiscal year 2023.

Equity Compensation Plans

On November 30, 2022, our Board of Directors and shareholders adopted the 2022 Equity Incentive Plan (the "Plan"). Pursuant to the Plan, we are authorized to grant options and other equity awards to officers, directors, employees and consultants. The exercise price of each share of common stock purchasable under an award issued pursuant to the Plan, shall be determined by our compensation committee, in its sole discretion, at the time of grant, but shall not be less than 100% of the fair market of such share of common stock on the date the award is granted, subject to adjustment and conditions further described in the Plan. Our compensation committee shall also have sole authority to set the terms of all awards at the time of grant. As of December 31, 2023, there are 441,500 shares available under the Plan.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the outstanding equity awards held by each named executive officer as of December 31, 2023. This table includes unexercised and unvested options and equity awards.

Outstanding Equity Awards as of December 31, 2023						
Option Awards						
Name	Date of Grant	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price (\$)	Option expiration date
Dane Saglio	March 17, 2023	43,750	31,250	-	\$ 2.80	March 17, 2033

Share Reserve. The number of shares of our common stock available for issuance under our 2022 Plan is 900,000 shares. Notwithstanding the number of shares available for issuance, on the first day of each month commencing January 1, 2023, or the first business day of the calendar year if the first day of the calendar year falls on a Saturday or Sunday, the number of shares eligible for awards under the 2022 Plan will automatically increase in an amount equal to 15% of the total number of shares of common stock outstanding as of December 31st of the preceding fiscal year.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (a)
Equity compensation plans approved by security holders	757,500	\$ 4.17	142,500
Equity compensation plans not approved by security holders	747,376	\$ 1.71	-
Total	1,504,876	\$ 2.95	\$ 142,500

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Payments upon Termination or Change-in-Control

The following table reflects amounts payable to our Named Executive Officers (1) assuming their employment was terminated without cause on December 31, 2023, and (2) assuming a change in control on December 31, 2023.

Name	Termination Without Cause ⁽¹⁾	Change in Control
Vininder Singh	\$ 400,000	\$ —

(1) Represents the payment made pursuant to contractual agreements with the Named Executive Officer as described above.

Compensation Committee Interlocks and Insider Participation

The members of the Compensation Committee during the fiscal year ended December 31, 2023 were William Enright, Don Elsey and Jason Hanson. During the fiscal year ended December 31, 2023:

- none of the members of the Compensation Committee was an officer (or former officer) or employee of our Company or any of its subsidiaries;
- none of the members of the Compensation Committee had a direct or indirect material interest in any transaction in which we were a participant and the amount involved exceeded \$120,000;
- none of our executive officers served on the compensation committee (or another board committee with similar functions or, if none, the entire board of directors) of another entity where one of that entity's executive officers served on our Compensation Committee;
- none of our executive officers was a director of another entity where one of that entity's executive officers served on our Compensation Committee; and
- none of our executive officers served on the compensation committee (or another board committee with similar functions or, if none, the entire board of directors) of another entity where one of that entity's executive officers served as a director on our Board.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than as set forth below and compensation arrangements, including employment, and indemnification arrangements, discussed, there have been no transactions since January 1, 2021, in which the amount involved in the transaction exceeded or will exceed the lesser of \$120,000 or one percent of the average of our total assets as at the year-end for the last two completed fiscal years, and to which any of our directors, executive officers or beneficial holders of more than 5% of our capital stock, or any immediate family member of, or person sharing the household with, any of these individuals, had or will have a direct or indirect material interest.

On July 8, 2021, the Company entered into a Simple Agreement for Future Equity (SAFE), with a related party, Tivoli Trust, our second largest shareholder (the "Investor"), in the amount of \$150,000, with 0% interest. Under the SAFE agreement, if there is an Equity Financing before the termination of this SAFE, on the initial closing of such Equity Financing, this SAFE will automatically convert into the number of shares of SAFE Preferred Stock equal to the Purchase Amount divided by the Conversion Price, which means either: (1) the SAFE Price (the price per share equal to the Post-Money Valuation Cap divided by the Company Capitalization) or (2) the Discount Price (the price per share of the Standard Preferred Stock sold in the Equity Financing multiplied by the Discount Rate), whichever calculation results in a greater number of shares of SAFE Preferred Stock.

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If there is a Liquidity Event before the termination of this SAFE, this SAFE will automatically be entitled (subject to the liquidation priority) to receive a portion of Proceeds, due and payable to the Investor immediately prior to, or concurrent with, the consummation of such Liquidity Event, equal to the greater of (i) the Purchase Amount (the "Cash-Out Amount") or (ii) the amount payable on the number of shares of Common Stock equal to the Purchase Amount divided by the Liquidity Price (the "Conversion Amount"). If any of the Company's securityholders are given a choice as to the form and amount of Proceeds to be received in a Liquidity Event, the Investor will be given the same choice, provided that the Investor may not choose to receive a form of consideration that the Investor would be ineligible to receive as a result of the Investor's failure to satisfy any requirement or limitation generally applicable to the Company's securityholders, or under any applicable laws.

This SAFE will automatically terminate (without relieving the Company of any obligations arising from a prior breach of or non-compliance with this SAFE) immediately following the earliest to occur of: (i) the issuance of Capital Stock to the Investor pursuant to the automatic conversion of this SAFE under agreement; or (ii) the payment, or setting aside for payment, of amounts due the Investor pursuant to the agreement.

As of December 31, 2021, the \$150,000 received from SAFE was recorded at 6% imputed interest. The SAFE was converted into 32,967 shares of common stock (post reverse stock split) upon the Company's IPO in February 2023.

On August 19, 2021, the company entered into a convertible loan agreement with a related party, with a principal balance of \$99,900 at 9% interest. The noteholder has the right to convert the principal and interest into common shares of the Company. This loan included an original issuance discount of 5% and included 99,900 Warrants at an exercise price of \$1.00, exercisable for 5 years from the issue date on the face of the Warrant. The maturity date of the loan was February 19, 2022. In May 2022, the Company and the note holder agreed to cancel and void previous warrants and entered into a new agreement for 115,185 warrants with an exercise price of \$2.50. As of December 31, 2022, the \$99,900 principal remained outstanding and had accrued interest of \$12,463. The warrants discussed above were initially discounted against the notes, and subsequent to year end December 31, 2021, they were deemed voided and new warrants in accordance with the new terms were issued. We assessed the differences in fair value and determined that they were de minimis and expensed the full value of the new warrants. The noteholder elected to convert the loan into 21,747 shares of common stock (post reverse stock split) upon the Company's IPO in February 2023.

On June 15, 2021, the company entered into an unsecured short term loan agreement with an Investor for an aggregate principal balance of \$34,000, with a one-year maturity date, accruing interest at 5% and imputing an additional 1% interest. The unsecured short-term loan was fully repaid in 2022.

On November 19, 2021, the company entered into an unsecured short term loan agreement with the same Investor for an aggregate principal balance of \$5,000, with a one-year maturity date, accruing interest at 5% and imputing an additional 1% interest. The unsecured short-term loan was fully repaid in 2022.

On December 13, 2021, the company entered into an unsecured short term loan agreement with the same Investor for an aggregate principal balance of \$10,000, with a one-year maturity date, accruing interest at 5% and imputing an additional 1% interest. The unsecured short-term loan was fully repaid in 2022.

On October 5, 2022, the Company entered into an exchange agreement with the Investor whereby all 734,493 shares of his common stock (post reverse split shares), were exchanged into 73,449 shares of Series A Convertible Preferred Stock that converts to common at a rate of ten common for one preferred. The Series A Preferred Stock is the economic equivalent of the common stock but has no voting rights and is subject to a blocker which prohibits the conversion into common stock if it would result in the Investor owning more than 4.99% of the Company's outstanding common stock at such time.

Policies and Procedures for Related Party Transactions

For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements, or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds the lesser of \$120,000 or 1% of the average of our total assets at year-end. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director, or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

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Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our Board of Directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our code of business conduct and ethics, our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our Board of Directors, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our Board of Directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our Board of Directors, determines in the good faith exercise of its discretion.

LEGAL MATTERS

The validity of the securities being offered by this prospectus has been passed upon for us by Sichenzia Ross FERENCE Carmel LLP, New York, New York.

EXPERTS

The consolidated financial statements of Bullfrog AI Holdings, Inc. as of and for the years ended December 31, 2023 and 2022 appearing in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 have been audited by M&K CPAs, PLLC, as set forth in its report thereon. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

Federal securities laws require us to file information with the SEC concerning our business and operations. Accordingly, we file annual, quarterly, and special reports, and other information with the Commission. The SEC maintains a web site (<http://www.sec.gov>) at which you can read or download our reports and other information.

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities being offered hereby. As permitted by the rules and regulations of the SEC, this prospectus does not contain all the information set forth in the registration statement and the exhibits and schedules thereto. For further information with respect to the Company and the securities offered hereby, reference is made to the registration statement, and such exhibits and schedules. The registration statement may be accessed at the SEC's web site.

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INCORPORATION BY REFERENCE

The SEC allows us to "incorporate by reference" into this prospectus the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Any statement contained herein or in a document incorporated or deemed to be incorporated by reference into this document will be deemed to be modified or superseded for purposes of the document to the extent that a statement contained in this document or any other subsequently filed document that is deemed to be incorporated by reference into this document modifies or supersedes the statement.

We also incorporate by reference the information contained in all other documents we will file with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (other than portions of these documents that are either (1) described in paragraph (e) of Item 201 of Regulation S-K or paragraphs (d)(1)-(3) and (e)(5) of Item 407 of Regulation S-K promulgated by the SEC or (2) deemed to have been furnished and not filed in accordance with SEC rules, including Current Reports on Form 8-K furnished under Item 2.02 or Item 7.01 (including any financial statements or exhibits relating thereto furnished pursuant to Item 9.01, unless otherwise indicated therein) after the date of the initial registration statement and prior to the effectiveness of this registration statement and prior to the completion of the offering of all securities covered by this prospectus and any applicable prospectus supplement. The information contained in any such document will be considered part of this prospectus from the date the document is filed with the SEC.

Notwithstanding the foregoing, information furnished under Items 2.02 and 7.01 of any Current Report on Form 8-K, including the related exhibits, is not incorporated by reference in this prospectus.

The information about us contained in this prospectus should be read together with the information in the documents incorporated by reference. You may request a copy of any or all of these filings, at no cost, by writing or telephoning us at: Vininder Singh, Bullfrog AI Holdings, Inc., 325 Ellington Blvd., Unit 317, Gaithersburg, MD 20878 telephone number (240) 658-6710.

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Bullfrog AI Holdings, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

	<u>September 30, 2024</u>	<u>December 31, 2023</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 4,238,988	\$ 2,624,730
Prepaid expenses	358,537	145,882
Total current assets	<u>4,597,525</u>	<u>2,770,612</u>
Property and equipment, net	4,681	5,974
Total assets	<u>\$ 4,602,206</u>	<u>\$ 2,776,586</u>
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 91,374	\$ 103,656
Accrued expenses	515,658	80,694
Short term insurance financing	172,005	-
Total current liabilities	<u>779,037</u>	<u>184,350</u>
Total liabilities	779,037	184,350
Stockholders' equity		
Series A Convertible Preferred stock, \$0.00001 par value, 5,500,000 shares authorized; 73,449 shares issued and outstanding as of September 30, 2024 and December 31, 2023.	1	1
Common stock, \$0.00001 par value, 100,000,000 shares authorized; 7,850,550 and 6,094,644 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively.	79	61
Additional paid-in capital	18,873,691	12,347,098
Accumulated deficit	(15,050,602)	(9,754,924)
Total stockholders' equity	<u>3,823,169</u>	<u>2,592,236</u>
Total liabilities and stockholders' equity	<u>\$ 4,602,206</u>	<u>\$ 2,776,586</u>

See accompanying notes to unaudited condensed consolidated financial statements.

Bullfrog AI Holdings, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	<u>Three Months Ended</u>		<u>Nine Months Ended</u>	
	<u>September 30,</u>		<u>September 30,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
Revenue				
Revenue	\$ -	\$ 65,000	\$ -	\$ 65,000
Total revenue	<u>-</u>	<u>65,000</u>	<u>-</u>	<u>65,000</u>
Cost of goods sold				
Cost of goods sold	-	5,200	-	5,200
Total cost of goods sold	<u>-</u>	<u>5,200</u>	<u>-</u>	<u>5,200</u>

Gross profit	-	59,800	-	59,800
Operating expenses				
Research and development	566,584	380,015	1,632,409	1,023,619
General and administrative	1,253,357	983,929	3,835,213	3,067,940
Total operating expenses	1,819,941	1,363,944	5,467,622	4,091,559
Loss from operations	(1,819,941)	(1,304,144)	(5,467,622)	(4,031,759)
Other income (expense), net				
Interest expense, net	(4,978)	(5,758)	(16,150)	(76,880)
Loss on conversion of notes	-	-	-	(92,959)
Other income, net	61,455	56,924	204,868	142,675
Total other income (expense), net	56,477	51,166	188,718	(27,164)
Net loss	(1,763,464)	(1,252,978)	(5,278,904)	(4,058,923)
Deemed dividend related to warrant exercise price adjustment	-	-	(16,774)	-
Net loss attributable to common stockholders	<u>\$ (1,763,464)</u>	<u>\$ (1,252,978)</u>	<u>\$ (5,295,678)</u>	<u>\$ (4,058,923)</u>
Net loss per common share attributable to common stockholders - basic and diluted	<u>\$ (0.22)</u>	<u>\$ (0.21)</u>	<u>\$ (0.67)</u>	<u>\$ (0.72)</u>
Weighted average number of shares outstanding - basic and diluted	<u>8,124,834</u>	<u>6,094,644</u>	<u>7,880,288</u>	<u>5,667,997</u>

See accompanying notes to unaudited condensed consolidated financial statements.

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Bullfrog AI Holdings, Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity
(Unaudited)

	Series A Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2022	73,449	\$ 1	4,021,935	\$ 40	\$ 1,341,662	\$ (4,399,055)	\$ (3,057,352)
Stock-based compensation	-	-	-	-	127,450	-	127,450
Issuance of common stock and warrants, net of issuance costs	-	-	1,297,318	13	7,293,638	-	7,293,651
Issuance of common stock for services	-	-	7,692	1	49,999	-	50,000
Conversion of convertible debt to common stock	-	-	331,166	3	1,535,612	-	1,535,615
Net loss	-	-	-	-	-	(1,325,547)	(1,325,547)
Balance at March 31, 2023	73,449	1	5,658,111	57	10,348,361	(5,724,602)	4,623,817
Stock-based compensation	-	-	-	-	262,267	-	262,267
Issuance of common stock pursuant to warrant exercises	-	-	436,533	4	1,494,654	-	1,494,658
Net loss	-	-	-	-	-	(1,480,398)	(1,480,398)
Balance at June 30, 2023	73,449	1	6,094,644	61	12,105,282	(7,205,000)	4,900,344
Stock-based compensation	-	-	-	-	121,460	-	121,460
Net loss	-	-	-	-	-	(1,252,978)	(1,252,978)
Balance at September 30, 2023	73,449	\$ 1	6,094,644	\$ 61	\$ 12,226,742	\$ (8,457,978)	\$ 3,768,826
Balance at December 31, 2023	73,449	\$ 1	6,094,644	\$ 61	\$ 12,347,098	\$ (9,754,924)	\$ 2,592,236
Stock-based compensation	-	-	-	-	335,417	-	335,417
Issuance of common stock and warrants, net of issuance costs	-	-	1,247,092	13	5,674,638	-	5,674,651
Issuance of common stock pursuant to warrant exercises	-	-	508,814	5	105,811	-	105,816
Deemed dividend related to warrant price adjustment	-	-	-	-	16,774	(16,774)	-
Net loss	-	-	-	-	-	(1,903,794)	(1,903,794)
Balance at March 31, 2024	73,449	1	7,850,550	79	18,479,738	(11,675,492)	6,804,326
Stock-based compensation	-	-	-	-	192,382	-	192,382
Net loss	-	-	-	-	-	(1,611,646)	(1,611,646)
Balance at June 30, 2024	73,449	1	7,850,550	79	18,672,120	(13,287,138)	5,385,062
Stock-based compensation	-	-	-	-	201,571	-	201,571
Net loss	-	-	-	-	-	(1,763,464)	(1,763,464)
Balance at September 30, 2024	73,449	\$ 1	7,850,550	\$ 79	\$ 18,873,691	\$ (15,050,602)	\$ 3,823,169

See accompanying notes to unaudited condensed consolidated financial statements.

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Bullfrog AI Holdings, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (5,278,904)	\$ (4,058,923)

Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation		1,293	1,293
Stock-based compensation		729,370	511,177
Shares issued for services		-	50,000
Loss on conversion of notes		-	92,959
Amortization of debt discount		-	20,000
Changes in operating assets and liabilities:			
Prepaid expenses		(212,655)	(337,433)
Accounts payable		(12,282)	(433,490)
Accrued expenses		434,964	(796,865)
Deferred revenue		-	(32,000)
Net cash used in operating activities		(4,338,214)	(4,983,282)
Cash flows from investing activities:			
Purchases of property and equipment		-	-
Net cash used in investing activities		-	-
Cash flows from financing activities:			
Proceeds from issuance of common stock and warrants, net of issuance costs		5,674,651	7,293,651
Proceeds from warrant exercises		105,816	1,494,658
Proceeds from notes payable		-	100,000
Payments on notes payable		-	(319,950)
Proceeds from short term insurance financing		561,885	697,534
Payments on short term insurance financing		(389,880)	(484,244)
Net cash provided by financing activities		5,952,472	8,781,649
Net increase in cash and cash equivalents		1,614,258	3,798,367
Cash and cash equivalents, beginning of period		2,624,730	57,670
Cash and cash equivalents, end of period		\$ 4,238,988	\$ 3,856,037
Supplemental cash flow information:			
Cash paid for interest	\$	16,150	\$ 93,916
Cash paid for taxes	\$	-	\$ -
Supplemental non-cash activity			
Issuance of common stock upon conversion of notes payable	\$	-	\$ 1,535,615

See accompanying notes to unaudited condensed consolidated financial statements.

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Bullfrog AI Holdings, Inc.
Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Organization and Nature of Business

Description of Business

Bullfrog AI Holdings, Inc. (“we”, “our” or the “Company”) was incorporated in the State of Nevada in February 2020. Bullfrog AI Holdings, Inc. is the parent company of Bullfrog AI, Inc. and Bullfrog AI Management, LLC which were incorporated in Delaware and Maryland, in 2017 and 2021, respectively. All of our operations are currently conducted through Bullfrog AI Holdings, Inc., which began operations in February 2020. We are a company focused specifically on advanced Artificial Intelligence and Machine Learning (AI/ML) driven analysis of complex data sets in medicine and healthcare. Our objective is to utilize our platform for a precision medicine approach to drug asset enablement through external partnerships and selective internal development.

Most new therapeutics will fail at some point in preclinical or clinical development. These failures are the primary drivers for the high cost of developing new therapeutics. A major part of the difficulty in developing new therapeutics is efficient integration of complex and highly dimensional data generated at each stage of development to de-risk subsequent stages of the development process. Artificial Intelligence and Machine Learning (AI/ML) has emerged as a digital solution to help address this problem.

We use artificial intelligence and machine learning to advance medicines for both internal and external projects. Most current AI/ML platforms still fall short in their ability to synthesize disparate, high-dimensional data for actionable insight. Our analytical platform is composed of an ensemble of state-of-the-art machine learning and artificial intelligence models. Our core platform technology, named bfLEAP™, is an analytical AI/ML platform developed at The Johns Hopkins University Applied Physics Laboratory (JHU-APL) which is able to surmount the challenges of scalability and flexibility currently hindering researchers and clinicians by providing a more precise, multi-dimensional understanding of their data. We are deploying our analytical platform, including bfLEAP™, for use in several critical stages of development of internal programs and through strategic partnerships and collaborations with the intention of streamlining data analytics in therapeutics development, decreasing the overall development costs by decreasing failure rates for new therapeutics, and impacting the lives of countless patients that may otherwise not receive the therapies they need.

The proprietary analytical platform utilizes both supervised and unsupervised machine learning. As such, it is able to reveal real and meaningful connections in the data without the need for a priori hypothesis. Algorithms used in the platform are designed to handle highly imbalanced data sets and successfully identify combinations of factors that are associated with outcomes of interest. Our platform leverages models that use both correlative and causative machine learning and artificial intelligence approaches which provide a comprehensive approach to predictive analysis which is expected to lead to meaningful insights including the molecular drivers of disease. In this regard, with our access to proprietary data sets such as our strategic data and commercialization agreements with the Lieber Institute for Brain Development (“LIBD”), we have increased our internal efforts on target discovery.

Our goal is to improve the odds of success at all stages of pre-clinical and clinical therapeutics development for in-house programs and for our strategic partners and collaborators. Our business model includes enabling the success of ongoing clinical trials and rescuing late stage failed drugs (i.e., Phase 2 or Phase 3 clinical trial failures) by bringing them in-house for development prior to eventual divestiture; although, we also consider entering collaborations for earlier stage drugs. We pursue our drug asset enhancement business by leveraging the powerful and proven bfLEAP™ AI/ML platform initially developed at JHU-APL. We believe the bfLEAP™ analytics platform is a potentially disruptive tool for analysis of pre-clinical and/or clinical data sets, such as the robust pre-clinical and clinical trial data sets being generated in translational R&D and clinical trial settings.

Liquidity and Going Concern

The Company has had negative cash flows from operations and operated at a net loss since inception. In the first quarter of 2023, we completed our initial public offering (“IPO”). In February 2024, we received net proceeds of approximately \$5.7 million from an underwritten secondary public offering of common stock and warrants. As of September 30, 2024, the Company has a cash balance of approximately \$4.2 million. In October 2024, we received net proceeds of approximately \$2.7 million from a registered direct offering of common stock and pre-funded warrants, and concurrent private placement of common stock warrants. In the absence of significant revenues in 2024 and 2025, the Company believes that its capital resources are sufficient to fund planned operations into the fourth quarter of 2025.

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Accordingly, we will require additional capital to continue to execute our strategy. We anticipate raising this additional capital through various avenues including sales of equity securities, debt transactions, licensing agreements and collaborative arrangements. Although management believes that such funding sources will be available, there can be no assurance that any such arrangements will be consummated to provide sufficient capital when needed to allow us to continue our operations, or if available, on terms acceptable to us. If we do not raise sufficient funds in a timely manner, among other things, we may be forced to delay, scale back or eliminate some or all our research and product development programs and/or our capital expenditures or to enter into arrangements on unfavorable terms. We currently do not have commitments for future funding from any source.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, realization of assets, and satisfaction of liabilities in the ordinary course of business. Accordingly, our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of Bullfrog AI Holdings, Inc. and our wholly owned subsidiaries and have been prepared in conformity with United States generally accepted accounting principles (“GAAP”) for interim financial information. All intercompany accounts and transactions have been eliminated in consolidation.

The condensed consolidated statements are unaudited and should be read in conjunction with the consolidated financial statements and related notes included in our 2023 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 29, 2024. The unaudited condensed consolidated financial statements have been prepared on a basis consistent with the audited annual consolidated financial statements included in Form 10-K and, in the opinion of management, include all adjustments of a normal recurring nature necessary to fairly state our financial position, our results of operations, and cash flows.

The results for the nine months ended September 30, 2024 are not necessarily indicative of the operating results expected for the year ending December 31, 2024 or any other future period.

In February 2023, we completed a 1-for-7 reverse split of our common stock. Stockholders’ equity and all references to shares and per share amounts in the accompanying unaudited condensed consolidated financial statements have been adjusted to reflect the reverse stock split for all periods presented.

Revenue Recognition

The Company recognizes revenue based on the following five step model:

- **Identification of the contract with a customer**
This step outlines the criteria that must be met when establishing a contract with a customer to supply goods or services.
- **Identification of the performance obligations in the contract**
This step describes how distinct performance obligations in the contract must be handled.
- **Determination of the transaction price**
This step outlines what must be considered when establishing the transaction price, which is the amount the business expects to receive for transferring the goods or services to the customer.
- **Allocation of the transaction price to the performance obligations in the contract**
This step outlines guidelines for allocating the transaction price across the contract’s separate performance obligations, and is what the customer agrees to pay for the goods or services.
- **Recognition of revenue when, or as, the Company satisfies a performance obligation**
Revenue can be recognized as the business meets each performance obligation. This step specifies how that should happen.

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Contract Services

The Company anticipates that the majority of its revenues to be recognized in the near future will result from discovery and monetization of new drug targets and intellectual property from data use partnerships focused on analysis of rich proprietary data sets. The target market for monetization will primarily be mid-size to large biopharmaceutical organizations seeking to build their new drug target pipeline. A secondary revenue channel is fee for service partnerships with biopharmaceutical companies and other organizations of all sizes that have challenges analyzing data throughout the drug development process. The Company provides the customer with an analysis of large complex data sets using the Company’s proprietary Artificial Intelligence / Machine Learning platform. This platform is aimed at predicting targets of interest, patterns, relationships, anomalies, and molecular drivers of disease. The Company believes that there will be additional on-going work requested from partners; therefore, the service model utilizes a master services agreement with work or task orders issued for discrete analysis performed at the discovery, preclinical, or clinical stages of drug development. The Company receives a cash fee and, in some instances, the potential for rights to new intellectual property generated from the analysis. Once data analysis and the analysis report are complete, the Company delivers the analysis set to the customer and recognizes revenue at that point in time.

Significant Accounting Policies

There have been no new or material changes to the significant accounting policies discussed in the Company’s audited financial statements and the notes thereto included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

Impact of Recently Issued Accounting Standards

The Company has evaluated issued Accounting Standards Updates (“ASUs”) not yet adopted and believes the adoption of these standards will not have a material impact on its consolidated financial statements.

3. Convertible Notes

August 2021 Note

In August 2021, the Company entered into a convertible loan agreement with an unrelated party for a commitment of up to \$95,000 with a 5% original issue discount and a 9% interest rate. The loan was repaid in its entirety in February 2023.

December 2021 Note

In December 2021, the Company entered into a loan agreement with an unrelated party with a principal amount of \$5,000, a 10% original issue discount and a 6% interest rate. Concurrent with the closing of the Company's IPO in February 2023, the note converted according to its terms into 6,939 shares of common stock. No gain or loss was recognized on the conversion.

Convertible Bridge Notes

In 2022, the Company received approximately \$991,000 of gross proceeds from the issuance of Convertible Bridge Notes from several offerings. Concurrent with the closing of the Company's IPO in February 2023, all of the Convertible Bridge Notes converted according to their terms into 269,513 shares of common stock. No gain or loss was recognized on the conversions.

4. Convertible Notes – Related Party

SAFE Agreement

In July 2021, the Company entered into a Simple Agreement for Future Equity (SAFE) with a related party at a purchase price of \$50,000. In February 2023, the SAFE terminated and converted into 32,967 shares of common stock according to its terms upon the closing of the Company's IPO. The conversion was considered a redemption for accounting purposes and consequently, the Company recognized a \$63,626 loss on the conversion.

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August 2021 Note

In August 2021, the Company entered into a convertible loan agreement with a related party in the amount of \$99,900. In February 2023, the related party elected to convert the convertible loan into 21,747 shares of common stock according to its terms upon the closing of the Company's IPO. The conversion was considered a redemption for accounting purposes and consequently, the Company recognized a \$29,333 loss on the conversion.

5. Notes Payable

In January 2023, the Company entered into a short-term note payable with a principal balance of \$100,000, an original issue discount of 20% and a 9% interest rate. The note was repaid in its entirety in February 2023.

In February 2023, the Company entered into an agreement to finance a portion of the premium for its Directors and Officers Insurance. The agreement provided for financing of \$697,534 of the premium, repayments in 10 equal monthly installments of \$71,485 each through December 2023 and accrued interest at 6.5%. The financing was repaid during 2023.

In February 2024, the Company again entered into an agreement to finance a portion of the premium for its Directors and Officers Insurance. The agreement provides for financing of \$561,885 of the premium, repayments in 10 equal monthly installments of \$58,005 each through December 2024 and accrued interest at 6.99%.

6. Stockholder's Equity

Preferred Stock

The Company has 10,000,000 shares of preferred stock authorized at a par value of \$0.00001 with 5,500,000 being designated as Series A Convertible Preferred Stock. Of the 5,500,000 authorized shares of Series A Convertible Preferred Stock, 73,449 were issued and outstanding as of September 30, 2024. Each share of Series A Convertible Preferred Stock is convertible at any time into 10 shares of the Company's common stock. The Series A Preferred Stock is the economic equivalent of the common stock but has no voting rights and is subject to a blocker which prohibits the conversion into common stock if it would result in the investor owning more than 4.99% of the Company's outstanding common stock at such time.

Common Stock

The Company has 100,000,000 shares of common stock authorized at a par value of \$0.00001.

In February 2023, the Company completed its IPO for the sale of 1,297,318 units (each, a "Unit," collectively, the "Units") at a price of \$6.50 per Unit for a total of approximately \$8.4 million of gross proceeds. Each Unit consisted of one share of the Company's common stock, one tradeable warrant (each, a "Tradeable Warrant," collectively, the "Tradeable Warrants") to purchase one share of common stock at an exercise price of \$7.80 per share, and one non-tradeable warrant (each, a "Non-tradeable Warrant," collectively, the "Non-tradeable Warrants"; together with the Tradeable Warrants, each, a "Warrant," collectively, the "Warrants") to purchase one share of the Company's common stock at an exercise price of \$8.125.

In connection with the completion of its IPO, the Company issued an aggregate of 331,166 shares of common stock upon the conversion of certain outstanding convertible debt (see Note 3 and Note 4).

In connection with the IPO, in February 2023, the Company completed a 1-for-7 reverse split of its common stock. Stockholders' equity and all references to shares and per share amounts in the accompanying unaudited condensed consolidated financial statements have been retroactively adjusted to reflect the reverse stock split for all periods presented.

In February 2023, the Company issued 7,692 shares of common stock for consulting services and recognized \$50,000 of compensation expense related to these shares.

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In February 2024, the Company received approximately \$6.5 million of gross proceeds from the sale of 1,247,092 shares of common stock, 478,429 pre-funded warrants and 1,725,521 warrants (collectively the "Units"). The Units were sold at a price of \$3.782 and the sale was completed via an underwritten secondary public offering and includes the underwriter's exercise of their over-allotment option. The warrants have an exercise price of \$4.16 and expire five years from issuance. The pre-funded warrants had an exercise price of \$0.001 and were exercised in their entirety in the first quarter of 2024.

Dilutive securities are excluded from the diluted earnings per share calculation when their effect is anti-dilutive. As of September 30, 2024, 73,449 shares of preferred stock, 5,307,444 warrants and 849,427 options for common shares were excluded from the calculation of net loss per share. As of September 30, 2023, 73,449 shares of preferred stock, 3,796,164 warrants and 507,717 options for common shares were excluded from the calculation of net loss per share.

2022 Equity Incentive Plan

In November 2022, the Company's Board of Directors adopted, and its shareholders approved, the 2022 Equity Incentive Plan (the "Plan"). The Plan provides for the granting of equity-based awards to employees, directors, and consultants. The Plan provides for equity-based awards including incentive stock options, non-qualified stock options, stock appreciation rights, performance share awards, cash awards and other equity-based awards. Awards are limited to a maximum term of 10 years and any exercise prices shall not be less than 100% of the fair market value of one share of common stock on the grant date.

Stock Options

The following tables summarize the stock option activity for the nine months ended September 30, 2024:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2023	527,717	\$ 4.17	9.00	\$ 112,141
Granted	368,000	\$ 3.71		
Exercised	-	\$ -		
Forfeited / canceled	(46,290)	\$ 3.95		
Outstanding at September 30, 2024	849,427	\$ 3.98	8.72	\$ 25,652
Vested at September 30, 2024	449,434	\$ 4.06	8.27	\$ 16,837

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2022	69,217	\$ 3.06	7.08	\$ 117,669
Granted	438,500	\$ 4.41		
Exercised	-	\$ -		
Forfeited / canceled	-	\$ -		
Outstanding at September 30, 2023	507,717	\$ 4.23	9.17	\$ 102,441
Vested at September 30, 2023	215,623	\$ 3.97	8.64	\$ 52,644

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The fair value of options granted during the nine months ended September 30, 2024 and 2023 was estimated using the Black-Scholes option pricing model based on the assumptions in the table below:

	Nine Months Ended September 30,	
	2024	2023
Expected dividend yield	0%	0%
Expected volatility	92% - 97%	87% - 92%
Risk-free interest rate	3.5% - 4.4%	3.4% - 4.1%
Expected life (in years)	5.3 - 6.0	5.0 - 6.0

- *Dividend yield* – The Company does not expect to pay a dividend in the foreseeable future.
- *Volatility* – The trading volatility was determined by calculating the volatility of the Company's peer group.
- *Risk-free interest rate* – This is the U.S. Treasury rate, having a term comparable to the expected life of the stock option.
- *Expected life of options* – The expected life of options granted to employees was determined using the simplified method.

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2024 and 2023 was \$2.83 and \$3.20, respectively.

During the three and nine months ended September 30, 2024, the Company recognized \$201,571 and \$726,363, respectively, of compensation expense related to stock options. During the three and nine months ended September 30, 2023, the Company recognized \$116,410 and \$475,465, respectively, of compensation expense related to stock options.

As of September 30, 2024, the total unrecognized compensation expense related to unvested stock options was approximately \$,084,000, which the Company expects to recognize over a weighted-average period of approximately 1.5 years.

Warrants

The following table provides details for the Company's outstanding warrants as of September 30, 2024:

Exercise Price	Expiration	Number of Warrants
\$0.0007	2030	274,286
\$2.10 - \$2.66	2026 - 2032	446,160
\$3.36 - \$4.27	2028 - 2029	1,933,226
\$6.51 - \$7.80	2026 - 2032	1,484,829
\$8.125	2027 - 2028	1,443,227
		5,581,728

Warrants Issued in Conjunction with Transactions

During the year ended December 31, 2023, the Company issued the following warrants as part of the Company's February 2023 IPO:

- 276,452 contingent warrants to certain debt holders with an exercise price of \$4.27 and an expiration date 5 years from issuance. As of September 30, 2024, 204,033 warrants have been exercised and 72,419 remain outstanding. As a result of the February 2024 secondary public offering transaction, the exercise price of the warrants was reduced to \$3.782 pursuant to the anti-dilution provision contained in the warrants. The effect of the change in price was recognized as a deemed dividend of \$5,794 which increases net loss available to common stockholders for the nine months ended September 30, 2024.
- 18,000 contingent warrants as fees to the Company's underwriters with an exercise price of \$8.125 and an expiration date 4 years from issuance. As of September 30, 2024, none of these warrants have been exercised. As a result of the February 2024 secondary public offering transaction, the exercise price of the warrants was reduced to \$3.782 pursuant to the anti-dilution provision contained in the warrants. The effect of the change in price was recognized as a deemed dividend of \$10,980 which increases net loss available to common stockholders for the nine months ended September 30, 2024.

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- 1,297,318 tradable warrants with an exercise price of \$7.80 and an expiration date 5 years from issuance. Through September 30, 2024, 100 warrants have been exercised.
- 1,297,318 non-tradable warrants with an exercise price of \$8.125 and an expiration date 5 years from issuance. As of September 30, 2024, 7,500 of these warrants have been exercised and 1,289,818 remain outstanding.
- 153,409 tradeable warrants to our underwriters pursuant to the overallotment options with an exercise price of \$7.80 and an expiration date 5 years from issuance. As of September 30, 2024, none of these warrants have been exercised.
- 153,409 non-tradeable warrants to our underwriters pursuant to the overallotment options with an exercise price of \$8.125 and an expiration date 5 years from issuance. As of September 30, 2024, none of these warrants have been exercised.

During the nine months ended September 30, 2024, the Company issued the following warrants as part of the Company's secondary public offering:

- 1,507,139 warrants to purchase shares of the Company's common stock at an exercise price of \$4.16 per share and an expiration date 5 years from issuance. In addition, the Company issued an additional 218,382 warrants with an exercise price of \$4.16 and an expiration date 5 years from issuance pursuant to the underwriters' overallotment option. As of September 30, 2024, 16,000 of these warrants have been exercised and 1,709,521 remain outstanding.
- 478,429 pre-funded warrants with an exercise price of \$0.001. As of September 30, 2024, all of these pre-funded warrants have been exercised.
- 90,428 warrants with an exercise price of \$4.16 per share and an expiration date 5 years from issuance to our underwriters. The warrants were valued at approximately \$263,000, and as of September 30, 2024, none of these warrants have been exercised.

Warrants Issued as Consideration for Services

The following table summarizes the activity for warrants issued as consideration for services for the nine months ended September 30, 2024 and the year ended December 31, 2023:

	Number of Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2022	678,176	\$ 1.57	7.6	\$ 2,131,123
Granted	-	\$ -	-	-
Exercised	-	\$ -	-	-
Forfeited / canceled	-	\$ -	-	-
Outstanding at December 31, 2023	678,176	\$ 1.57	6.6	\$ 1,209,136
Granted	-	\$ -	-	-
Exercised	(14,285)	\$ 2.66	-	-
Forfeited / canceled	-	\$ -	-	-
Outstanding at September 30, 2024	663,891	\$ 1.55	5.8	\$ 964,513
Vested at September 30, 2024	663,891	\$ 1.55	5.8	\$ 964,513

During the three and nine months ended September 30, 2024, the Company recognized \$0 and \$3,007, respectively, of compensation expense related to certain warrants. During the three and nine months ended September 30, 2023, the Company recognized \$5,050 and \$35,712, respectively, of compensation expense related to certain warrants.

As of September 30, 2024, there was no unrecognized compensation expense related to unvested warrants.

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7. Income Taxes

The Company has not recorded any tax provision or benefit for the nine months ended September 30, 2024 and 2023. The Company has provided a valuation allowance for the full amount of its net deferred tax assets since realization of any future benefits from deductible temporary differences, net operating loss carryforwards, and research and development credits are not more-likely-than-not to be realized at September 30, 2024 and December 31, 2023.

8. Material Agreements

JHU-APL Technology License

In February 2018, the Company entered into an exclusive, world-wide, royalty-bearing license from JHU-APL. The license covers three (3) issued patents, one (1) new provisional patent application, non-patent rights to proprietary libraries of algorithms and other trade secrets, as well as modifications and improvements. In October 2021, the Company executed an amendment to the original license for improvements and new advanced analytics capabilities. In consideration of the rights granted to the Company under the License Agreement, JHU received a warrant equal to five percent (5%) of the then fully diluted equity base of the Company, which was diluted following the closing of the IPO. Under the terms of the License Agreement, JHU will be entitled to an eight percent (8%) royalty on net sales for the services provided by the Company as well as fifty percent (50%) of all sublicense revenues received by the Company on services and sublicenses in which the JHU licensed technology was utilized. In addition, the Company is required to pay JHU an annual maintenance fee of \$1,500. Minimum annual royalty payments are \$20,000 for 2022, \$80,000 for 2023, and \$300,000 per year for 2024 and beyond. If cumulative annual royalty payments do not reach these levels, the amount due to JHU to reach the annual minimum is due by January 1st of the following year. Failure to make annual royalty payments is considered a material breach under the agreement and upon notice from JHU of a material breach, the Company shall have 60 days to cure the material breach. In July 2022, the Company entered into an exclusive, world-wide, royalty-bearing license from JHU-APL for the additional technology developed to enhance the bfLEAP™ platform. The new license provides additional intellectual property rights including patents, copyrights, and knowhow to be utilized under the Company's bfLEAP™ analytical AI/ML platform. This license supersedes the previous license. In consideration of the new license, the Company issued 39,879 shares of common stock to JHU. Under the terms of the new License Agreement, JHU will be entitled to eight percent (8%) of net sales for the services provided by the Company to other parties and three percent (3%) for internally developed drug projects in which the JHU license was utilized. The new license also contains tiered sub licensing fees that start at

50% and reduce to 25% based on revenues. In addition, under the new license agreement, the minimum annual royalty payments are \$30,000 for 2022, \$80,000 for 2023, and \$300,000 per year for 2024 and beyond.

In May 2023, the Company and JHU-APL entered into Amendment number 1 of the July 2022 License Agreement whereby the Company gained access to certain improvements including additional patents and knowhow in exchange for a series of payments totaling \$275,000. The first of these payments for \$75,000 was paid in July 2023 and the remaining payments of \$75,000, \$75,000, and \$50,000 are due in years 2025, 2026, and 2027, respectively. The amendment also reduced the 2023 minimum annual royalty payment to \$60,000, all other financial terms remain the same. As of September 30, 2024, we have accrued \$25,000 of the 2024 minimum annual royalty payments.

George Washington University - Beta2-spectrin siRNA License

In January 2022, the Company entered into an exclusive, world-wide, royalty-bearing license from George Washington University (GWU) for rights to use siRNA targeting Beta2-spectrin in the treatment of human diseases, including hepatocellular carcinoma (HCC). The license covers methods claimed in three US and worldwide patent applications, and also includes use of this approach for treatment of obesity, non-alcoholic fatty liver disease, and non-alcoholic steatohepatitis.

In consideration of the rights granted to the Company under the License Agreement, the Company paid GWU a \$20,000 License Initiation Fee. Under the terms of the License Agreement, GWU will be entitled to a three percent (3%) royalty on net sales subject to quarterly minimums once the first sale has occurred subsequent to regulatory approval, as well sublicense or assignment fees in the event the Company sublicenses or assigns their rights to use the technology. The Company will also reimburse GWU for previously incurred and ongoing patent costs. The Sublicense and Assignment fee amounts decline as the Company advances the clinical development of the licensed technology. The license agreement also contains milestone payments for clinical development through the approval of an NDA and commercialization. As of September 30, 2024, there has been no accrual for royalties since we have not begun to generate applicable revenue. The Company assessed whether the license should be capitalized and determined that the licensed program is in the early stage and therefore may not be recoverable; the Company expensed the license fee and will expense development costs until commercial viability is likely.

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Johns Hopkins University – Mebendazole License

In February 2022, the Company entered into an exclusive, world-wide, royalty-bearing license from Johns Hopkins University (JHU) for the use of an improved formulation of Mebendazole for the treatment of any human cancer or neoplastic disease. This formulation shows potent activity in animal models with different types of cancer and has been evaluated in a Phase I clinical trial in patients with high-grade glioma (NCT01729260). The trial, an open-label dose-escalation study, assessed the safety and efficacy of the improved formulation with adjuvant temozolomide in 24 patients with newly diagnosed gliomas. Investigators observed no dose-limiting toxicity in patients receiving all but the highest tested dose (200mg/kg/day). Four of the 15 patients receiving the maximum tested dose of 200mg/kg/day experienced dose-limiting toxicity, all of which were reversed by decreasing or eliminating the dose given. There were no serious adverse events attributed to Mebendazole at any dose during the trial. 41.7% of patients who received Mebendazole were alive at two years after enrollment, and 25% were alive at four years (Gallia et al., 2021).

The license covers six (6) issued patents and one (1) pending application. In consideration of the rights granted to the Company under the License Agreement, JHU will receive a staggered Upfront License Fee of \$250,000. The Company initially paid \$50,000 and the remaining balance of \$200,000 was paid after the Company completed its IPO. The Company will also reimburse JHU for previously incurred and ongoing patent costs. Under the terms of the License Agreement, JHU will be entitled to three and one-half percent (3.5%) royalty on net sales by the Company in which the JHU license was utilized. In addition, the Company is required to pay JHU minimum annual royalty payments of \$5,000 for 2022, \$10,000 for 2023, \$20,000 for 2024, \$30,000 for 2025, and \$50,000 for 2026 and each year after until the first commercial sale, after which, the annual minimum royalty shall be \$250,000. The license agreement also contains milestone payments for clinical development steps through the approval of an NDA and commercialization. As of September 30, 2024 and December 31, 2023, the balance of accrued expense related to this license agreement was \$15,000 and \$10,000, respectively. The Company assessed whether the license should be capitalized and determined that the licensed program is in the early stage and therefore may not be recoverable; the Company expensed the license fee and will expense development costs until commercial viability is likely.

Johns Hopkins University – Prodrug License

In October 2022, the Company entered into an exclusive, world-wide, royalty-bearing license from JHU and the Institute of Organic Chemistry and Biochemistry (IOCB) of the Czech Academy of Sciences for rights to commercialize N-substituted prodrugs of Mebendazole that demonstrate improved solubility and bioavailability. The license covers prodrug compositions and use for treating disease as claimed in multiple US and worldwide patent applications. In consideration for the rights granted to the Company under the License Agreement, JHU and IOCB will receive a staggered upfront license fee of \$100,000. The Company will also reimburse JHU and IOCB for previously incurred patent costs. Under the terms of the License Agreement, JHU and IOCB will be entitled to four percent (4.0%) royalty on net sales by the Company in which the JHU and IOCB license was utilized. In addition, the Company is required to pay JHU and IOCB minimum annual royalty payments of \$5,000 for 2026, \$10,000 for 2027, \$20,000 for 2028, \$30,000 for 2029, and \$50,000 for 2030 and each year after until the first commercial sale, after which, the annual minimum royalty shall be \$150,000. The license agreement also contains milestone payments for patent grants, clinical development steps through the approval of an NDA and commercialization. No expenses have been accrued as of any of the periods presented. The Company assessed whether the license should be capitalized and determined that the licensed program is in the early stage and therefore may not be recoverable; the Company expensed the license fee and will expense development costs until commercial viability is likely.

9. Subsequent Events

The Company evaluates subsequent events and transactions that occur after the balance sheet date up to the date that the unaudited condensed consolidated financial statements are issued.

Other than as disclosed in this Note 9 and as may be disclosed elsewhere in the notes to the accompanying unaudited condensed consolidated financial statements, there have been no subsequent events that require adjustment or disclosure in the accompanying unaudited condensed consolidated financial statements.

On October 18, 2024, the Company entered into a securities purchase agreement with certain institutional investors (the “Purchasers”), pursuant to which the Company agreed to issue to the Purchasers, in a registered direct offering, (i) 862,602 shares of the Company’s common stock (the “Shares”), par value \$0.00001 per share (“Common Stock”), pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to 702,398 shares of Common Stock (the “Pre-funded Warrants Shares”) with an exercise price of \$0.0001 per share, at a purchase price of \$2.00 per share of Common Stock and a purchase price of \$1.9999 per Pre-Funded Warrant, and (ii) in a concurrent private placement, warrants (the “Common Warrants”) to purchase an aggregate of 1,565,000 shares of Common Stock (the “Common Warrant Shares”) with an exercise price of \$2.00 per share, which are exercisable after six (6) months from the date of issuance for a five-year period from the initial exercise date. The transaction closed on October 21, 2024, with the Company earning gross proceeds of approximately \$3.13 million, and net proceeds of approximately \$2.7 million. Concurrently with the securities purchase agreement, on October 18, 2024, the Company also entered into a placement agency agreement with WallachBeth Capital, LLC, as the placement agent (the “Placement Agent”), pursuant to which the Company agreed to pay the Placement Agent an aggregate cash fee of 8.0% of the gross proceeds from the sale of securities in the transaction, reimburse for certain out-of-pocket expenses, and issue to the Placement Agent (or its designees) warrants to purchase an aggregate of 62,600 shares of Common Stock, equal to 4% of the aggregate number of shares of Common Stock and/or Pre-Funded Warrants sold in the registered direct offering, at an exercise price per share equal to \$2.00, which is equal to the exercise price of the Common Warrants. The placement agent warrants are exercisable six (6) months from the date of issuance and expire on the five-year anniversary of initial exercise date.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Bullfrog AI Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Bullfrog AI Holdings, Inc. (the Company) as of December 31, 2023 and 2022, and the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for the years ended December 31, 2023 and 2022, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022 and the results of its operations and its cash flows for flows for the two-year period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which they relate.

As discussed in Note 2, the Company had a going concern disclosure in the previous year due to continued net losses from operations and negative cash flows in operations. Auditing management's evaluation of a going concern can be a significant judgment given the fact that the Company uses management estimates on future revenues and expenses, which are difficult to substantiate.

We evaluated the appropriateness of the removal of the going concern, we examined and evaluated the financial information along with management's plans to mitigate the going concern and management's disclosure on going concern.

/s/ M&K CPAS, PLLC

We have served as the Company's auditor since 2021.
Houston, Texas
March 29, 2024

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**BULLFROG AI HOLDINGS, INC.
CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,624,730	\$ 57,670
Prepaid expenses	145,882	15,000
Total current assets	2,770,612	72,670
Property and equipment, net	5,974	7,699
Total assets	\$ 2,776,586	\$ 80,369
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 103,656	\$ 543,993
Accrued expenses	80,694	982,988
Deferred revenue	-	32,000
Convertible notes	-	1,323,890
Convertible notes - related party	-	254,850
Total current liabilities	184,350	3,137,721
Total liabilities	\$ 184,350	\$ 3,137,721
Stockholders' equity (deficit):		
Series A Convertible Preferred stock, \$0.00001 par value, 5,500,000 shares authorized; 73,449 shares issued and outstanding, as of December 31, 2023 and 2022.	1	1

Common stock, \$0.00001 par value, 100,000,000 shares authorized; 6,094,644 and 4,021,935 shares issued and outstanding as of December 31, 2023 and 2022, respectively.	61	40
Additional paid-in capital	12,347,098	1,341,662
Accumulated deficit	(9,754,924)	(4,399,055)
Total stockholders' equity (deficit)	<u>2,592,236</u>	<u>(3,057,352)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 2,776,586</u>	<u>\$ 80,369</u>

The accompanying notes are an integral part of these consolidated financial statements.

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BULLFROG AI HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2023	2022
Revenue:		
Revenue, net Revenue	\$ 65,000	\$ 10,000
Total revenue	<u>65,000</u>	<u>10,000</u>
Cost of goods sold:		
Cost of goods sold	5,200	800
Total cost of goods sold	<u>5,200</u>	<u>800</u>
Gross profit	59,800	9,200
Operating expenses:		
Research and development	1,432,614	609,270
General and administrative	3,994,710	1,855,731
Total operating expenses	<u>5,427,324</u>	<u>2,465,001</u>
Loss from operations	(5,367,524)	(2,455,801)
Other income (expense), net		
Interest expense, net	(79,089)	(347,145)
Loss on conversion of notes	(92,959)	-
Interest income	183,703	459
Total other income (expense), net	<u>11,655</u>	<u>(346,686)</u>
Net loss	<u>\$ (5,355,869)</u>	<u>\$ (2,802,487)</u>
Net loss per common share attributable to common stockholders - basic and diluted	<u>\$ (0.89)</u>	<u>\$ (0.70)</u>
Weighted average number of shares outstanding - basic and diluted	<u>6,049,819</u>	<u>4,009,852</u>

The accompanying notes are an integral part of these consolidated financial statements.

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BULLFROG AI HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
FOR THE YEARS ENDED DECEMBER 31, 2023 AND 2022

	Series A Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at December 31, 2021	-	\$ -	4,622,789	\$ 46	\$ 587,415	\$ (1,596,568)	(1,009,107)
Imputed interest	-	-	-	-	9,221	-	9,221
Stock-based compensation	-	-	-	-	340,152	-	340,152
Reclassification of warrant	-	-	-	-	(11,097)	-	(11,097)
Conversion of convertible notes	-	-	205,984	2	226,136	-	226,138
Shares cancellation	-	-	(112,225)	(1)	1	-	-
Shares issuance for license	-	-	39,879	-	189,828	-	189,828
Common stock converted to Series A Preferred Stock	73,449	1	(734,492)	(7)	6	-	-
Net loss	-	-	-	-	-	(2,802,487)	(2,802,487)
Balance at December 31, 2022	73,449	1	4,021,935	40	1,341,662	(4,399,055)	(3,057,352)
Stock-based compensation	-	-	-	-	631,533	-	631,533
Issuance of common stock (initial public offering), net of issuance costs	-	-	1,297,318	13	7,293,638	-	7,293,651
Issuance of common stock for services	-	-	7,692	1	49,999	-	50,000
Conversion of convertible debt to common stock	-	-	331,166	3	1,535,612	-	1,535,615
Issuance of common stock pursuant to warrant exercises	-	-	436,533	4	1,494,654	-	1,494,658
Net loss	-	-	-	-	-	(5,355,869)	(5,355,869)
Balance at December 31, 2023	73,449	\$ 1	6,094,644	\$ 61	\$ 12,347,098	\$ (9,754,924)	\$ 2,592,236

The accompanying notes are an integral part of these consolidated financial statements.

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BULLFROG AI HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (5,355,869)	\$ (2,802,487)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,725	1,045
Stock-based compensation	631,533	340,152
Shares issued for license	-	189,828
Shares issued for services	50,000	-
Loss on conversion of notes	92,959	-
Amortization of debt discount	20,000	214,429
Imputed interest	-	9,221
Changes in operating assets and liabilities:		
Prepaid expense	(130,882)	(15,000)
Accounts payable	(440,337)	475,399
Accrued expenses	(838,428)	373,273
Accrued expenses - related party	-	281,250
Deferred revenue	(32,000)	22,000
Net cash used in operating activities	(6,001,299)	(910,890)
Cash flows from investing activities:		
Purchases of property and equipment	-	(8,744)
Net cash used in investing activities	-	(8,744)
Cash flows from financing activities:		
Proceeds from issuance of common stock (initial public offering), net of issuance costs	7,293,651	-
Proceeds from exercise of warrants	1,494,658	-
Proceeds from convertible notes payable	-	1,016,290
Proceeds from notes payable	100,000	-
Payments of notes payable	(319,950)	-
Repayment of note payable and interest - related party	-	(49,000)
Proceeds from short term insurance financing	697,534	-
Payments of short term insurance financing	(697,534)	-
Net cash provided by financing activities	8,568,359	967,290
Net increase in cash and cash equivalents	2,567,060	47,656
Cash and cash equivalents, beginning of period	57,670	10,014
Cash and cash equivalents, end of period	\$ 2,624,730	\$ 57,670
Supplemental cash flow information:		
Cash paid for interest	\$ 93,916	\$ 5,757
Cash paid for taxes	-	-
Supplemental non-cash activity		
Reclassification of warrant	\$ -	\$ 11,097
Issuance of common stock upon conversion of notes payable	\$ 1,535,615	\$ -
Conversion of convertible note payable	\$ -	\$ 226,138
Cancellation of common stock	\$ -	\$ 8

The accompanying notes are an integral part of these consolidated financial statements.

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BULLFROG AI HOLDINGS, INC.
NOTES TO FINANCIAL STATEMENTS
December 31, 2023 and 2022

1. Organization and Nature of Business

Description of Business

Bullfrog AI Holdings, Inc. (“we”, “our” or the “Company”) was incorporated in the State of Nevada on February 6, 2020. Bullfrog AI Holdings, Inc. is the parent company of Bullfrog AI, Inc. and Bullfrog AI Management, LLC which were incorporated in Delaware and Maryland, in 2017 and 2021, respectively. All of our operations are currently conducted through Bullfrog AI Holdings, Inc., which began operations on February 6, 2020. We are a company focused specifically on advanced AI/ML-driven analysis of complex data sets in medicine and healthcare. Our objective is to utilize our platform for precision medicine approach to drug asset enablement through external partnerships and selective internal development.

Most new therapeutics will fail at some point in preclinical or clinical development. This is the primary driver of the high cost of developing new therapeutics. A major part of the difficulty in developing new therapeutics is efficient integration of complex and highly dimensional data generated at each stage of development to de-risk subsequent stages of the development process. Artificial Intelligence and Machine Learning (AI/ML) has emerged as a digital solution to help address this problem.

We use artificial intelligence and machine learning to advance medicines for both internal and external projects. Most current AI/ML platforms still fall short in their ability to synthesize disparate, high-dimensional data for actionable insight. Our platform technology, named, bfLEAP™ is an analytical AI/ML platform developed at The Johns Hopkins University Applied Physics Laboratory (JHU-APL) which is able to surmount the challenges of scalability and flexibility currently hindering researchers and clinicians by providing a more precise, multi-dimensional understanding of their data. We are deploying bfLEAP™ for use at several critical stages of development for internal programs

and through strategic partnerships and collaborations with the intention of streamlining data analytics in therapeutics development, decreasing the overall development costs by decreasing failure rates for new therapeutics, and impacting the lives of countless patients that may otherwise not receive the therapies they need.

The bfLEAP™ platform utilizes both supervised and unsupervised machine learning – as such, it is able to reveal real/meaningful connections in the data without the need for a priori hypothesis. Algorithms used in the bfLEAP™ platform are designed to handle highly imbalanced data sets to successfully identify combinations of factors that are associated with outcomes of interest.

Our primary goal is to improve the odds of success at any stage of pre-clinical and clinical therapeutics development, for in house programs, and our strategic partners and collaborators. Our primary business model is enabling the success of ongoing clinical trials or rescue of late stage failed drugs (i.e., Phase 2 or Phase 3 clinical trial failures) for development and divestiture; although, we will also consider collaborations for earlier stage drugs. We hope to accomplish this through strategic acquisitions of current clinical stage and failed drugs for in-house development, or through strategic partnerships with biopharmaceutical industry companies. We are able to pursue our drug asset enhancement business by leveraging a powerful and proven AI/ML platform (trade name: bfLEAP™) initially developed at JHU-APL. We believe the bfLEAP™ analytics platform is a potentially disruptive tool for analysis of pre-clinical and/or clinical data sets, such as the robust pre-clinical and clinical trial data sets being generated in translational R&D and clinical trial settings.

Liquidity and Going Concern

The Company has had negative cash flows from operations and operated at a net loss since inception. In the first quarter of 2023, we completed our initial public offering (“IPO”). In February 2024 the Company received net proceeds of approximately \$4.9 million dollars from an underwritten public offering of 1,507,139 shares of common stock (or pre-funded warrants in lieu thereof) and accompanying warrants to purchase 1,507,139 shares of common stock at an offering price of \$.782. The 5 year warrants have an exercise price of \$4.16. On February 21, 2024, the underwriters elected to take an over-allotment of 218,382 common shares and the Company received net proceeds of approximately \$750,000. In the absence of significant revenues in 2024 the Company believes that its capital resources are sufficient to fund planned operations for more than 12 months from the date of this filing.

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2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of Bullfrog AI Holdings, Inc. and our wholly owned subsidiaries and have been prepared in conformity with United States generally accepted accounting principles (“GAAP”). All intercompany accounts and transactions have been eliminated in consolidation.

On February 13, 2023, we completed a 1-for-7 reverse split of our common stock Stockholders’ equity and all references to shares and per share amounts in the accompanying consolidated financial statements have been adjusted to reflect the reverse stock split for all periods presented.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. These estimates include, but are not limited to, revenue recognition, allowances for doubtful accounts, recoverability of deferred tax assets and certain other of our accrued liabilities. Actual results could differ from these estimates.

Revenue Recognition

The Company recognizes revenue based on the following five step model:

- **Identification of the contract with a customer**
This step outlines the criteria that must be met when establishing a contract with a customer to supply goods or services.
- **Identification of the performance obligations in the contract**
This step describes how distinct performance obligations in the contract must be handled.
- **Determination of the transaction price**
This step outlines what must be considered when establishing the transaction price, which is the amount the business expects to receive for transferring the goods and services to the customer.
- **Allocation of the transaction price to the performance obligations in the contract**
This step outlines guidelines for allocating the transaction price across the contract’s separate performance obligations, and is what the customer agrees to pay for the goods and services.
- **Recognition of revenue when, or as, the Company satisfies a performance obligation**
Revenue can be recognized as the business meets each performance obligation. This step specifies how that should happen.

Contract Services

The Company anticipates that the majority of revenues to be recognized in the near future will result from our fee for service partnership offering, designed for biopharmaceutical companies, as well as other organizations, of all sizes that have challenges analyzing data throughout the drug development process. The Company provides the customer with an analysis of large complex data sets using the Company’s proprietary Artificial Intelligence / Machine Learning platform called bfLEAP™. This platform is designed to predict targets of interest, patterns, relationships, and anomalies. The Company believes that there will be additional on-going work requested from partners therefore the service model utilizes a master services agreement with work or task orders issued for discrete analysis performed at the discovery, preclinical, or clinical stages of drug development. The Company receives a cash fee and in some instances the potential for rights to new intellectual property generated from the analysis. Once data analysis and the analysis report are complete, the Company delivers the analysis set to the customer and recognizes revenue at that point in time.

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Financial Instruments

The carrying value of short-term instruments, including cash and cash equivalents, accounts payable and accrued expenses approximate fair value due to the relatively short period to maturity for these instruments.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. The Company utilizes a three-level valuation hierarchy for disclosures of fair value measurements, defined as follows:

Level 1 - inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 - inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the assets or liability, either directly or indirectly, for substantially the full term of the financial instruments.

Level 3 - inputs to the valuation methodology are unobservable and significant to the fair value. The Company does not have any assets or liabilities that are required to be measured and recorded at fair value on a recurring basis.

Cash

The Company considers cash to consist of cash on hand and temporary investments having an original maturity of 90 days or less that are readily convertible into cash. As of December 31, 2023 and 2022, cash balances were \$2,624,730 and \$57,670, respectively.

Concentrations of Credit Risk

The Company's financial instruments that are exposed to a concentration of credit risk are cash and accounts receivable. Occasionally, the Company's cash in interest-bearing accounts may exceed FDIC insurance limits. The financial stability of these institutions is periodically reviewed by senior management.

Cost of Sales

Cost of sales is comprised of royalties and the cost of outsourced services provided to the Company related to customer service contracts.

Property and Equipment

Property and equipment are stated at cost. When retired or otherwise disposed, the related carrying value and accumulated depreciation are removed from the respective accounts and the net difference less any amount realized from disposition is reflected in earnings. For financial statement purposes, property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives.

Advertising

The Company follows the policy of charging the costs of advertising to expense as incurred.

Income Taxes

Deferred income tax assets and liabilities are determined based on the estimated future tax effects of net operating loss and credit carry forwards and temporary differences between the tax basis of assets and liabilities and their respective financial reporting amounts measured at the current enacted tax rates. The Company records an estimated valuation allowance on its deferred income tax assets if it is not more likely than not that these deferred income tax assets will be realized.

The Company recognizes a tax benefit from an uncertain tax position if it is more likely than not that the tax position will be sustained on examination by taxing authorities. Interest and penalties associated with such uncertain tax positions are classified as a component of income tax expense.

Stock-Based Compensation

Employee and non-employee share-based compensation is measured at the grant date, based on the fair value of the award, and is recognized as an expense over the requisite service period.

Net Loss per Share

We calculate basic net loss per share by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period.

Diluted earnings per share is computed by giving effect to all potentially dilutive common stock equivalents in the period, including unvested stock options and warrants. As we have reported losses for all periods presented, all potentially dilutive securities have been excluded from the calculation of diluted net loss per share as their effect would be antidilutive.

Recent Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2024-09: Income Taxes (Topic 740): Improvements to Income Tax Disclosures that requires entities to disclose additional information about federal, state, and foreign income taxes primarily related to the income tax rate reconciliation and income taxes paid. The new standard also eliminates certain existing disclosure requirements related to uncertain tax positions and unrecognized deferred tax liabilities. The guidance is effective for our fiscal year ending December 31, 2025. The guidance does not affect recognition or measurement in our consolidated financial statements.

The Company does not believe that any other recently issued effective pronouncements, or pronouncements issued but not yet effective, if adopted, would have a material effect on the accompanying financial statements.

3. Property and Equipment

Property and equipment consisted of \$8,744 of equipment and has accumulated depreciation of \$2,770 and \$1,045, as of December 31, 2023 and 2022, respectively.

Depreciation expense totaled \$1,725 and \$1,045 in the years ended December 31, 2023 and 2022, respectively.

4. Convertible Notes

March 2020 Note

On March 27, 2020, the Company entered into a convertible loan agreement with the Maryland Technology Development Corporation with a principal balance of \$200,000 at 6% interest. The maturity date of the loan was September 27, 2021. During the year ended December 31, 2022, the full amount of the loan and interest totaling \$26,138 was converted into 205,984 shares of common stock of the Company, in accordance with the conversion notice submitted by the noteholder. Pursuant to the note agreement, the number of shares that the note converted into was based on the note balance plus accrued interest, divided by \$5,000,000, times the fully diluted equity of the company, excluding convertible securities issued for capital raising purposes. There was no gain or loss due to conversion being within the terms of the agreement.

August 2021 Note

In August 2021, the Company entered into a convertible loan agreement with an unrelated party for a commitment of up to \$95,000 with a 5% original issue discount and a 9% interest rate. The loan provided for a maturity date of February 9, 2022. We borrowed \$72,000 and \$123,000 of principal in the years ended December 31, 2021 and 2022, respectively. The noteholder had the right to convert the principal and interest into common shares of the Company at the IPO at a 20% discount to the IPO price.

As of December 31, 2022, the loan was outstanding with a principal balance of \$95,000 and accrued interest of \$35,078. The loan was paid in its entirety in February 2023.

In connection with the convertible loan agreement, the Company also issued 195,000 Warrants with an exercise price of \$1.00 exercisable for five years from issuance. In May 2022, the Company and the note holder agreed to cancel and void the warrants and enter into a new agreement for 225,000 warrants with an exercise price of \$2.50. The Company assessed the differences in fair value and determined that they were de minimis and expensed the full value of the new warrants.

December 2021 Note

On December 20, 2021, the Company entered into a loan agreement with an unrelated party. The loan provided for a December 19, 2022 maturity, a 10% original issue discount and a 6% interest rate. The Company received \$25,000 of proceeds from this note.

The note was automatically convertible into shares of common stock at a discount to the IPO price or based on the valuation of the Company, whichever was more favorable to the holder.

Initially, the loan was estimated to be issued with 355,114 warrants. Subsequent to the closing of the loan agreement, the Company enhanced the terms of the Bridge Note Offering under which the loan was closed and in April 2022 closed on the sale of approximately \$1 million in face value of convertible bridge notes. Pursuant to the enhanced terms, the warrants were issued concurrently with the conversion of the note.

Concurrent with the closing of the Company's IPO, the note converted according to its terms into 6,939 shares of common stock. No gain or loss was recognized on the conversion.

Convertible Bridge Notes

On April 11, 2022, the Company entered into an Exclusive placement agent and/or underwriter agreement with WallachBeth Capital LLC in connection with a proposed private and/or public offerings by the Company. On April 28, 2022, the Company received approximately \$775,000 of proceeds, net of approximately \$91,000 of fees and a 10% original issue discount from the sale of Convertible Bridge Notes and Warrants to several institutional investors and several individual accredited investors. In addition, the Company also received \$100,000 from the sale of a Convertible Bridge Note and Warrants to a related party earlier in April. In September 2022, the Company received an additional \$25,000 of proceeds, net of a 10% original issue discount from the sale of an additional Convertible Bridge Note and Warrant to an unrelated party.

The Convertible Bridge Notes were initially convertible at the IPO at a 20% discount to the IPO price. The Convertible Bridge Notes provided for an original maturity date of October 31, 2022.

In connection with the Convertible Bridge Notes, the purchasers were also entitled to conditional warrants to be issued upon completion of the Company's IPO. The agreement provided for the warrants to be exercisable for a period of five years from issuance at an exercise price equal to 110% of the IPO price or, if the Company failed to complete the IPO before October 22, 2022, 90% of the IPO price.

In the fourth quarter of 2022, the Company amended the Convertible Bridge Notes to (a) extend the maturity date until December 31, 2022, (b) provide that the conversion right would include interest through November 30, 2022, with interest accruing beyond that date being paid in cash and (c) revise the conversion price to be \$4.27 based on a \$25 million Company valuation.

Concurrent with the closing of the Company's IPO in February 2023, all of the Convertible Bridge Notes converted according to their terms into 269,513 shares of common stock. No gain or loss was recognized on the conversion.

5. Convertible Notes – Related Party

SAFE Agreement

On July 8, 2021, the Company entered into a Simple Agreement for Future Equity (SAFE), with a related party, at a purchase price of \$150,000. The SAFE provided for no interest and terminated after conversion upon completion of the Company's IPO. The SAFE provided for automatic conversion into the number of shares of SAFE Preferred Stock equal to the Purchase Amount divided by the Conversion Price, defined as either: (1) the SAFE Price (the price per share equal to the Post-Money Valuation Cap divided by the Company Capitalization) or (2) the Discount Price (the price per share of the Standard Preferred Stock sold in the Equity Financing multiplied by the Discount Rate), whichever calculation results in a greater number of shares of SAFE Preferred Stock.

In February 2023, the SAFE terminated and converted into 32,967 shares of common stock according to its terms upon the Company's closing of its IPO. The conversion was considered a redemption for accounting purposes and consequently, the Company recognized a \$63,626 loss on the conversion.

As of December 31, 2022, the \$150,000 received from the SAFE was recorded at 6% imputed interest.

August 2021 Note

On August 19, 2021, the Company entered into a convertible loan agreement with a related party, with a principal balance of \$99,900, an original issuance discount of 5% and a 9% interest rate. The loan provided for a maturity date of February 19, 2022. The noteholder had the right to convert the principal and interest into common shares of the Company at a conversion price based on a discount to the IPO price.

In February 2023, the related party elected to convert the convertible loan into 21,747 shares of common stock according to its terms upon the Company's closing of its IPO. The conversion was considered a redemption for accounting purposes and consequently, the Company recognized a \$29,333 loss on the conversion.

In connection with the convertible loan agreement, the Company also issued 99,000 warrants with an exercise price of \$1.00 exercisable for five years from issuance. In May 2022, the Company and the note holder agreed to cancel and void previous warrants and enter into a new agreement for 115,185 warrants with an exercise price of \$2.50. The Company assessed the differences in fair value and determined that they were de minimis and expensed the full value of the new warrants.

6. Related Party

During the year ended December 31, 2023, the Company issued 75,000 stock options to its Chief Financial Officer for services rendered.

During the year ended December 31, 2021, the Company issued 29,286 common stock options to related parties for services rendered. The options have an original life of 10 years and vest over different periods for up to 24 months. During the years ended December 31, 2023 and 2022, the Company recognized \$1,707 and \$1,803, respectively of stock-based compensation related to these options.

At various times in 2021, the Company entered into unsecured short term loan agreements with a related party for an aggregate principal balance of \$9,000, each with a one-year maturity date, accruing interest at 5% and imputing an additional 1% interest. The full amount of the loans and interest was repaid in 2022.

7. Notes Payable

In January 2023 the Company entered into a short-term note payable with a principal balance of \$100,000, an original discount of 20% and a 9% interest rate. The note was paid in its entirety in February 2023.

In February 2023, the Company entered into an agreement to finance a portion of the premium for its Directors and Officers Insurance. The agreement provides for financing of \$697,534 of the premium, repayments in 10 equal monthly installments of \$71,485 each through December 2023 and accrued interest at 6.5%. The financing was repaid during 2023.

8. Stockholders' Equity

Preferred Stock

The Company has 10,000,000 shares of preferred stock authorized at a par value of \$0.00001 with 5,500,000 being designated as Series A Convertible Preferred Stock. On October 5, 2022, the Company entered into an exchange agreement with an Investor providing for the exchange of 734,492 shares of common stock into 73,449 shares of Series A Convertible Preferred Stock. Each share of Series A Convertible Preferred Stock is convertible at any time into 10 shares of the Company's common stock. The Series A Preferred Stock is the economic equivalent of the common stock but has no voting rights and is subject to a blocker which prohibits the conversion into common stock if it would result in the Investor owning more than 4.99% of the Company's outstanding common stock at such time. The Company evaluated the terms of the exchange and determined there was no significant change in fair value and therefore the Series A Preferred Stock was valued at \$315,000 which is the Investor's basis in the common stock that was exchanged.

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Common Stock

The Company has 100,000,000 shares of common stock authorized at a par value of \$0.00001. During the year ended December 31, 2022, the Company:

- Exchanged 734,429 shares of common stock for shares of Series A Convertible Preferred stock as noted above,
- Issued 205,984 shares of common stock pursuant to a conversion of \$26,138 worth of convertible notes principal and interest,
- Cancelled 112,225 shares of common stock as the change in number of shares issued as part of the cancellation of the prior agreements and new agreements with advisors, and
- Issued 39,879 shares of common stock pursuant to a license agreement valued at \$189,828.

After the Company signed two licenses for two drug programs from universities in the first half of 2022 it engaged an independent valuation firm to perform an Enterprise-Equity valuation. The results of this engagement resulted in an increase in the value per share of common stock used in the Black Scholes option pricing model employed to value the Company's equity grants and warrant issuances.

In February 2023, the Company completed its IPO for the sale of 1,297,318 units (each, a "Unit," collectively, the "Units") at a price of \$6.50 per Unit for a total of approximately \$8.4 million of gross proceeds. Each Unit consisted of one share of the Company's common stock, one tradeable warrant (each, a "Tradeable Warrant," collectively, the "Tradeable Warrants") to purchase one share of common stock at an exercise price of \$7.80 per share, and one non-tradeable warrant (each, a "Non-tradeable Warrant," collectively, the "Non-tradeable Warrants"; together with the Tradeable Warrants, each, a "Warrant," collectively, the "Warrants") to purchase one share of the Company's common stock at an exercise price of \$8.125.

In connection with the completion of its IPO, the Company issued an aggregate of 331,166 shares of common stock upon the conversion of certain outstanding convertible debt.

In connection with the IPO, in February 2023, the Company completed a 1-for-7 reverse split of our common stock. Stockholders' equity and all references to shares and per share amounts in the accompanying consolidated financial statements have been retroactively adjusted to reflect the reverse stock split for all periods presented.

In February 2023, the Company issued 7,692 shares of common stock for consulting services and recognized \$50,000 of compensation expense related to these shares.

In the second quarter of 2023, we issued 436,533 shares of common stock following the exercise of 436,533 warrants for proceeds of \$1,494,658.

Dilutive securities are excluded from the diluted earnings per share calculation because their effect is anti-dilutive. As of December 31, 2023 and December 31, 2022, 3,521,880 and 927,373 warrants were not included in the calculation of net loss per share, respectively. In addition, 527,717 and 69,217 options for common shares were not included in the calculation of net loss per share, respectively.

2022 Equity Incentive Plan

In November 2022, the Company's Board of Directors adopted, and its shareholders approved the 2022 Equity Incentive Plan (the "Plan"). The Plan provides for the granting of equity-based awards to employees, directors, and consultants. The Plan provides for equity-based awards including incentive stock options, non-qualified stock options, stock appreciation rights, performance share awards, cash awards and other equity-based awards. Awards are limited to a maximum term of 10 years and any exercise prices shall not be less than 100% of the fair market value of one share of common stock on the grant date. The Plan authorizes an initial maximum number of shares underlying awards of 900,000 with an automatic annual 15% increase beginning in 2024. As of December 31, 2023, there were 441,500 awards authorized but unissued available under the Plan.

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Stock Options

The following tables summarize the stock option activity for the years ended December 31, 2023 and 2022:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2021	468,571	\$ 3.32	7.4	\$ -
Granted	-	\$ -		
Exercised	-	\$ -		
Forfeited / canceled	(399,354)	\$ -		
Outstanding at December 31, 2022	69,217	\$ 3.06	7.1	\$ -
Granted	458,500	\$ 4.34		
Exercised	-	\$ -		
Forfeited / canceled	-	\$ -		
Outstanding at December 31, 2023	527,717	\$ 4.17	9.0	\$ 112,141
Vested at December 31, 2023	255,826	\$ 4.01	8.5	\$ 62,193

The fair value of options granted in the year ended December 31, 2023 was estimated using the Black-Scholes option pricing model based on the assumptions in the table below:

	2023
Expected dividend yield	0%
Expected volatility	87% - 92%
Risk-free interest rate	3.4% - 4.4%
Expected life (in years)	5.0 - 6.0

- *Volatility* - The trading volatility was determined by calculating the volatility of the Company's peer group.
- *Expected life of options* - The expected life of options granted to employees was determined using the simplified method.
- *Risk-free interest rate* - This is the U.S. Treasury rate, having a term comparable to the expected life of the stock option.
- *Dividend yield* - The Company does not expect to pay a dividend in the foreseeable future.

The weighted-average grant-date fair value of options granted during the year ended December 31, 2023 was \$.15. The total grant-date fair value of options granted and vested during the year ended December 31, 2023 was approximately \$1,445,200 and \$585,500, respectively.

No options were exercised in any of the periods presented.

During the years ended December 31, 2023 and 2022, the Company recognized \$592,268 and \$2,010, respectively of compensation expense related to stock options.

As of December 31, 2023, the total unrecognized compensation expense related to unvested stock options, was approximately \$61,000, which the Company expects to recognize over a weighted-average period of approximately 1.9 years.

Warrants

During the years ended December 31, 2023 and 2022, the Company granted a total of 3,195,906 and 415,247 warrants, respectively. The warrants have an original life of ten years and vest over varying periods up to 24 months from the grant date. During the year ended December 31, 2023, warrants to purchase 27,867 shares vested and had a fair value of \$39,265. During the year ended December 31, 2022, 350,908 shares of warrants vested and amended with a fair value of \$337,269, 51,941 shares of warrants were reclassified with a fair value of \$11,097, and 42,057 shares of warrants with a fair value of \$1,883 were forfeited.

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During the year ended December 31, 2021, the Company granted a total of 431,659 warrants. Of this amount, 200,000 warrants, with a fair value of \$12,462, were granted to advisors related to the Company's IPO objective. The warrants have an original life of five years and vest 30 days before the intended IPO. During the year ended December 31, 2021, 0 shares of these warrants were vested. As of June 30, 2022, the warrants for 200,000 shares were cancelled and voided per agreement of the warrant holder and the Company. There was no gain or loss recognized due to this cancellation.

During the year ended December 31, 2021, the Company issued 92,859 warrants with a fair value of \$12,980, in connection with convertible bridge debt agreements with multiple parties including a related party. The warrants had an original life of five years. During the period ending June 30, 2022, the Company determined that 50,735 warrants, with a fair value of \$11,097, should not have been issued. The fair value was reclassified to additional paid in capital. In May 2022, the Company and the noteholders agreed to cancel and void the previous 99,000 warrants and entered into a new agreement for 115,185 warrants and the exercise price increased to \$2.50 from \$1.00, with a fair value of \$15,412. In May 2022, the Company and the note holders agreed to cancel and void the previous 195,000 warrants and entered into a new agreement for 225,000 warrants with an exercise price of \$2.50, with a fair value of \$64,978.

The 92,859 warrants discussed above were initially discounted against the notes, subsequent to the year ended December 31, 2021, they were deemed voided and these individuals were issued new warrants in accordance with the new terms as stated above. We assessed the differences in fair values and determined the values were de minimis and expensed the full value of the new warrants.

During the year ended December 31, 2023, the Company issued the following warrants:

- In February 2023, in connection with the completion of the initial public offering, the Company issued 276,452 contingent warrants to certain debt holders with an exercise price of \$4.27 and an expiration date 5 years from issuance.
- In February 2023, in connection with the completion of the initial public offering, the Company issued 18,000 contingent warrants as fees to the Company's underwriters with an exercise price of \$8.125 and an expiration date 4 years from issuance.
- As part of the sale of units in the Company's initial public offering the Company issued 1,297,318 tradable warrants with an exercise price of \$7.80 and an expiration date 5 years from issuance. Also, as part of the sale of units in the Company's initial public offering, the Company issued 1,297,318 non-tradable warrants with an exercise price of \$8.125 and an expiration date 5 years from issuance.
- In February 2023, as part of the Company's initial public offering, the Company issued 153,409 tradeable warrants to our underwriters pursuant to the overallotment options with an exercise price of \$7.80 and an expiration date 5 years from issuance. Also in February 2023, as part of the Company's initial public offering the Company issued 153,409 non-tradeable warrants to our underwriters pursuant to the overallotment options with an exercise price of \$8.125 and an expiration date 5 years from issuance.

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The following table provides details over the Company's outstanding warrants including those issued as consideration for services and those issued in conjunction with transactions as of December 31, 2023:

Exercise Price	Expiration	Number of Warrants
\$0.0007	2030	274,286
\$2.10 - \$2.66	2026 - 2032	460,445
\$3.36 - \$4.27	2028 - 2029	115,277
\$6.51 - \$7.80	2026 - 2032	1,484,929
\$8.125	2027 - 2028	1,461,227
		<u>3,796,164</u>

During the years ended December 31, 2023 and 2022, the Company recognized \$39,265 and \$338,142, respectively of compensation expense related to certain warrants.

Warrants Issued as Consideration for Services

The following table summarizes the activity for warrants issued as consideration for services for the years ended December 31, 2023 and 2022:

	Number of Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2021	885,373	\$ 2.59	7.4	\$ 2,147
Granted	56,629	\$ 3.87		
Exercised	-	\$ -		
Forfeited / canceled	(263,826)	\$ 5.50		
Outstanding at December 31, 2022	678,176	\$ 1.57	7.6	\$ 2,131,123
Granted	-	\$ -		
Exercised	-	\$ -		
Forfeited / canceled	-	\$ -		
Outstanding at December 31, 2023	<u>678,176</u>	<u>\$ 1.57</u>	<u>6.6</u>	<u>\$ 1,209,136</u>
Vested at December 31, 2023	<u>671,789</u>	<u>\$ 1.56</u>	<u>6.6</u>	<u>\$ 1,205,305</u>

The fair value of options granted in the years ended 2022 were estimated using the Black-Scholes option pricing model based on the assumptions in the table below:

	2022
Expected dividend yield	0%
Expected volatility	89%
Risk-free interest rate	1.86% - 1.97%
Expected life (in years)	10

- *Volatility* - The trading volatility was determined by calculating the volatility of the Company's peer group.
- *Expected life of options* - The expected life of options granted to employees was determined using the simplified method.
- *Risk-free interest rate* - This is the U.S. Treasury rate, having a term comparable to the expected life of the stock option.
- *Dividend yield* - The Company does not expect to pay a dividend in the foreseeable future.

No warrants were issued in the year ended December 31, 2023.

As of December 31, 2023, the total unrecognized compensation expense related to unvested warrants was approximately \$,000, which the Company expects to recognize over a weighted-average period of approximately 0.2 years.

The total grant-date fair value of warrants vested during the year ended December 31, 2023 was approximately \$9,300.

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9. Income Taxes

Deferred income taxes reflect the net tax effects of loss and credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets for federal and state income taxes are as follows:

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating losses	\$ 1,432,634	\$ 924,000
Capitalized research and development	283,353	-
Stock-based compensation	175,213	-
Intangibles	173,273	-
Other	9,438	-
Total deferred tax assets	2,073,911	924,000
Valuation allowance	(2,073,459)	(924,000)
Net deferred tax asset	452	-
Deferred tax liabilities:		
Property and equipment	(452)	-
Total deferred tax liabilities	(452)	-
Net deferred tax asset / (liability)	<u>\$ -</u>	<u>\$ -</u>

Realization of our deferred tax assets is dependent upon future earnings, if any, the timing, and amount of which are uncertain. Because of our lack of U.S. earnings history, the net U.S. deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$1,151,827 and \$585,000 during the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023, the Company has available for federal income tax purposes a net operating loss carry forward of approximately \$1.1 million and a total state net operation loss carryforward of approximately \$2 million. The net operating loss carryforwards do not expire and may be used to offset future taxable income. Utilization of some of the federal and state net operating loss carryforwards are subject to annual limitations due to the “change in ownership” provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitations may result in the expiration of net operating losses and credits before utilization.

The Company has provided a valuation reserve against the full amount of the net operating loss benefit, since in the opinion of management, based upon the earnings history of the Company; it is more likely than not that the benefits will not be realized. All or portion of the remaining valuation allowance may be reduced in future years based on an assessment of earnings sufficient to fully utilize these potential tax benefits.

We have incurred net operating losses since inception and we do not have any significant unrecognized tax benefits. Our policy is to include interest and penalties related to unrecognized tax benefits, if any, within the provision for taxes in the consolidated statements of operations. If we are eventually able to recognize our uncertain positions, our effective tax rate would be reduced. We currently have a full valuation allowance against our net deferred tax asset which would impact the timing of the effective tax rate benefit should any of these uncertain tax positions be favorably settled in the future. Any adjustments to our uncertain tax positions would result in an adjustment of our net operating loss or tax credit carry forwards rather than resulting in a cash outlay.

We file income tax returns in the U.S. and certain state jurisdictions. We are not currently under examination in these jurisdictions for any tax year. The Company’s tax years beginning with 2020 are open tax years. Because of net operating losses and research credit carryovers, substantially all of our tax years remain open to examination.

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The Company did not have unrecognized tax benefits as of December 31, 2023 and 2022, and does not anticipate this to change significantly over the next 12 months. The Company will recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. Reconciliations between the statutory federal income tax rate and the effective income tax rate of income tax expense is as follows:

	December 31, 2023
U.S. Federal statutory tax rate	21.0%
Stock-based compensation	(1.1)
Other	(3.3)
Change in valuation allowance	(16.6)
	_%

10. Material Agreements

JHU-APL Technology License

On February 7, 2018, the Company entered into an exclusive, world-wide, royalty-bearing license from JHU-APL for the technology. The license covers three (3) issued patents, one (1) new provisional patent application, non-patent rights to proprietary libraries of algorithms and other trade secrets, the license also includes modifications and improvements. In October of 2021, the Company executed an amendment to the original license which represents improvements and new advanced analytics capabilities. In consideration of the rights granted to the Company under the License Agreement JHU received a warrant equal to five percent (5%) of the then fully diluted equity base of the Company, which shall be diluted following the closing of the IPO. Under the terms of the License Agreement, JHU will be entitled to eight percent (8%) royalty on net sales for the services provided by the Company in which the JHU licensed technology was utilized, as well as fifty percent (50%) of all sublicense revenues received by the Company. In addition, the Company is required to pay JHU an annual maintenance fee of \$1,500. Minimum annual royalty payments are \$20,000 for 2022, \$80,000 for 2023, and \$300,000 for 2024 and beyond, if cumulative annual royalty payments do not reach these levels, the amount due to JHU to reach the annual minimum is due by January 31st of the following year. Failure to make annual royalty payments is considered a material breach under the agreement and upon notice from JHU of a material breach, the Company shall have 60 days to cure the material breach. On July 8, 2022, the company entered into an exclusive, world-wide, royalty-bearing license from JHU-APL for the additional technology developed to enhance the bLEAP™ platform. The new license provides additional intellectual property rights including patents, copyrights, and knowhow to be utilized under the Company’s bLEAP™ analytical AI/ML platform. This license supersedes the previous license. In consideration of the new license, the Company issued 39,879 shares of common stock. Under the terms of the new License Agreement, JHU will be entitled to eight percent (8%) of net sales for the services provided by the Company to other parties and three percent (3%) for internally development drug projects in which the JHU license was utilized. The new license also contains tiered sub licensing fees that start at 50% and reduce to 25% based on revenues. In addition, under the new license agreement, the minimum annual royalty payments are \$30,000 for 2022, \$60,000 for 2023, and \$300,000 for 2024 and beyond.

On May 31, 2023, the Company and JHU-APL entered into Amendment number 1 of the July 8, 2022 License Agreement whereby the Company gained access to certain improvements including additional patents and knowhow in exchange for a series of payments totaling \$275,000. The first of these payments for \$75,000 was due in July 2023 followed by payments of \$75,000, \$75,000, and \$50,000 in years 2025, 2026 and 2027, respectively. The amendment also reduced the 2023 minimum annual royalty payment to \$60,000, all other financial terms remain the same. As of December 31, 2023, we have accrued \$0,000 of the 2023 minimum annual royalty payments.

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George Washington University - Beta2-spectrin siRNA License

On January 14, 2022, the Company entered into an exclusive, world-wide, royalty-bearing license from George Washington University (GWU) for rights to use siRNA targeting Beta2-spectrin in the treatment of human diseases, including hepatocellular carcinoma (HCC). The license covers methods claimed in three US and worldwide patent applications, and also includes use of this approach for treatment of obesity, non-alcoholic fatty liver disease, and non-alcoholic steatohepatitis.

In consideration of the rights granted to the Company under the License Agreement the Company paid GWU a \$20,000 License Initiation Fee. Under the terms of the License Agreement, GWU will be entitled to a three percent (3%) royalty on net sales subject to quarterly minimums once the first sale has occurred subsequent to regulatory approval, as well sublicense or assignment fees in the event the Company sublicenses or assigns their rights to use the technology. The Company will also reimburse GWU for previously incurred and ongoing patent costs. The Sublicense and Assignment fee amounts decline as the Company advances the clinical development of the licensed technology. The license agreement also contains milestone payments for clinical development through the approval of an NDA and commercialization. As of December 31, 2023 and 2022, there has been no accrual for royalties since we have not begun to generate applicable revenue. The Company assessed whether the license should be capitalized and determined that the licensed program is in the early stage and therefore may not be recoverable; the Company expensed the license fee and will expense development costs until commercial viability is likely.

Johns Hopkins University – Mebendazole License

On February 22, 2022, the Company entered into an exclusive, world-wide, royalty-bearing license from Johns Hopkins University (JHU) for the use of an improved formulation of Mebendazole for the treatment of any human cancer or neoplastic disease. This formulation shows potent activity in animal models of different types of cancer and has been evaluated in a Phase I clinical trial in patients with high-grade glioma (NCT01729260). The trial, an open-label dose-escalation study, assessed the safety and efficacy of the improved formulation with adjuvant temozolomide in 24 patients with newly diagnosed gliomas. Investigators observed no dose-limiting toxicity in patients receiving all but the highest tested dose (200mg/kg/day). Four of the 15 patients receiving the maximum tested dose of 200mg/kg/day experienced dose-limiting toxicity, all of

which were reversed by decreasing or eliminating the dose given. There were no serious adverse events attributed to Mebendazole at any dose during the trial. 41.7% of patients who received Mebendazole were alive at two years after enrollment, and 25% were alive at four years (Gallia et al., 2021).

The license covers six (6) issued patents and one (1) pending application. In consideration of the rights granted to the Company under the License Agreement, JHU will receive a staggered Upfront License Fee of \$250,000. The initial payment for \$50,000 was paid and the remaining balance of \$200,000 was paid after the Company completed its IPO. The Company will also reimburse JHU for previously incurred and ongoing patent costs. Under the terms of the License Agreement, JHU will be entitled to three and one-half percent (3.5%) royalty on net sales by the Company. In addition, the Company is required to pay JHU minimum annual royalty payments of \$5,000 for 2023, \$10,000 for 2024, \$20,000 for 2025, \$30,000 for 2026 and \$50,000 for 2027 and each year after until the first commercial sale after which the annual minimum royalty shall be \$250,000. The license agreement also contains milestone payments for clinical development steps through the approval of an NDA and commercialization. As of December 31, 2023 and 2022, the balance of accrued expense related to this license agreement was \$10,000 and \$242,671, respectively. The Company assessed whether the license should be capitalized and determined that the licensed program is in the early stage and therefore may not be recoverable; the Company expensed the license fee and will expense development costs until commercial viability is likely.

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Johns Hopkins University – Prodrug License

On October 13, 2022, the Company entered into an exclusive, world-wide, royalty-bearing license from JHU and the Institute of Organic Chemistry and Biochemistry (IOCB) of the Czech Academy of Sciences for rights to commercialize N-substituted prodrugs of Mebendazole that demonstrate improved solubility and bioavailability. The license covers prodrug compositions and use for treating disease as claimed in multiple US and worldwide patent applications. In consideration for the rights granted to the Company under the License Agreement JHU and IOCB will receive a staggered upfront license fee of \$100,000. The Company will also reimburse JHU and IOCB for previously incurred patent costs. Under the terms of the License Agreement, JHU and IOCB will be entitled to four percent (4.0%) royalty on net sales by the Company. In addition, the Company is required to pay JHU and IOCB minimum annual royalty payments of \$5,000 for 2027, \$10,000 for 2028, \$20,000 for 2029, \$30,000 for 2030 and \$50,000 for 2031 and each year after until the first commercial sale after which the annual minimum royalty shall be \$150,000. The license agreement also contains milestone payments for patent grants, clinical development steps through the approval of an NDA and commercialization. As of December 31, 2023 and 2022, the balance of accrued expense related to this license agreement was \$0 and \$133,238, respectively. The Company assessed whether the license should be capitalized and determined that the licensed program is in the early stage and therefore may not be recoverable; the Company expensed the license fee and will expense development costs until commercial viability is likely.

11. Commitments and Contingencies

While not assured, management does not believe, based upon information available at this time, that a loss contingency will have a material adverse effect on the Company's financial position, results of operations or cash flows. Additionally, the Company does not have any material commitments.

12. Subsequent Events

On February 5, 2024 the Company received net proceeds of approximately \$4.9 million dollars from an underwritten public offering of 1,507,139 shares of common stock (or pre-funded warrants in lieu thereof) and accompanying warrants to purchase 1,507,139 shares of common stock at an offering price of \$.782. The 5 year warrants have an exercise price of \$4.16. On February 21, 2024, the underwriters elected to take an overallotment of 218,382 common shares and the Company received net proceeds of approximately \$750,000.

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PART II- INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the costs and expenses payable by the Company in connection with the issuance and distribution of the securities being registered hereunder. All amounts are estimates except the SEC registration fee.

SEC registration fees	\$	250.00
Accounting fees and expenses	\$	4,500.00
Legal fees and expenses	\$	25,000.00
Miscellaneous	\$	5,000.00
Total	\$	<u>34,750.00</u>

Item 14. Indemnification of Directors and Officers.

NRS 78.7502(1) provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, except an action by or in the right of the corporation, by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with the action, suit or proceeding if he: (a) is not liable pursuant to NRS 78.138; or (b) acted in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful.

NRS Section 78.7502(2) provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses, including amounts paid in settlement and attorneys' fees actually and reasonably incurred by him in connection with the defense or settlement of the action or suit if he: (a) is not liable pursuant to NRS 78.138; or (b) acted in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the corporation. Indemnification may not be made for any claim, issue or matter as to which such a person has been adjudged by a court of competent jurisdiction, after exhaustion of all appeals there from, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court in which the action or suit was brought or other court of competent jurisdiction determines upon application that in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for such expenses as the court deems proper.

Our Articles of Incorporation provides that very person who was or is a party to, or is threatened to be made a party to, or is involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he, or a person of whom he is the legal representative, is or was a director or officer of the Company, or is or was serving at the request of the Company as a director or officer of another corporation, or as its representative in a partnership, joint venture, trust or other enterprise, shall be indemnified and held harmless to the fullest extent legally permissible under the laws of the State of Nevada from time to time against all expenses, liability and loss (including attorney's fees, judgments, fines and amounts paid or to be paid in settlement) reasonably incurred or suffered by him in connection therewith. Such right of indemnification shall be a contract right which may be enforced in any matter desired by such person. The expenses of the officers and directors incurred in defending a civil

or criminal action, suit or proceeding must be paid by the Company as they are incurred and in advance of the final disposition of the action, suit or proceeding, upon receipt of an undertaking by or on behalf of the director or officer to repay the amount if it is ultimately determined by a court of competent jurisdiction that he is not entitled to be indemnified by the Company. Such right of indemnification shall not be exclusive of any other right which such directors, officers or representatives may have or hereafter acquire, and, without limiting the generality of such statement, they shall be entitled to their respective rights of indemnification under any bylaw, agreement, vote of stockholders, provision of law, or otherwise, as well as their rights under this Article.

NRS Section 78.747 provides that except as otherwise provided by specific statute, no director or officer of a corporation is individually liable for a debt or liability of the corporation, unless the director or officer acts as the alter ego of the corporation. The court as a matter of law must determine the question of whether a director or officer acts as the alter ego of a corporation.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or controlling persons of ours, pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act of 1933, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by us of expenses incurred or paid by a director, officer or controlling person of ours in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered hereunder, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

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Item 15. Recent Sales of Unregistered Securities.

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act. The information provided below does not give effect to the proposed reverse stock split described in the accompanying prospectus.

On October 18, 2024 the Company entered into a securities purchase agreement with certain institutional and accredited investors, pursuant to which securities purchase agreement the Company agreed to issue to the Purchasers, in a registered direct offering, (i) 862,602 shares of the Company's common stock, pre-funded warrants to purchase up to 702,398 shares of Common Stock, with an exercise price of \$0.0001 per share, at a purchase price of \$2.00 per share of Common Stock and a purchase price of \$1.9999 per Pre-Funded Warrant, and (ii) in a concurrent private placement, warrants to purchase an aggregate of 1,565,000 shares of Common Stock with an exercise price of \$2.00 per share, which are exercisable after six (6) months from the date of issuance for a five-year period from the Initial Exercise Date (as defined in the Purchase Agreement). Such registered direct offering and concurrent private placement are referred to herein as the "Transactions."

On October 18, 2024 the Company entered into a Placement Agency Agreement with Wallachbeth Capital, LLC, as the placement agent in connection with the Transactions. As part of the Placement Agent fee, in connection with the Transactions, the Company issued to the Placement Agent (or its designees) a warrant (the "Placement Agent Warrant") to purchase an aggregate of 62,600 shares of Common Stock, at an exercise price per share equal to \$2.00 per share.

In December 2021, the Company initiated a placement of Bridge Notes seeking \$1.5M in operating capital to ensure the Company had operating capital while it finished the audit of its financial statements and prepared the S-1 registration statement related to the IPO. In December, the Company sold a convertible promissory note to an unrelated party for \$25,000. On April 11, 2022, the Company entered into an Exclusive placement agent and/or underwriter agreement with WallachBeth Capital LLC in connection with a proposed private and/or public offerings by the Company. As discussed in Footnote 2, a significant component of the Company's plan to secure capital is the intention of the Company to seek to be listed on a national exchange through an initial public offering ("IPO") of its common stock. WallachBeth was engaged in this regard and on April 28, 2022 the Company received net proceeds of approximately \$775,000 from the sale of Convertible Bridge Notes and Warrants to several institutional investors as well as several individual accredited investors. In addition to the money received on April 28th, the Company also received \$100,000 from the sale of a Convertible Bridge Note and Warrants to a related party in early April. The Company also received net proceeds of \$20,000 from the sale of one additional Convertible Bridge Note in September 2022. The bridge notes are convertible at the IPO at a 20% discount to the IPO price and the purchasers will also a warrant for each share of common stock issued upon conversion. The warrant exercise price will be 90% of the per share IPO price.

In November 2021, 400,000 shares of common stock were issued under a consulting agreement with Dane Saglio, for services consistent with the responsibilities of a Chief Financial Officer. In addition, a total of 972,500 warrants with exercises prices of \$0.30-\$0.38 were issued to consultants who have been engaged as Company management and advisors. These warrant agreements have vesting terms that range for 12 to 36 months. In addition, the Company issued 205,000 options to employees with an exercise price of \$0.38 with vesting terms that range from 12 -24 months.

Except as otherwise set forth above, in connection with the foregoing, the Company relied upon the exemption from registration under Section 4(a)(2) of the Securities Act of 1933, as amended, for transactions not involving a public offering.

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Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

Exhibit	Description
3.1	Amended and Restated Articles of Incorporation of Bullfrog AI Holdings, Inc. incorporated by reference to Exhibit 3.1 to the Company's Amendment to the Registration Statement on Form S-1 (No. 333-267951) filed with the Securities and Exchange Commission on February 13, 2023.
3.2	Bylaws of Bullfrog AI Holdings, Inc. incorporated by reference to Exhibit 3.2 to the Company's Amendment to the Registration Statement on Form S-1 (No. 333-267951) filed with the Securities and Exchange Commission on February 13, 2023.
4.1	Form of Common Warrant, incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 21, 2024.
4.2	Form of Placement Agent Warrant, incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 21, 2024.
5.1**	Opinion of Sichenzia Ross Ference Carmel LLP.
10.1	Acquisition Agreement with Bullfrog AI, Inc. incorporated by reference to Exhibit 10.1 to the Company's Amendment to the Registration Statement on Form S-1 (No. 333-267951) filed with the Securities and Exchange Commission on February 13, 2023.
10.2	Advisor Agreement between the Company and Greentree Financial Group, Inc. incorporated by reference to Exhibit 10.2 to the Company's Amendment to the Registration Statement on Form S-1 (No. 333-267951) filed with the Securities and Exchange Commission on February 13, 2023.
10.3	Consulting Agreement between the Company and Garrett Newman incorporated by reference to Exhibit 10.3 to the Company's Amendment to the Registration Statement on Form S-1 (No. 333-267951) filed with the Securities and Exchange Commission on February 13, 2023.
10.4	Employment Agreement with Vininder Singh incorporated by reference to Exhibit 10.4 to the Company's Amendment to the Registration Statement on Form S-1 (No. 333-267951) filed with the Securities and Exchange Commission on February 13, 2023.
10.5	Patent License Agreement between the Company and George Washington University, dated January 14, 2022 incorporated by reference to Exhibit 10.6 to the Company's Amendment to the Registration Statement on Form S-1 (No. 333-267951) filed with the Securities and Exchange Commission on February 13, 2023.

10.6	Exclusive License Agreement between the Company and Johns Hopkins University, dated February 22, 2022 incorporated by reference to Exhibit 10.7 to the Company's Amendment to the Registration Statement on Form S-1 (No. 333-267951) filed with the Securities and Exchange Commission on February 13, 2023.
10.7	License Agreement between the Company and Johns Hopkins Applied Physics Laboratory LLC, dated July 8, 2022 incorporated by reference to Exhibit 10.8 to the Company's Amendment to the Registration Statement on Form S-1 (No. 333-267951) filed with the Securities and Exchange Commission on February 13, 2023.
10.8	License Agreement between the Company and Johns Hopkins Applied Physics Laboratory LLC, dated February 7, 2018 incorporated by reference to Exhibit 10.5 to the Company's Amendment to the Registration Statement on Form S-1 (No. 333-267951) filed with the Securities and Exchange Commission on February 13, 2023.
10.9	License Agreement between the Company and Johns Hopkins University (JHU) and the Institute of Organic Chemistry and Biochemistry (IOCB) of the Czech Academy of Sciences, dated October 13, 2022 incorporated by reference to Exhibit 10.9 to the Company's Amendment to the Registration Statement on Form S-1 (No. 333-267951) filed with the Securities and Exchange Commission on February 13, 2023.
10.10	2022 Equity Compensation Plan, incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 25, 2023.
10.11	Amendment No. 1 to License Agreement between Bullfrog AI, Inc. and the John's Hopkins University Applied Physics Laboratory LLC dated June 1, 2023 incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 5, 2023.
10.12	Data Use and Technology Partnership Agreement dated September 7, 2023 incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 14, 2023.
10.13+	Commercial Agreement by and between the Company and the Lieber Institute for Brain Development dated October 13, 2023 to the Company's Current Report on Form 8-K, filed with the SEC on October 20, 2023.
10.14	Form of Securities Purchase Agreement, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 21, 2024.
10.15	Form of Placement Agency Agreement, incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 21, 2024.
14	Code of Ethics, incorporated by reference herein to Exhibit 14 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 29, 2024.
19	Insider Trading Policy, incorporated by reference herein to Exhibit 14 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 29, 2024.
21.1	List of significant subsidiaries of Bullfrog AI Holdings, Inc., incorporated by reference to Exhibit 21.1 to the Company's Amendment to the Registration Statement on Form S-1 (No. 333-267951) filed with the Securities and Exchange Commission on February 13, 2023.
23.1*	Consent of M&K CPAs, PLLC.
23.2**	Consent of Sichenzia Ross Ference Carmel LLP (included in Exhibit 5.1).
24.1**	Power of Attorney (included in signature page to this registration statement).
97	Clawback Policy, incorporated by reference herein to Exhibit 14 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 29, 2024.
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)
107**	Filing Fee table.

* Filed herewith

** Previously filed

+ Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the U.S. Securities and Exchange Commission, certain portions of this exhibit have been omitted because it is both not material and the type of information that the Company treats as private or confidential.

(b) Financial Statement Schedule

All schedules have been omitted because the information required to be set forth in the schedules is either not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933, as amended (the "Securities Act");

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purposes of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of the securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) For the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
- (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities, other than the payment by the registrant of expenses incurred and paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding, is asserted by such director, officer or controlling person in connection with the securities being registered hereby, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(c) The undersigned Registrant hereby undertakes that it will:

(1) for determining any liability under the Securities Act, treat the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant under Rule 424(b)(1), or (4) or 497(h) under the Securities Act as part of this registration statement as of the time the Commission declared it effective.

(2) for determining any liability under the Securities Act, treat each post-effective amendment that contains a form of prospectus as a new registration statement for the securities offered in the registration statement, and that offering of the securities at that time as the initial bona fide offering of those securities.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Gaithersburg, State of Maryland, on November 25, 2024.

Bullfrog AI Holdings, Inc.

By: /s/ Vininder Singh
Vininder Singh
Its: Chief Executive Officer
(Principal Executive Officer)

By: /s/ Dane Saglio
Dane Saglio
Its: Chief Financial Officer
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.

/s/ Vininder Singh November 25, 2024
Vininder Singh
Chief Executive Officer and Director (Principal Executive Officer)

/s/ Dane Saglio November 25, 2024
Dane Saglio
Chief Financial Officer
(Principal Financial and Accounting Officer)

/s/ * November 25, 2024
R. Donald Elsey
Director

/s/ * November 25, 2024
William Enright
Director

/s/ * November 25, 2024
Jason D. Hanson
Director

*
/s/ Vininder Singh
Vininder Singh
Attorney-in-Fact

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CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the inclusion in this Registration Statement of Bullfrog AI Holdings, Inc. on Form S-1, as amended, of our report dated March 29, 2024, with respect to our audit of the consolidated financial statements for the years ended December 31, 2023 and 2022, and our report dated April 25, 2023, with respect to our audit of the consolidated financial statements for the years ended December 31, 2022 and 2021. We also consent to the reference to our firm under the caption “Experts” in the Registration Statement.

/s/ M&K CPAS, PLLC

www.mkacpas.com

The Woodlands, Texas

November 25, 2024
