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

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to_____

Commission file number: 001-41160

ALLARITY THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**87-2147982**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
24 School Street, 2nd Floor, Boston, MA	**02108**
(Address of principal executive offices)	(Zip Code)

(401) 426-4664
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	ALLR	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act**: None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the issuer was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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 pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of voting stock held by non-affiliates of the registrant, as of June 30, 2023, the last day of the registrant's most recently completed second fiscal quarter, was $3,323,760 (based on the closing price for shares of the registrant's common stock as reported by the Nasdaq Capital Market on June 30, 2023). Shares of common stock held by each executive officer and director have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 7, 2024, there were 6,178,892 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2024 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2023.

ALLARITY THERAPEUTICS, INC.

ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2023

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When used herein, unless the context requires otherwise, references to the "Company," "we," "our" and "us" refer to Allarity Therapeutics, Inc., a Delaware corporation.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the "Annual Report") contains forward-looking statements that involve substantial risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the U.S. Private Securities Litigation Reform Act, Section 21E of the Securities Exchange Act of 1934, as amended, and other federal securities laws. All statements, other than statements of historical fact, contained in this Annual Report. including statements regarding our strategy, future preclinical studies and clinical trials, future financial position, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," 'will" "would," or the negative of these words or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. If one or more of these risk factors or uncertainties materialize, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements. Furthermore, we operate in a competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements relating to Allarity in this Annual Report include, but are not limited to, statements about:

- our ability to continue as a going concern as addressed in the independent registered public accounting firm's report on our audited financial statements for the year ended December 31, 2023, included in this report;
- our ability to secure immediate substantial funding for our operations, working capital and to pursue our clinical trials. If we are unable to raise capital when needed or on favorable terms, we could be forced to delay, reduce or terminate our operations, product development, other operations or commercialization efforts;
- on January 26, 2024, we received a Termination Notice from Novartis due to a material breach of our license agreement. Accordingly, under the terms of the Agreement (i) we shall cease all development and commercialization activities with respect to all licensed products; (ii) all rights and licenses granted by Novartis to Allarity shall revert to Novartis; and all liabilities due to Novartis became immediately due and payable in the amount of USD $4,900,000 plus interest;
- on December 8, 2023, James G. Cullem was terminated as our Chief Executive Officer for cause under his employment agreement. Mr. Cullem has indicated that his termination should be without cause. Any potential dispute with Mr. Cullem could result in substantial costs and be a distraction to our business;
- our ability to meet the Nasdaq Capital Market ("Nasdaq") continued listing standards. The listing of our Common Stock on Nasdaq is contingent on our compliance with Nasdaq's conditions for continued listing. We have a history of non-compliance and currently are not in compliance with the continued listing requirements. Pursuant to a Nasdaq letter dated July 14, 2023, the Company is subject to a panel monitor for a period of one year, which includes continued compliance with the stockholders' equity requirement and other continued listing requirements. Failure to meet the stockholders' equity requirement of $2,500,000 will result in immediate delisting, subject to the Company's right to appeal. On October 27, 2023, we received notification from the Nasdaq Listing Qualifications staff that it intends to delist our Common Stock because the bid price of our Common Stock has closed at less than $1 per share over the previous 30 consecutive business days. On November 16, 2023, we received an additional notification indicating that the Company's stockholders' equity as reported in its Quarterly Report on Form 10-Q for the period ended September 30, 2023, did not satisfy the continued listing requirement under Nasdaq Listing Rule 5810(c)(3) which serves as an additional basis for delisting. The Company filed a notice of appeal and is awaiting the results of a February 1, 2024 Nasdaq hearing. In the event our Common Stock is no longer listed for trading on Nasdaq, our trading volume and share price may decrease, and you may have a difficult time selling your shares of Common Stock. In addition, we may experience difficulties in raising capital which would materially adversely affect our operations and financial results. Further, delisting from Nasdaq markets could also have other negative effects, including potential loss of confidence by partners, lenders, suppliers and employees;
- our ability to maintain effective internal control over financial reporting, disclosures and procedures. If we do not maintain effective internal controls, our ability to record, process and report financial information timely and accurately could be adversely affected and could result in a material misstatement in our financial statements, which could subject us to litigation or investigations, require management resources, increase our expenses, negatively affect investor confidence in our financial statements and adversely impact the trading price of our Common Stock;
- our plans to develop and commercialize the Company's drug candidates;
- our ability to generate any revenue or become profitable;
- the impact of adjustments to our outstanding warrants because of future dilutive financings resulting in the decrease of exercise price and increase the number of shares of issuable under outstanding warrants, adjustment and exercise of such warrants would result in the material dilution of the percentage ownership of our stockholders and increase the number of shares of Common Stock in the public markets. The perception that such sales could occur could cause our stock price to fall;
- the initiation, cost, timing, progress and results of our current and future preclinical studies and clinical trials, as well as our research and development programs;
- the impacts of the ongoing COVID-19 pandemic and related restrictions as they may related to our clinical trials;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;

- the unknown consequences of a request for documents from the SEC;
- the market price of our common stock has been and may continue to be volatile;
- our ability to successfully acquire or in-license additional product candidates on reasonable terms;
- our ability to maintain and establish collaborations or obtain additional funding;
- our ability to obtain regulatory approval of its current and future drug candidates;
- our expectations regarding the potential market size and the rate and degree of market acceptance of such drug candidates;
- our expectations regarding our ability to fund operating expenses and capital expenditure requirements with our existing cash and cash equivalents, and future expenses and expenditures;
- our ability to perform our contractual obligations we have under the transaction documents for financings relating to our Series A Preferred Stock and bridge loans;
- our ability to enroll patients in our clinical trials, our clinical development activities;
- our ability to retain key employees, consultants and advisors;
- our ability to retain reliable third parties to perform the chemistry work associated with our drug discovery, preclinical activities and to conduct our preclinical studies and clinical trials in a satisfactory manner;
- our ability to secure reliable on third party manufacturers to produce clinical and commercial supplies of API for our therapeutic candidates;
- our ability to obtain, maintain, protect and enforce sufficient patent and other intellectual property rights for our therapeutic candidates and technology;
- our anticipated strategies and our ability to manage our business operations effectively;
- the impact of governmental laws and regulations;
- the possibility that we may be adversely impacted by other economic, business, and/or competitive factors;
- any future currency exchange and interest rates; and
- other risks and uncertainties indicated in this report, including those set forth in the section titled “Risk Factors” as set forth in this report, which is incorporated herein by reference.

These forward-looking statements are based on information available as of the date of this report, and current expectations, forecasts and assumptions, and involve a number of risks and uncertainties. We do not assume any obligation to update any forward-looking statements, Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date, and we do not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

PART I

Item 1. Business.

Overview

Allarity is a clinical-stage, precision medicine pharmaceutical company actively advancing in-licensed oncology therapeutics for patients with difficult-to-treat cancers leveraging Allarity's core technology, the Drug Response Predictor (DRP®) platform, to identify the patients most likely to derive clinical benefit from any individual therapeutic. In Q4, 2023, Allarity made significant changes to its business to align with current financial realities and to streamline the Allarity pipeline in order to focus resources on the clinical asset with the highest likelihood to create near and mid-term value, stenoparib. Other assets in the portfolio, namely dovitinib and Ixempra, have been terminated or deprioritized, respectively. Outlicensed assets, namely 2X-111, LiPlaCis and Irofulven, are being developed exclusively by partners in a variety of indications at the partner's discretion with support from Allarity limited to the DRP® technology for each asset. Our DRP® technology has been broadly validated across an extensive array of therapies and tumor types with a high degree of accuracy for matching the right patient to the right drug. By identifying those patients who will and who will not respond to a cancer therapeutic, the DRP® companion diagnostics platform has the potential to transform cancer therapeutic development by isolating and enrolling only those patients most likely to receive benefit. As a consequence, clinical trials can be smaller and more efficient and can provide profound clinical outcomes, enabling an enhanced probability of clinical and regulatory success. Stenoparib (formerly known as E7449 or 2X-121) is a novel dual inhibitor of poly-ADP-ribose polymerase (PARP) as well as Tankyrases, enzymes critically important in the WNT pathway. Stenoparib is currently being explored in a phase 2 clinical study in patients with advanced, recurrent ovarian cancer who have been pre-selected for enrollment using the stenoparib DRP®. As per the press release from December 5, 2023, emerging clinical data from this trial in heavily pre-treated, advanced ovarian cancer patients show promising clinical benefit across all evaluable patients and include a patient with complete response (i.e. absence of active disease).

In 2023, Allarity seated two new independent directors to its board- Laura Benjamin, PhD and Joe Vazzano. Along with the Chairman of the board, Jerry McLaughlin, Dr. Benjamin and Mr. Vazzano took the decision to replace the CEO, Mr. James Cullen, with Thomas Jensen. Mr. Jensen serves as interim CEO and is a co-founder of Allarity. He has extensive experience not only with the DRP® platform but also with capital fund raising. Mr. Jensen is currently in the process of streamlining the organization and its finances to fuel the focused development of stenoparib in ovarian cancer.

Our Corporate Approach to Developing Novel Cancer Therapeutics using the DRP® Platform

Our focused approach to address major unmet needs in oncology leverages our management's expertise in cancer drug discovery and development and in deploying Allarity's proprietary DRP® platform to identify patients whose tumors have a particular gene expression signature that reflects high likelihood of drug sensitivity. As a result, we have created substantial intellectual property around the composition of matter for our in-licensed clinical assets. The foundations of our approach include:

- ***The pursuit of clinical-stage assets:*** We strive to identify and pursue novel oncology therapeutic candidates that have advanced beyond Phase 1 clinical trials and are preferably Phase 2 to Phase 3 clinical stage assets. Accordingly, the assets we have acquired, and intend to acquire, have undergone prior clinical trials by other pharmaceutical companies. The clinical data from these programs helps us evaluate whether these candidates have shown anti-cancer activity that would support additional clinical trials in patients selected for clinical study using our DRP® platform. We have largely focused our acquisition/ in-licensing efforts on therapeutic candidates that have been the subject of prior clinical trials conducted by large pharmaceutical companies in unselected patient populations. Further we intend to select therapeutic candidates for which development can be enhanced using our drug-specific DRP® technology to advance in parallel with the therapeutic candidate in further clinical trials as a companion diagnostic.

- ***Our proprietary DRP® companion diagnostics:*** We believe our proprietary and patented DRP® platform provides us with a substantial competitive advantage for clinical and regulatory success for each of the therapeutic candidates in our pipeline. Our DRP® companion diagnostic platform is a proprietary, predictive biomarker technology that employs complex systems biology and bio-analytics with a proprietary clinical relevance filter to bridge the gap between *in vitro* cancer cell responsiveness to a given therapeutic candidate and *in vivo* likelihood of actual patient benefit from that therapeutic candidate. The DRP® companion diagnostic platform has been validated using retrospective observational studies in 35 clinical trials that were conducted or sponsored by other companies. We intend to develop and validate a drug-specific DRP® biomarker for each and every therapeutic candidate in our portfolio that can be used as a companion diagnostic to select and treat patients most likely to respond to that therapeutic candidate. Although we are in the early stages of our companion diagnostic development and have not yet received a Pre-Marketing Authorization (PMA) from the U.S. Food and Drug Administration (FDA), our DRP® technology has been peer-reviewed by numerous publications and we have patented our DRP® platform for more than 70 anti-cancer drugs. While retrospective analyses of prior clinical trials guide the clinical development of our companion diagnostics, prospective clinical trials are typically required in order to receive a PMA from the FDA.

- ***A precision oncology approach driven by our DRP®*** platform***:*** Our focused strategy is to advance our pipeline of therapeutic candidates, in parallel with DRP® companion diagnostics, to bring these therapeutic candidates, once approved, to market and to patients. Our DRP® companion diagnostic platform provides a gene expression signature that we believe reveals whether a specific tumor in a specific patient is likely to respond to one of our therapeutic candidates and therefore can be used to identify those patients who are most likely to respond to a particular therapeutic treatment in order to guide therapy decisions and lead to better treatment outcomes. We believe our DRP® companion diagnostic platform may be used both to identify a susceptible patient population for inclusion in clinical trials during the drug development process (and to exclude the non-susceptible patient population), and further to select the optimal anti-cancer drug for individual patients in the treatment setting once an anti-cancer drug is approved and marketed. By including only patients that have tumors that we believe may respond to our therapeutic candidate, we believe our proprietary DRP® companion diagnostics platform has the potential to improve the overall clinical benefit in our clinical trials and thereby improving our chances for regulatory approval to market our therapeutic candidate, while potentially reducing the time, cost, and risk of clinical development.

While we have not yet successfully received regulatory or marketing approval for any of our therapeutic candidates or companion diagnostics, and while we believe that our approach has the potential to reduce the cost and time of drug development through the identification and selection of patient populations more likely to respond to therapy, our strategy involves risks and uncertainties that differ from other biotechnology companies that focus solely on new therapeutic candidates that do not have a history of clinical development. By utilizing our DRP® platform to generate a drug-specific companion diagnostic for each of our therapeutic candidates, we believe our therapeutic candidates have the potential to advance the goal of personalized medicine by selecting only the patients most likely to benefit from each of our therapeutic candidates. Moreover, this pre-selection excludes patients who are unlikely to get benefit from a specific therapy, allowing those patients to find more effective therapeutic options. As used in this report, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that a therapeutic candidate may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for any of our therapeutic candidates or DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate or companion diagnostic may only be determined by the FDA or other applicable regulatory authorities in jurisdictions outside the United States.

Our Lead Clinical Asset, Stenoparib

Stenoparib is a novel inhibitor of the key DNA damage repair enzyme PARP. Distinct from other PARP inhibitors, stenoparib also inhibits Tankyrases, enzymes critically important in the WNT pathway- a pathway commonly activated in many different cancers that drives cancer cell survival and proliferation as well as invasion and metastasis. Stenoparib was formerly developed by Eisai, Inc. (Eisai) through Phase 1 clinical trials. We have in-licensed the intellectual property rights to develop, use and market stenoparib. Consequently, we must perform all of the obligations under these license agreements, including the payment to Esai pharmaceuticals of substantial development milestones and royalties on future sales in the event we receive marketing approval for stenoparib. If we fail to perform our obligations under our license agreement, we may lose the intellectual property rights to this therapeutic candidate, which would have a material adverse effect on our business. We are currently advancing a Phase 2 clinical trial of this therapeutic candidate for the treatment of ovarian cancer at trial sites in the U.S. and Europe together using the stenoparib-specific DRP® companion diagnostic for which the FDA has previously approved an Investigational Device Exemption (IDE) application to prospectively enroll patients onto clinical trial.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) 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. 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, for complying with new or revised accounting standards.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including presenting only the two most recent fiscal years of audited financial statements and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. 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. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

Corporate Information

Our former parent, Allarity Therapeutics A/S, was founded in Denmark in 2004 by our chief scientific officer, Steen Knudsen, Ph.D., and our Interim Chief Executive Officer, Director and Senior Vice President of Investor Relations, Thomas Jensen, both of whom were formerly academic researchers at the Technical University of Denmark working to advance novel bioinformatic and diagnostic approaches to improving cancer patient response to therapeutics. On May 20, 2021, we entered a Plan of Reorganization and Asset Purchase Agreement (the "Recapitalization Share Exchange"), between us, Allarity Acquisition Subsidiary, our wholly owned Delaware subsidiary ("Acquisition Sub"), and Allarity Therapeutics A/S, an Aktieselskab organized under the laws of Denmark. Pursuant to the terms of the Recapitalization Share Exchange, our Acquisition Sub acquired substantially all of the assets and liabilities of Allarity Therapeutics A/S in exchange for shares of our common stock on December 20, 2021, and our common stock began trading on the Nasdaq Global Market on that same day. See section titled "*BUSINESS — Recapitalization Share Exchange, Asset Acquisition and Financing.*"

Our principal executive offices are located at 24 School Street, 2nd Floor, Boston, MA 02108 and our telephone number is (401) 426-4664. Our corporate website address is *www.allarity.com*. Information contained on or accessible through our website is not a part of this report, and the inclusion of our website address in this report is an inactive textual reference only.

Allarity and its subsidiaries own or have rights to trademarks, trade names and service marks that they use in connection with the operation of their business. In addition, their names, logos and website names and addresses are their trademarks or service marks. Other trademarks, trade names and service marks appearing in this report are the property of their respective owners. Solely for convenience, in some cases, the trademarks, trade names and service marks referred to in this report are listed without the applicable ®, ™ and SM symbols, but they will assert, to the fullest extent under applicable law, their rights to these trademarks, trade names and service marks.

BUSINESS

This Annual Report contains estimates, projections and other information concerning our industry, our business and the markets for our therapeutic candidates, including data regarding the estimated size of such markets and the incidence of certain medical conditions. We obtained the industry, market and similar data set forth in this Annual Report from our internal estimates and research and from academic and industry research, publications, surveys and studies conducted by third parties, including governmental agencies. In some cases, we do not expressly refer to the sources from which this data is derived. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. While we believe our internal research is reliable, such research has not been verified by any third party.

Our Corporate History

We were founded in Denmark in 2004 by our chief scientific officer, Steen Knudsen, Ph.D., and our Interim Chief Executive Officer, Director, and Senior Vice President of Investor Relations, Thomas Jensen, both of whom were formerly academic researchers at the Technical University of Denmark working to advance novel bioinformatic and diagnostic approaches to improving cancer patient response to therapeutics. On May 20, 2021, we entered a Plan of Reorganization and Asset Purchase Agreement (the "Recapitalization Share Exchange"), between us, Allarity Acquisition Subsidiary, our wholly owned Delaware subsidiary ("Acquisition Sub"), and Allarity Therapeutics A/S, an Aktieselskab organized under the laws of Denmark. Pursuant to the terms of the Recapitalization Share Exchange, our Acquisition Sub acquired substantially all of the assets and liabilities of Allarity Therapeutics A/S in exchange for shares of our common stock on December 20, 2021, and our common stock began trading on Nasdaq on that same day.

Our Business

Our DRP® companion diagnostic platform has been retrospectively validated by us using retrospective observational studies in 35 clinical trials that were conducted or sponsored by other companies. The FDA considers a retrospective observational study to be one in which the study identifies the population and determines the exposure/treatment from historical data (i.e. data generated prior to the initiation of the study) with the variables and outcomes of interest determined at the time the study is designed. See, *Framework for FDA's Real-World Evidence Program,* page 6 (December 2018), *https://www.fda.gov/media/120060/download*. The FDA has accepted our retrospective validation in support of two IDE applications to conduct clinical trials, one with respect to LiPlaCis® and one with respect to stenoparib. However, while retrospective studies guide our clinical development of our companion diagnostics, prospective clinical trials are typically required in order to receive a PMA from the FDA.

We submitted a New Drug Application (NDA) to the FDA for our now de-prioritized therapeutic candidate, dovitinib, a second-generation "pan"-tyrosine kinase inhibitor (TKI), on December 21, 2021, for the third line treatment of mRCC in patients selected by our Dovitinib-DRP® companion diagnostic. Subsequently the FDA determined that our NDA was not sufficiently complete to permit a substantive review and therefore or NDA was not accepted for filing. The primary grounds of rejection asserted by the FDA relates to our use of prior Phase 3 clinical trial data, generated by Novartis in a "superiority" endpoint study against sorafenib (Bayer), to support a "non-inferiority" endpoint in connection with the DRP® Dovitinib companion diagnostic. We anticipate that the FDA will require a prospective Phase 3 clinical trial as well as additional dosage studies before regulatory approval of Dovitinib as a monotherapy and its companion diagnostic Dovitinib-DRP can be obtained. We have decided that the costs, risks and potential benefits of conducting these studies for dovitinib as a monotherapy for mRCC are no longer the best path toward regulatory or commercial success.

While we have suffered delays due to the COVID-19 pandemic, we continue to expand patient enrollment in our ongoing Phase 2 clinical trial for our priority program, stenoparib, a novel dual inhibitor of the key DNA damage repair enzyme PARP, as well as tankyrases, key enzymes in the WNT pathway implicated in many cancer types. We also intend to opportunistically acquire other promising oncology assets that can benefit from DRP® platform based patient identification. Our programs for dovitinib and Ixempra have been de-prioritized. Novartis has terminated the license agreement for dovitinib. These pro-active decisions to trim the pipeline allow us to funnel all resources into the development of stenoparib.

The Private Placement (PIPE Financing)

Concurrently with the execution of the Recapitalization Share Exchange on May 20, 2021, we entered into a Securities Purchase Agreement ("SPA") and related agreements with an institutional investor (the "Investor") wherein we agreed to sell, and the Investor agreed to purchase, 20,000 shares of our Series A Preferred Stock and a warrant to purchase additional shares of our common stock (the "PIPE Warrant") for an aggregate purchase price of $20 million with a closing conditioned upon the consummation of our Recapitalization Share Exchange and a listing of our common stock on Nasdaq. Simultaneously with the execution of the SPA, we also entered into a Registration Rights Agreement ("RRA") with the Investor wherein we agreed to register a number of shares of our common stock equal to the maximum number of shares of our common stock that could be issued upon conversion of the Series A Preferred Stock using a conversion price equal to 20% of $80,000,000 divided by the number of shares of common stock then outstanding (the "Floor Price") price plus 125% of the shares of common stock issuable upon exercise of the PIPE Warrant, or a maximum of 12,618,590 shares of our common stock. Such shares were registered for resale on a Registration Statement on Form S-1 originally filed with the SEC on September 13, 2021 (SEC File No. 333-259484), which was declared effective on December 20, 2021. Under the terms of the RRA, if we fail to maintain the effectiveness of the registration statement beyond defined allowable grace periods set forth in the RRA, we will incur certain registration delay payments equal to 2% of the Investor's investment upon our failure to maintain the effectiveness of the registration statement and every 30 days thereafter. Failure to maintain the effectiveness of the registration statement also constitutes a "triggering event" under the Certificate of Designations for the Series A Preferred Stock that would result in the accrual and payment of a dividend and provide the Investor the right to have its remaining Series A Preferred Stock redeemed for a premium of a minimum of 125% of the Conversion Amount of the Series A Preferred Stock, as more specifically described below.

Simultaneously with the closing of its Recapitalization Share Exchange, we closed on the PIPE Investment pursuant to the SPA. On December 20, 2021, we issued 20,000 shares of Series A Preferred Stock at $1,000 per share and a common stock purchase warrant to purchase 2,018,958 shares of common stock at an initial exercise price of $9.9061 to the Investor for an aggregate purchase price of $20 million. Each share of Series A Preferred Stock has a right to convert into shares of our common stock at an initial fixed conversion price of $9.9061. However, if (i) the price of our shares of common stock trade below $9.9061 (a "Price Failure") for a specified period of time; or (ii) in the event that the sum of (x) the aggregate daily dollar trading volume (as reported on Bloomberg) of our common stock on Nasdaq during the 10 trading day period ending on the trading day immediately preceding such date of determination, divided by (y) 10, is less than $1,500,000 (a "Volume Maximum Failure"), each share of Series A Preferred Stock is entitled to convert at a price equal to 90% of the sum of the two lowest VWAPs during the 10 trading day period immediately preceding delivery divided by two (the "90% Conversion Price"), but not less than the Floor Price, or, at the time of such Price Failure or Volume Maximum Failure, the sum of the average daily U.S. Dollar volume for our common stock during the 10 days previous to conversion divided by 10 is less than $2,000,000 (a "Volume Alternate Failure"), then each share of Series A Preferred Stock is entitled to convert at the lower of the fixed conversion price or a price equal to 80% of the sum of the two lowest VWAPs during the 10 trading day period immediately preceding delivery divided by two (the "80% Conversion Price"), but not less than the Floor Price (such 90% Conversion Price or 80% Conversion Price, as the case may be, the "Alternate Conversion Price"). If certain defined "Triggering Events" defined in the Certificate of Designations occur, such as a breach of the Registration Rights Agreement, suspension of trading, or our failure to convert the Series A Preferred Stock into common stock when a conversion right is exercised, failure to issue our common stock when the PIPE Warrant is exercised, failure to declare and pay to any holder any dividend on any dividend date, certain defaults on our debts or contractual obligations, or upon a "bankruptcy triggering event" (as defined in the Certificate of Designations), then we may be required to pay a dividend that is added to the stated value on the Series A Preferred Stock in the amount of 18% per annum, but paid quarterly in cash, so long as the triggering event is continuing, or to redeem the Series A Preferred Stock for cash in an amount of a minimum of 125% of the Conversion Amount (as defined in the Certificate of Designations) of the Series A Preferred Stock or 125% of the Conversion Amount of the Series A Preferred Stock would be entitled to convert into our common stock at the Alternate Conversion Price. In the event that we experience a "Change of Control" (as defined in the Certificate of Designations) we may also be required to redeem the Series A Preferred Stock for cash at a minimum of 125% of their Conversion Amount. In addition, if thirty days after our common stock commences trading on Nasdaq the sum of the average daily dollar volume for the 10 days previous to conversion divided by 10 is less than $2,500,000, then the Series A Preferred Stock shall be entitled to a one-time dividend equal to an 8% increase in the stated value of the Series A Preferred Stock, or an $80 increase per share in stated value, resulting in a stated value of $1,080 per share of Series A Preferred Stock. This dividend was paid during the first quarter of 2022. The Certificate of Designations of Series A Convertible Preferred Stock of Allarity Therapeutics, Inc. was filed as Exhibit 3.4 to the Company's Registration Statement on Form S-1, as amended, filed with the SEC on September 13, 2021.

On May 4, 2022, the Company and the Investor entered into a Forbearance Agreement and Waiver, dated April 27, 2022, wherein the Investor confirmed that no Triggering Event as defined under the Certificate of Designations has occurred prior to April 27, 2022, that a Triggering Event under Section 5(a)(ii) will and has occurred on April 29, 2022, and that in consideration for the Registration Delay Payments the Company is obligated to pay under the RRA, and additional amounts the Company is obligated to pay under the Certificate of Designations and the Investor's legal fees incurred in the preparation of the Forbearance Agreement and Waiver in the aggregate of $538,823 paid upon execution of the Forbearance Agreement and Waiver, and so long as the Company pays the Registration Delay Payments that become due and payable under the RRA after the execution of the Forbearance Agreement and Waiver, the Investor has agreed to forbear exercising any rights or remedies that it may have under the Certificate of Designations that arises as a result of a Triggering Event under Section 5(a)(ii) of the Certificate of Designations and Section 4(c)(ii) of the PIPE Warrant until the earlier to occur of (i) the date immediately prior to the date of occurrence of a Bankruptcy Triggering Event, (ii) the date of occurrence of any other Triggering Event under Section 5(a) of the Certificate of Designations (excluding any Triggering Event arising solely as a result of Section 5(a)(ii) of the Certificate of Designations and Section 4(c)(ii) of the PIPE Warrant), (iii) the time of any breach by the Company under the Forbearance Agreement and Waiver, (iv) the Resale Availability Date as defined therein and (v) June 4, 2022, which was subsequently extended to June 20, 2022 (such period, the "Forbearance Period"). Provided that the Company is not in breach of its obligations under Forbearance Agreement and Waiver, effective as of the Trading Day immediately following the Resale Availability Date, the Investor agrees to waive any rights or remedies that it may have under the Certificate of Designations that arises as a result of a Triggering Event under Section 5(a) of the Certificate of Designations and Section 4(c)(ii) of the PIPE Warrant that may have arisen prior to the date of the Forbearance Agreement and Waiver. The Resale Availability Date was achieved on June 6, 2022, resulting in the Investor waiving any rights or remedies that it may have under the Certificate of Designations that arises as a result of a Triggering Event under Section 5(a) of the Certificate of Designations and Section 4(c)(ii) of the PIPE Warrant that may have arisen prior to the date of the Forbearance Agreement and Waiver.

On June 6, 2022, we entered into that certain First Amendment to the Forbearance Agreement and Waiver with 3i, LP (the "Amendment") to extend the forbearance period date under subsection 5 of Section 2 of the Forbearance Agreement and Waiver dated April 27, 2022 (the "Original Agreement") from June 4, 2022, to June 20, 2022. In addition, the parties agreed that the forbearance period of June 20, 2022 may also be extended for an additional 15 days to July 5, 2022, provided that, on June 20, 2022 the Company will remove the restrictive legend on 441,005 shares of common stock of the Company issued in connection with the conversion of certain shares of Series A Preferred Stock ("Conversion Shares") by 3i, LP pursuant to the conversion notice dated May 2, 2022, and 3i, LP is able to sell the Conversion Shares free of restrictions (including volume restrictions) pursuant to SEC Rule 144(b)(1)(i).

On December 9, 2022, the Company and 3i, LP entered into a letter agreement which provided that pursuant to Section 8(g) of the Certificate of Designations for the Series A Preferred Stock, the parties agreed that the Conversion Price (as defined in such Certificate of Designations) was modified to mean the lower of: (i) the Closing Sale Price (as defined in the Certificate of Designations) on the trading date immediately preceding the Conversion Date (as defined in the Certificate of Designations) and (ii) the average Closing Sale Price of the common stock for the five trading days immediately preceding the Conversion Date, for the Trading Days (as defined in the Certificate of Designations) through and until the Company and 3i agree to terminate that definition.

On January 14, 2024, pursuant to the terms of the January 14th, 2024, 3i, LP Bridge Loan, the Company modified the conversion price of the 3i Exchange Warrants from $1.00 to $0.4476, thereby increasing the number of Exchange Warrants outstanding from 4,407,221 at December 31, 2023, to 9,846,339 outstanding at January 14, 2024. Also on January 14, 2024, the conversion price of the outstanding 1,417 shares of Series A Preferred Stock was revised from $1.00 to $0.4476. We filed the Fifth Certificate of Amendment to Amended and Restated Certificate of Designations of Series A Convertible Preferred Stock (the "Fifth Amendment") with the Secretary of State of the State of Delaware to reflect the new conversion price of the Series A Preferred Stock of $0.4476. At a stated value of $1,080 for each share of Series A Preferred Stock, the revised price of $0.4476 per share results in the 1,417 shares being convertible into 3,419,035 common shares as of January 14, 2024.

On February 13, 2024, pursuant to the terms of the February 13, 2024, 3i, LP Bridge Loan, the Company modified the conversion price of the 3i Exchange Warrants from $0.4476 to $0.4050 and thereby increased the number of Exchange Warrants outstanding from 9,846,339 on January 18, 2024, to 10,882,028 on February 13, 2024. The Company also agreed to amend the conversion price of the Series A Preferred Stock to equal $0.405 as soon as practicable. We filed the Sixth Certificate of Amendment to Amended and Restated Certificate of Designations of Series A Convertible Preferred Stock (the "Sixth Amendment") with the Secretary of State of the State of Delaware to reflect the new conversion price of the Series A Preferred Stock of $0.405. At a stated value of $1,080 for each share of Series A Preferred Stock, the revised price of $0.405 per share results in the 1,296 shares being convertible into 3,456,000 common shares.

Bridge Loans

On November 22, 2022, the Company entered into a Secured Note Purchase Agreement with 3i, LP (the "Secured Note Purchase Agreement") for a bridge loan to extend the Company's cash runaway beyond December 31, 2022, in order to provide the Company with more time to complete the process of amending its Certificate of Incorporation to increase it authorized share capital and proposed reverse stock split to facilitate additional capital investments (the "Bridge Loan"). Under the Secured Note Purchase Agreement, the Company has authorized the sale and issuance of three 3i Promissory Notes, with the first note in an aggregate principal amount of $350,000 to be issued at closing (which was received in November 2022); the second note in the principal amount of $1,666,640 to be issued at closing and which represents the payment of $1,666,640 due to 3i, LP in Alternative Conversion Floor Amounts, as defined in the Certificate of Designations, that began to accrue on July 14, 2022; and the third note in an aggregate principal amount of $650,000 with respect to a new loan to be funded upon the Company filing a registration statement with SEC in connection with a registered offering. As of December 31, 2022, all of the notes have been issued and are outstanding. Each 3i Promissory Note matures on January 1, 2024, carries an interest rate of 5% per annum, and is secured by all of the Company's assets pursuant to the Security Agreement. In addition, 3i, LP may exchange the 3i Promissory Notes for the Company's common stock, or other equity security, at an exchange price equal to the lowest price per share of the equity security sold to other purchasers, rounded down to the nearest whole share, if the Company concludes a future equity financing prior to the maturity date or other repayment of the 3i Promissory Notes. In addition, each 3i Promissory Note and interest earned thereon may be redeemed by the Company at its option or the holder may demand redemption if the Company obtains gross proceeds of at least $5 million in a financing in an amount of up to 35% of the gross proceeds of the financing.

On April 19, 2023, 3i, provided the Company with a loan for $350,000, which was evidenced by a Secured Promissory Note dated April 19, 2023 (the "April Note").

On April 20, 2023, the Company entered into a Cancellation of Debt Agreement with 3i, which became effective as of the April Offering Closing. Upon the closing, pursuant to the terms of the Cancellation of Debt Agreement, all of the Company's outstanding indebtedness under the Notes (as defined therein) and the Alternative Conversion Amount (as defined therein) due by the Company to 3i were paid in full. Accordingly, any and all obligations in connection therewith were extinguished without any additional further action on the part of 3i upon payment of $3,348 in cash from a portion of the proceeds from the April Offering.

On June 29, 2023, the Company entered into a Secured Note Purchase Agreement with 3i, (the "June 2023 Purchase Agreement"), pursuant to which, on June 30, 2023, 3i purchased a secured promissory note for a principal amount of $350,000 (the "3i June Promissory Note"). Such note matured on July 31, 2023, and carried an interest rate of 5% per annum, and is secured by all of the Company's assets pursuant to that certain security agreement dated June 29, 2023 (the "Security Agreement"). As contemplated by the June 2023 Purchase Agreement, the Company filed the Second Certificate of Amendment with the Delaware Secretary of State on June 30, 2023. From the proceeds of the July Offering, on July 10, 2023, the Company redeemed the 3i June Promissory Note for $351,000 in cash.

On January 18th, 2024, we entered into a Securities Purchase Agreement with 3i, pursuant to which we issued and sold 3i a senior convertible promissory notes in an aggregate principal amount of $440,000 due on January 18, 2025 (the "First Note", and together with the Purchase Agreement, the "Transaction Documents") for an aggregate purchase price of $400,000, representing an approximate 10% original issue discount (the "Transaction"). We agreed to use the net proceeds from the sale of the Note for accounts payable and working capital purposes. Unless the Transaction Documents state otherwise, we may not prepay any portion of the principal amount of the Note without the Purchaser's prior written consent.

On February 13, 2024 (the "Second Closing"), the Parties entered into a Limited Waiver Agreement (the "Waiver Agreement") and agreed that the Second Closing can be consummated prior to the 30th calendar day following January 18, 2024. The Parties further waive any rights or remedies that they may have under Section 2.3 of the Purchase Agreement, solely in connection with the Second Closing, including any rights of termination, defaults, amendment, acceleration or cancellation that be triggered under the Purchase Agreement solely as a result of accelerating the Second Closing. As of the Second Closing, we issued and sold to the Purchaser a senior convertible promissory note in an aggregate principal amount of $440,000 (the "Principal Amount") due on February 13, 2025 (the "Second Note," and together with the First Note dated January 18, 2024, and Purchase Agreement, the "Second Transaction Documents") for an aggregate purchase price of $400,000, representing an approximately 10% original issue discount (the "Second Transaction"). We agreed to use the net proceeds from the sale of the Second Note for accounts payable and working capital purposes. Unless the Transaction Documents state otherwise, we may not prepay any portion of the principal amount of the Second Note without the Purchaser's prior written consent.

Amendments to the Certificate of Designation of Series A Preferred Stock

On November 22, 2022, the Company amended Section 12 of the Certificate of Designation of Series A Preferred Stock to provide for voting rights. Subject to a 9.99% beneficial ownership limitation, the holders of Series A Preferred Stock were granted the right to vote on all matters presented to the stockholders for approval together with the shares of common stock, voting together as a single class, on an "as converted" basis using the "Conversion Price" (initially $9.9061 per share before any adjustment) (rounded down to the nearest whole number and using the record date for determining the stockholders of the Company eligible to vote on such matters), except as required by law (including without limitation, the DGCL) or as otherwise expressly provided in the Company's Certificate of Incorporation or the Certificate of Designations of Series A Preferred Stock. The voting rights described above expired on February 28, 2023.

On December 9, 2022, the Company and 3i entered into a letter agreement which provided that pursuant to Section 8(g) of the Certificate of Designations for the Series A Preferred Stock, the parties agreed that the Conversion Price was modified to mean the lower of: (i) the Closing Sale Price on the trading date immediately preceding the Conversion Date and (ii) the average Closing Sale Price of the common stock for the five trading days immediately preceding the Conversion Date, for the Trading Days through and inclusive of January 19, 2023. Any conversion which occurs shall be voluntary at the election of the Holder, which shall evidence its election as to the Series A being converted in writing on a conversion notice setting forth the then Minimum Price. Management determined that the adjustment made to the Conversion Price is not a modification of the COD which allows for adjustments to the Conversion Price at any time by the Company and the other terms of the Certificate of Designations remained unchanged.

On January 23, 2023, we and 3i amended the letter agreement entered into on December 8, 2022, to provide that the modification of the term Series A Preferred Stock Conversion Price ("Series A Preferred Stock Conversion Price") to mean the lower of: (i) the Closing Sale Price (as defined in the Certificate of Designations of Series A Preferred Stock ("Series A Certificate of Designations")) on the trading date immediately preceding the Conversion Date (as defined in the Series A Certificate of Designations and (ii) the average Closing Sale Price of the common stock for the five trading days immediately preceding the Conversion Date, for the Trading Days (as defined in the Series A Certificate of Designations) will be in effect until terminated by us and 3i.

On April 20, 2023, the Company entered into a certain Modification and Exchange Agreement (the "Exchange Agreement") with 3i pursuant to which the parties agreed to, among other things, subject to the April Offering Closing, (i) amend the Certificate of Designations for the Series A Convertible Preferred Stock (the "Amended COD"), which among other things, eliminates the Series A Preferred Stock redemption right and dividend (except for certain exceptions as specified in the Amended COD), and provides for the conversion of Series A Preferred Stock into Common Stock at a conversion price of $0.75 which is equal to the price for a share of Common Stock sold in the April Offering, (ii) exchange 50,000 shares of Series C Preferred Stock (the "Series C Shares") beneficially owned by 3i for 5,577 shares of Series A Preferred Stock (the "Exchange Shares"), (iii) exchange a warrant to purchase common stock issued on December 20, 2021 to 3i (the "Original Warrant") for a new warrant (the "Exchange Warrant"), which reflects an exercise price of $30.00 (the "New Exercise Price") and represents a right to acquire 315,085 shares of Common Stock (the "New Warrant Shares").

In addition to the satisfaction or waiver of customary and additional closing conditions set forth in the Exchange Agreement, the transactions contemplated by the Exchange Agreement were subject to (a) the occurrence of the closing of the Offering and (b) the filing of the Amended COD with the Delaware Secretary of State. On April 21, 2023, the closing of the transactions contemplated by the Exchange Agreement occurred and the Exchange Warrant and the Exchange Shares were issued to 3i, and the Original Warrant and the Series C Shares were cancelled. In addition, on April 21, 2023, the Amended COD was filed with the Delaware Secretary of State.

On April 20, 2023, the Company also entered into a Cancellation of Debt Agreement. Pursuant to such agreement, 1,550 shares of Series A Preferred Stock (the "Redemption Shares") beneficially owned by 3i were redeemed in full for a purchase price of $1,652, which redemption price was paid in cash from the portion of the proceeds from the April Offering. The Company also entered into the First Amendment to the Registration Rights Agreement dated May 20, 2023 (the "RRA"), which became effective upon the April Offering Closing, to amend certain defined terms under the RRA to include the Exchange Shares, the New Warrant Shares and the Note Conversion Shares.

On April 21, 2023, in connection with the transactions contemplated under the Exchange Agreement, the Company filed an Amended and Restated Certificate of Designations of Series A Convertible Preferred Stock of the Company (the "Amended and Restated Series A COD") with the Delaware Secretary of State. The Amended and Restated Series A COD eliminates the Series A Preferred Stock redemption right and dividend (except for certain exceptions as specified therein), and provides for the conversion of Series A Preferred Stock into Common Stock at a conversion price equal to the price for a share of Common Stock sold in the April Offering, $30.00 per share, and based on a stated value of $1,080 per share. As a result of the Amended and Restated Series A COD, the Company determined that the Series A Preferred Stock met the definition of equity and reclassified it from mezzanine equity.

On May 30, 2023, the Company filed an amendment to the Amended and Restated Certificate of Designations for the Series A Preferred Stock with the Delaware Secretary of State (the "Amended COD") to amend the voting rights of the Series A Preferred Stock which among other things provided additional voting rights to the Series A Preferred Stock.

Under the Amended COD, holders of the Series A Preferred Stock have the following voting rights: (1) holders of the Series A Preferred Stock have a right to vote on all matters presented at the Special Meeting together with the Common Stock as a single class on an "as converted" basis using the conversion price of $30.00 and based on stated value of $1,080 subject to a beneficial ownership limitation of 9.99%, and (2), in addition, holders of Series A Preferred Stock have granted the Board the right to vote, solely for the purpose of satisfying quorum and casting the votes necessary to adopt a reverse stock split of the Company's issued and outstanding shares of Common Stock (the "Reverse Stock Split Proposal") and to adjourn any meeting of stockholders called for the purpose of voting on reverse stock split (the "Adjournment Proposal") under Delaware law, that will "mirror" the votes cast by the holders of shares of Common Stock and Series A Preferred Stock, voting together as a single class, with respect to the Reverse Stock Split Proposal and the Adjournment Proposal. The number of votes per each share of Series A Preferred Stock that may be voted by the Board shall be equal to the quotient of (x) the sum of (1) the original aggregated stated value of the Series A Preferred Stock when originally issued on December 20, 2021 (calculated based on the original stated value of $1,000 of the Series A Preferred Stock multiplied by 20,000 shares of Series A Preferred Stock) and (2) $1,200,000, which represents the purchase price of the Series C Preferred Stock when originally issued; divided by (y) the conversion price of $30.00. If the Board decides to cast the vote, it must vote all votes created by the Amended COD in the same manner and proportion as votes cast by the holders of Common Stock and Series A Preferred Stock, voting as single class. The Series A Preferred Stock voting rights granted to the holders thereof relating to the Reverse Stock Split Proposal and the Adjournment Proposal 2 expired automatically on July 31, 2023.

On June 6, 2023, 3i and the Company entered into a separate limited waiver and amendment agreement whereby 3i ("3i Waiver Agreement") agreed to waive certain rights granted under a Series A Preferred Stock securities purchase agreement dated December 20, 2021, the Exchange Agreement, and the securities purchase agreement related to the April Offering in exchange for, among other things, amending the conversion price of the Series A Preferred Stock to equal the public offering price of the shares of Common Stock in the July Offering. Upon the consummation of the July Offering, the conversion price of the Series A Preferred Stock was reduced to $4.50. On July 10, 2023, the Company filed a Third Certificate of Amendment to the Amended and Restated Certificate of Designations of Series A Preferred Stock ("Third Amendment") to effect the change to conversion price.

In connection with the September 2023 Inducement Letter and the transactions contemplated therein, the Company and 3i, LP entered into a limited waiver agreement (the "Waiver") pursuant to which 3i, LP agreed to allow the filing of the Resale Registration Statement not otherwise permitted under certain agreements with 3i, LP. In consideration of entering in the Waiver, the Company agreed to amend the "Conversion Price" of the Series A Convertible Preferred Stock to equal $1.00 as soon as practicable. On September 22, 2023, the Company filed the Fourth Certificate of Amendment to the Amended and Restated Certificate of Designations of Series A Convertible Preferred Stock ("Fourth Amendment") with the Secretary of State of the State of Delaware to reflect the new conversion price of the Series A Preferred Stock of $1.00. In addition, as a result of the issuance of the Inducement Warrants, pursuant to the terms of the Exchange Warrant, in September 2023 the number of shares exercisable and the exercise price of the Exchange Warrant was adjusted to 9,452,667 shares of Common Stock and $1.00 per share, respectively.

On January 14, 2024, pursuant to the terms of the January 14th, 2024, 3i, LP Bridge Loan, the Company modified the conversion price of the 3i Exchange Warrants from $1.00 to $0.4476, thereby increasing the number of Exchange Warrants outstanding from 4,407,221 at December 31, 2023, to 9,846,339 outstanding at January 14, 2024. Also on January 14, 2024, the conversion price of the outstanding 1,417 shares of Series A Preferred Stock was revised from $1.00 to $0.4476. We filed the Fifth Amendment with the Secretary of State of the State of Delaware to reflect the new conversion price of the Series A Preferred Stock of $0.4476. At a stated value of $1,080 for each share of Series A Preferred Stock, the revised price of $0.4476 per share results in the 1,417 shares being convertible into 3,419,035 common shares as of January 14, 2024.

On February 13, 2024, pursuant to the terms of the February 13, 2024, 3i, LP Bridge Loan, the Company modified the conversion price of the 3i Exchange Warrants from $0.4476 to $0.4050 and thereby increased the number of Exchange Warrants outstanding from 9,846,339 on January 18, 2024, to 10,882,028 on February 13, 2024. The Company also agreed to amend the conversion price of the Series A Preferred Stock to equal $0.405 as soon as practicable. We filed the Sixth Amendment with the Secretary of State of the State of Delaware to reflect the new conversion price of the Series A Preferred Stock of $0.405. At a stated value of $1,080 for each share of Series A Preferred Stock, the revised price of $0.405 per share results in the 1,296 shares being convertible into 3,456,000 common shares.

Modifications to Conversion Price of Series A Preferred Stock

On December 9, 2022, the Company and 3i, LP, the holder of outstanding shares of Series A Preferred Stock, entered into a letter agreement which provided that pursuant to Section 8(g) of the Certificate of Designations, the parties agreed that the Conversion Price (as defined in such Certificate of Designations) was modified to mean the lower of: (i) the Closing Sale Price (as defined in the Certificate of Designations) on the trading date immediately preceding the Conversion Date (as defined in the Certificate of Designations) and (ii) the average Closing Sale Price of the common stock for the five trading days immediately preceding the Conversion Date, for the Trading Days (as defined in the Certificate of Designations) through and inclusive of January 19, 2023. On January 23, 2023, the Company and 3i, LP amended the Letter Agreement to provide the term Conversion Price will be in effect until terminated by the Company and 3i, LP.

Establishment of Series B Preferred Stock

On November 22, 2022, the Company's Board of Directors established the Series B Preferred Stock, par value $0.0001 per share ("Series B Preferred Stock"). Each share of Series B Preferred Stock has 400 votes and is subject to certain redemption rights and voting limitations. See description in exhibit titled "*Description of Capital Stock – Series B Preferred Stock.*"

Issuance of Series B Preferred Stock Dividend

Effective December 5, 2022, the Company issued a stock dividend to be distributed as follows to stockholders of record as of close of business on December 5, 2022: (i) 0.016 shares of Series B Preferred Stock for each outstanding share of common stock; and (ii) 1.744 shares of Series B Preferred Stock for each outstanding share of Series A Preferred Stock. An aggregate of 190,786 shares of Series B Preferred Stock were issued as a stock dividend.

Annual Stockholder Meeting and Redemption of Series B Preferred Stock

On February 3, 2023, we held our previously adjourned annual meeting of stockholders (the "Annual Meeting"). Nine proposals were submitted to our stockholders for a vote at the Annual Meeting including a proposal to increase the number of authorized shares and a proposal to effect a reverse stock split. Upon conclusion of the Annual Meeting, all of the 190,786 shares of Series B Preferred Stock were automatically redeemed, with the holders of the Series B Preferred Stock only having a right to receive the purchase price for the redemption, which was $0.01 per share of Series B Preferred Stock. In addition, the proposals to increase the number of authorized shares and to effect a reverse stock split did not pass by the requisite shareholder vote at the Annual Meeting. In light of our financing needs and our obligations to 3i, L.P., as holder of the Series A Preferred Stock and PIPE Warrant, we conducted a private placement offering pursuant to which we issued 50,000 shares of Series C Preferred Stock.

Establishment of Series C Preferred Stock and Sale of Series C Preferred Stock

On February 24, 2023, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Redeemable Preferred Stock (the "Series C COD") with the Delaware Secretary of State designating 50,000 shares of its authorized and unissued preferred stock as Series C Preferred Stock with a stated value of $27.00 per share. On February 28, 2023, the Company filed a Certificate of Amendment to the Series C COD (the "COD Amendment") to clarify the terms of conversion price and floor price based on definitions provided in the Series C COD (the COD Amendment, together with the Series C COD, the "COD"). Each share of Series B Preferred Stock has 620 votes and is subject to certain redemption rights and voting limitations. See description in exhibit titled "*Description of Capital Stock - Series C Preferred Stock.*"

On February 28, 2023, we entered into a SPA with 3i, L.P. for the purchase and sale of 50,000 shares of Series C Convertible Redeemable Preferred Stock, par value of $0.0001 per share of Series C Preferred Stock at a purchase price of $24.00 per share, for a subscription receivable in the aggregate amount equal to the total purchase price of $1.2 million (the "Series C Offering"). The Shares are convertible into shares of the Company's common stock, subject to the terms of the COD. The conversion price for the Series C Preferred Stock is initially equal the lower of: (i) $0.182, which is the official closing price of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) on the Trading Day (as defined in the COD) immediately preceding the Original Issuance Date (as defined in the COD); and (ii) the lower of: (x) the official closing price of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) on the Trading Day immediately preceding the Conversion Date or such other date of determination; and (y) the average of the official closing prices of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) for the 5 Trading Days immediately preceding the Conversion Date (as defined in the COD) or such other date of determination, subject to adjustment herein (the "Conversion Price"), with the Conversion Price being no less than $0.0370 (the "Floor Price"). In the event that the Conversion Price on a Conversion Date would have been less than the applicable Floor Price if not for the immediately preceding sentence, then on any such Conversion Date the Company will pay the Holder an amount in cash, to be delivered by wire transfer out of funds legally and immediately available therefor pursuant to wire instructions delivered to the Company by the Holder in writing, equal to the product obtained by multiplying (A) the higher of (I) the highest price that the Common Stock trades at on the Trading Day immediately preceding such Conversion Date and (II) the applicable Conversion Price and (B) the difference obtained by subtracting (I) the number of shares of Common Stock delivered (or to be delivered) to the Holder on the applicable Share Delivery Date with respect to such conversion of Series C Preferred Stock from (II) the quotient obtained by dividing (x) the applicable Conversion Amount that the Holder has elected to be the subject of the applicable conversion of Series C Preferred Stock, by (y) the applicable Conversion Price without giving effect to clause (x) of such definition. The Offering closed on February 28, 2023.

In connection with the Series C Offering, concurrently with the SPA, the Company entered into a registration rights agreement with 3i, L.P. (the "RRA") pursuant to which the Company is required to file a registration statement with the SEC to register for resale the shares of Common Stock that are issued upon the potential conversion of the Shares. Under the terms of the RRA, if we fail file an Initial Registration Statement (as defined in the RRA) on or prior to its Filing Date (as defined in the RRA), or fail to maintain the effectiveness of the registration statement beyond defined allowable grace periods set forth in the RRA, we will incur certain registration delay payments, in cash and as partial liquidated damages and not as a penalty, equal to 2.0% of 3i, L.P.'s subscription amount of the Shares pursuant to the SPA. In addition, if we fail to pay any partial liquidated damages in full within 7 days after the date payment, we will have to pay interest at a rate of 18.0% per annum, accruing daily from the date such partial liquidated damages are due until such amounts, plus all such interest thereon, are paid in full. The Company has also agreed to pay all fees and expenses incident to the performance of the RRA, except for any broker or similar commissions. In connection with the Series C Offering, the Company and 3i, L.P. entered into a limited waiver agreement pursuant to which 3i, L.P. confirmed that the sale and issuance of the Shares will not give rise to any, or trigger any, rights of termination, defaults, amendment, anti-dilution or similar adjustments, acceleration or cancellation under the existing agreements with 3i, L.P.

Special Meeting of Stockholders

Pursuant to a proxy statement filed with the SEC on or about March 6, 2023, (the "Proxy Statement"), the Company will be holding a Special Meeting of Stockholders (the "Special Meeting") virtually online on March 20, 2023. Stockholders of record of our outstanding shares of Common Stock and Series C Preferred Stock on March 3, 2023 (the "Record Date") will be entitled to notice of, and to vote at, the Special Meeting and any adjournments, continuations or postponements thereof that may take place At the Special Meeting, the stockholders of Common Stock and Series C Preferred Stock will be voting on the following proposals: (1) to approve an amendment to our Certificate of Incorporation, as amended, to increase the number of authorized shares from 30,500,000 to 750,500,000, and to increase the number of our common stock from 30,000,000 to 750,000,000, in substantially the form attached to the Proxy Statement as Appendix A (the "Share Increase Proposal"); and (2) to approve an amendment to our Certificate of Incorporation, as amended, in substantially the form attached to the Proxy Statement as Appendix B, to, at the discretion of the Board of Directors of the Company (the "Board"), effect a reverse stock split with respect to the Company's issued and outstanding common stock, par value $0.0001 per share, at a ratio between 1-for-20 and 1-for-35 (the "Range"), with the ratio within such Range to be determined at the discretion of the Board (the "Reverse Stock Split Proposal") and included in a public announcement. Under the terms of the Series C Preferred Stock, the holders thereof may only vote on Proposal 1 (Share Increase Proposal) and Proposal 2 (Reverse Stock Split Proposal) and for no other matters. Each holder of one share of Series C Preferred Stock is entitled to 620 votes representing 31,000,000 votes in the aggregate assuming 50,000 shares of Series C Preferred Stock is outstanding.

The Allarity Therapeutic Candidate Portfolio

Our priority therapeutic candidate, stenoparib, is a dual inhibitor of the key DNA damage repair enzyme PARP, as well as Tankyrases, critical enzymes involved in the WNT signaling pathway commonly activated in many cancers. DNA damage repair mechanisms are crucial to mammalian cell survival and replication. Inhibition of key DNA damage repair enzymes, such as PARP, has clinically demonstrated to be therapeutically beneficial in the treatment of cancers, including ovarian cancers. Tankyrases are enzymes involved in the stabilization and maintenance of telomeres (the ends of chromosomal DNA) during cell replication, Inhibition of tankyrases may provide an additional mechanism of impeding cancer cell survival and growth. Tankyrases also play a key role in the WNT signaling pathway- a pathway that is activated in most solid cancers and that drives cellular proliferation, survival and metastatic capacity.

There are four PARP inhibitors currently approved and used for the treatment of cancers, primarily ovarian and breast cancers but now also pancreatic and prostate cancers. Most of these approved PARP inhibitors use mutation of BRCA genes, which encode another important DNA damage repair enzyme, as a biomarker for whether the patient will respond to a PARP inhibitor. The theory is that tumors already defective in BRCA, which are then treated with an inhibitor of PARP, will suffer higher cell/tumor death than cells with active, unmutated BRCA, effectively resulting from a synergistic inhibition of multiple DNA damage repair pathways. Stenoparib has demonstrated a differentiated therapeutic and toxicity profile compared to other currently approved PARP inhibitors. In addition to stenoparib's dual PARP and Tankyrase inhibitory activity, preclinical data suggest that stenoparib may cross the blood-brain barrier (BBB) — potentially leading to treatment opportunities for primary brain cancers as well as brain metastases from other cancers. Importantly, clinical evidence to date shows that stenoparib is well tolerated and does not cause the myelotoxicity typical of other approved PARP inhibitors.

Additionally, we have developed and retrospectively validated our Stenoparib-DRP® companion diagnostic using clinical trial biopsies from the prior Phase 1 clinical trial of this therapeutic candidate. In retrospective analysis of this trial, we have observed that patients selected with our Stenoparib-DRP® have a fourfold (4X) improvement in overall survival when compared to DRP® negative patients. Our putative Stenoparib-DRP® companion diagnostic identified a substantially broader patient subgroup than those identified by BRCA mutation or homologous repair deficiency, thus potentially enabling the treatment of more patients. We plan to apply for initial market approval for stenoparib, in the U.S., for the treatment of advanced ovarian cancer, using our Stenoparib- DRP® companion diagnostic to select and treat patients likely to derive clinical benefit from stenoparib. We are currently advancing a Phase 2 clinical trial for stenoparib for the treatment of advanced, recurrent ovarian cancer at trial sites in the U.S. and Europe, leveraging the Stenoparib-specific DRP® companion diagnostic to pre-select patients for enrollment. The use of the stenoparib-specific DRP companion diagnostic has been previously approved through the FDA's Investigational Device Exemption (IDE) application.

Partnerships and Out-Licensing Leverage the DRP® Platform for Other Cancer Therapeutics

We have also developed external partnerships and out-licensing arrangements to enable the advance of other therapeutic candidates, LiPlaCis®, 2X-111 and Irofulven, leveraging a DRP® companion diagnostic for each drug. LiPlaCis® is an advanced, targeted liposomal formulation of Cisplatin. While we previously had an exclusive in-license to develop this drug from LiPlasome Pharma ApS, on March 28, 2022, we agreed to transfer our exclusive development rights to Chosa ApS, an affiliate of Smerud Medical Research International AS and have out-licensed our DRP® companion diagnostic for LiPlaCis® to Chosa. The specific LiPlaCis® formulation utilizes a proprietary phospholipase A (sPLA2-IIA) cleavage substrate for controlled, selective hydrolyzation, disruption and release of drug payload in the presence of tumor cells. This delivery vehicle may result in drug accumulation directly at tumor site, thereby potentially increasing drug targeting at the tumor and reducing negative, off target drug effects and toxicity that is well known for cisplatin. We have previously developed and retrospectively validated a DRP® companion diagnostic specific for cisplatin, which we believe enables us to identify and treat the patients most likely to respond to this therapeutic candidate.

2X-111 is an advanced, targeted liposomal formulation of Doxorubicin, that remains one of the world's most widely used chemotherapies. We exclusively in-licensed this therapeutic candidate from 2BBB Medicines, B.V. The specific 2X-111 formulation, which exploits a glutathione enhanced PEG-liposomal delivery system, we believe may allow 2X-111 to cross the BBB, thereby potentially enabling the treatment of primary brain tumors, such as glioblastoma multiforme (GBM), and secondary brain tumors that originated from cancers outside the brain, such as metastatic breast cancer. The treatment of such brain tumors is a significant unmet need in cancer care, given that patients with primary brain tumors and metastases have few or no meaningful therapy options. We have previously developed and retrospectively validated a DRP® companion diagnostic specific for epirubicin, which may enable us to identify and treat the patients most likely to respond to this therapeutic candidate. 2X-111 has previously shown encouraging results in a Phase 2 trial (without use of a DRP® companion diagnostic) for the treatment of both GBM and brain metastases of mBC. In June of 2020, we out-licensed this program to Smerud Medical Research International, our long-time CRO partner in Europe, which was subsequently terminated on March 28, 2022, in connection with our out-licensing of our DRP® companion diagnostic for LiPlaCis® to Chosa discussed above.

Irofulven (6-hydroxymethylacylfulvene), is a unique DNA damaging agent, is a semi-synthetic sesquiterpene derivative of illudin S, a natural toxin isolated from the Jack O'lantern mushroom (*Omphalotus illudens*). Until July 23, 2021, we exclusively in-licensed this therapeutic candidate from Lantern Pharma, Inc. Irofulven has two primary anti-tumor mechanisms of action: first, it produces bulky single strand DNA adducts that are only repairable by the transcription coupled nucleotide excision repair (TC-NER) pathway; and second, it stalls RNA polymerase II leading to transcription and cell cycle arrest and apoptosis. The therapeutic candidate was formerly developed, between 1995 and 2007, in 41 different clinical trials, including through Phase 3 clinical trials, which demonstrated Irofulven's single agent activity in a range of indications, including castration-resistance prostate cancer (CRPC), ovarian, liver, and pancreatic cancer, and clinical activity in combination treatments targeting CRPC, colorectal and thyroid cancers. We have previously developed and patented a putative DRP® companion diagnostic specific for Irofulven, which we believe enables us to identify and treat the patients most likely to respond to this therapeutic candidate although we have not yet filed a PMA with the FDA for this companion diagnostic. In order to devote more of our development resources to our priority therapeutic candidates, on July 23, 2021, we terminated our drug development agreement for Irofulven and sold our inventory of API, our clinical data and records, and our know-how relating to Irofulven to Lantern Pharma, and granted a non-exclusive license to Lantern Pharma to use our putative DRP® companion diagnostic specific for Irofulven in exchange for $1 million and future additional milestone and royalties. Although we may be entitled to future milestone payments and royalties if Lantern Pharma advances the development of Irofulven with or without our putative DRP® companion diagnostic specific for Irofulven, we will no longer devote any of our development resources to advance this therapeutic candidate.

We retain exclusive worldwide rights to all the therapeutic candidates in our pipeline, with the exception of IXEMPRA® for which we have exclusive European rights and our putative DRP® companion diagnostic specific for Irofulven, which we have out-licensed to Lantern Pharma, Inc. and our DRP® companion diagnostic for LiPlaCis® which we have out-licensed to Chosa. We have a broad intellectual property portfolio comprised of more than 17 granted DRP® patents covering 70 different cancer drugs, and another 27 DRP® patent applications pending covering 2 additional cancer drugs. Our rolling patent strategy allows our DRP® patents to be listed in FDA's Orange Book for the drugs where they occur in the approval label. We also control remaining composition of matter, formulation, and methods of use patent coverage on stenoparib which extends out to 2028 or 2032 depending on the relevant patents.

Strategy Revised in Q4 2023

We strive to deliver meaningful benefit to patients with serious unmet medical needs in oncology by developing potentially breakthrough therapies, guided by our proprietary DRP® companion diagnostics, in a personalized medicine approach. The core elements of our strategy now include:

- Focus all internal resources on accelerating the development of stenoparib in advanced, recurrent ovarian cancer. We are currently enrolling patients in both the US and in the UK on a phase 2 study evaluating stenoparib as monotherapy given twice daily (600 mg total dose per day) in patients with advanced recurrent ovarian cancers regardless of BRCA mutational or homologous DNA repair status or prior PARP inhibitor treatment. As reported in a press release December 5, 2023, this trial has already shown promising clinical benefit across all evaluable patients, including a complete RECIST response. All patients are pre-selected for enrollment using the steoparib-specific DRP® companion diagnostic. The promise of these emerging clinical benefit data have prompted the company to deprioritize all other internal clinical development programs to enable acceleration of the stenoparib monotherapy program in ovarian cancer.

- ***Support the continuing, external clinical development of our secondary pipeline assets towards value inflection points***. We have previously out-licensed both LiPlaCis® and 2X-111, to our longtime CRO partner SMERUD MEDICAL RESEARCH INTERNATIONAL, in our efforts to advance the clinical development of these assets. In March 2022, we restructured our LiPlaCis® license agreements with Smerud and original drug owner LiPlasome Pharma ApS, in a way that will enable Smerud to step into the shoes of Allarity and assume full control of this program for further development in a Smerud affiliate, Chosa ApS, and to secure additional investment funding and collaborative development of the program through the affiliate. Allarity and SMERUD are currently in discussions about a revised agreement, together with original drug owner 2BBB Medicines, B.V., about future clinical advancement of 2X-111. We intend to provide support for both of these clinical programs with our proprietary DRP® companion diagnostics and our clinical trial and regulatory expertise, and are in ongoing negotiations with SMERUD to extend the financing pathways and timeframe for these programs.

Overview of Our DRP® Companion Diagnostic Platform

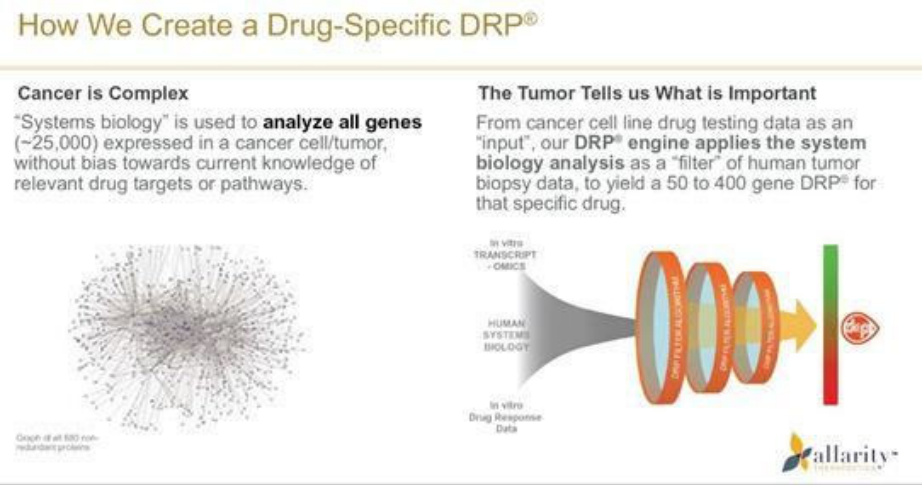
Our patented DRP® platform is a proprietary technology that enables the development of drug-specific companion diagnostics that are used to identify patients that will most likely benefit from a particular cancer therapy. While our strategy is to use our DRP® platform to advance our own therapeutic candidates, we believe our DRP® platform could be used by many other cancer drugs, both for drugs in clinical development and for those already on the market.

A companion diagnostic is an *in vitro* diagnostic device or test that provides information that is essential for the safe and effective use of a corresponding therapeutic product. After the companion diagnostic is approved for use by the FDA, the use of the companion diagnostic with an approved therapeutic product is stipulated in the instructions for use in the labeling of both the companion diagnostic and the corresponding therapeutic product.

In cancer therapy, personalized medicine, also known as precision medicine, aims to match therapeutic products to those patients (and only those patients) who will positively benefit from that therapeutic product. Personalized medicine in the field of oncology therefore depends on (1) understanding the molecular pathophysiology of cancer and (2) the ability of companion diagnostics to accurately and reliably detect and measure molecular biomarkers. Consequently, these companion diagnostics inform both the clinical development of therapeutic candidates and the approved use of therapeutic products.

Our DRP® platform facilitates personalized medicine in cancer patients by addressing the crucial fact that the specific cancer tumor biology within a patient that determines whether a patient will (or will not) respond to a particular cancer drug is largely unique to that patient:

We believe our DRP® platform addresses the great complexity of cancer, and is fundamentally different from classical or competitive approaches, in that we let the tumor tell us what cellular mechanisms are important to its response (or resistance) to a given cancer drug:

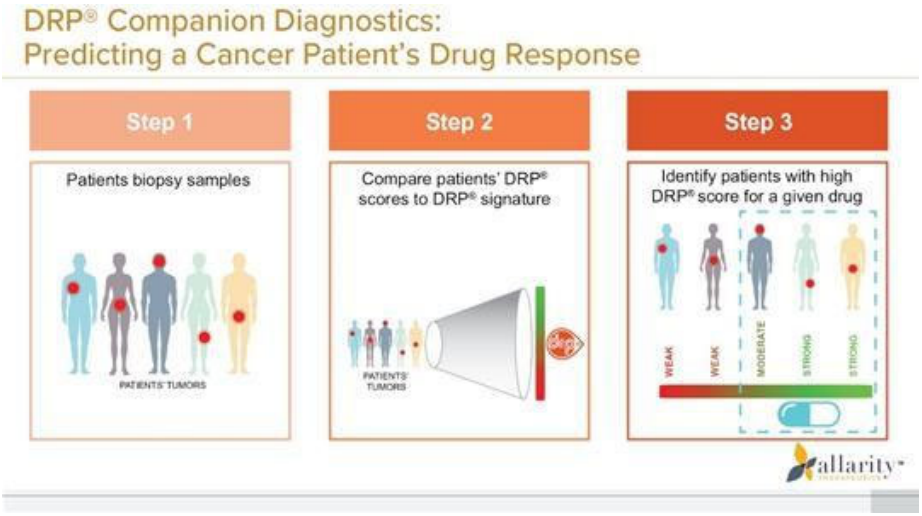


Our DRP® platform is a powerful bioinformatic engine that is based on advanced systems biology and transcriptomics, meaning that it analyzes all genes that are transcribed (*i.e.* expressed) as RNA and/or microRNA in a tumor and whether those transcribed genes are affected in response to treatment of the tumor (or cancer cells) with a given approved drug or therapeutic candidate. Our approach differs greatly from simple genetic tests, such as those for a critical mutation in a single gene and provides a much deeper level of insight into a tumor's likelihood of responding to a particular approved drug or therapeutic candidate, that may not be observed by simply looking at a patient's DNA sequence information.

When we create a new, drug-specific DRP® companion diagnostic using our DRP® platform, we start with an established panel of cancer cell lines, which have been treated with the cancer drug or therapeutic candidate, to correlate the genetic expression profile of cell lines that are either sensitive or resistant to the drug or therapeutic candidate. In our development of a companion diagnostic, we usually use a well-known collection of 60 human tumor cell lines from the National Cancer Institute known as the "NCI-60" panel, however we also use proprietary cancer cell line panels. Gene expression profiles of the cancer cell lines are derived from a microarray (commercially available Affymetrix Gene Chips) to quantify the level of mRNA and/or microRNA that have been transcribed from genes in those cells. The advanced bioinformatic algorithm at the heart of our DRP® platform then identifies, from all mRNA, the specific ones that are correlated with either drug or therapeutic candidate response or resistance, and the collection of these biomarkers becomes a "fingerprint" of response (or resistance) to that drug or therapeutic candidate. Our DRP® platform then applies what we believe to be a unique "biological relevance filter" — created from analyzing more than 3,000 actual biopsy samples from human clinical trials across a broad range of cancer types — to remove biomarkers that are not relevant to actual clinical response of tumors (from patients) and thus reduce the background noise from our observations. This process generates a putative DRP® companion diagnostic, specific for the drug or therapeutic candidate, which identifies a subpopulation of cancer patients most likely to respond to the drug or therapeutic candidate. Typically, between 50 and 400 biomarkers (*i.e.* expressed genes) comprise a putative DRP® companion diagnostic for a specific drug or therapeutic candidate.

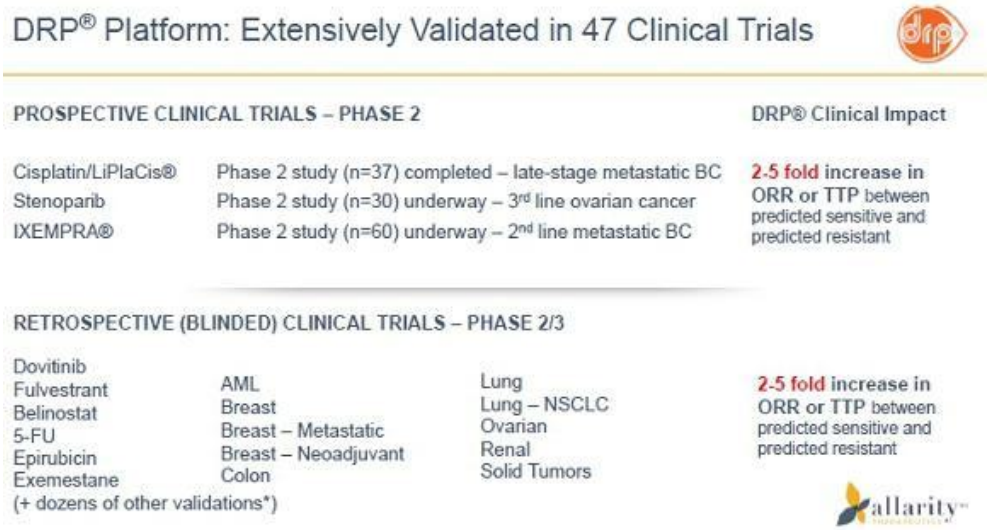
However, before we can confidently use the DRP® companion diagnostic with real cancer patients, either in clinical trials for a therapeutic candidate or for an approved and on-market drug, we must retrospectively validate the predictive power of the DRP® for that drug or therapeutic candidate by accessing tumor biopsies (or gene expression data from such biopsies) from prior clinical trials of the drug or therapeutic candidate, and then retrospectively predicting which patients will respond to the drug or therapeutic candidate. When possible, we do our analysis in a "blinded" manner, meaning that we have no access to patient information and whether they did or did not respond to the drug or therapeutic candidate. Using this protocol of analysis, we believe we are able to retrospectively validate whether our putative DRP® companion diagnostic would have correctly identified those patients who did respond to the drug or therapeutic candidate. At this stage, we also establish a cutoff score for the putative DRP® companion diagnostic, in order to capture most of the responsive patients while excluding most of the nonresponsive patients in the tested population. Typically, we set a DRP® cutoff score for a given cancer drug at 50%, although we may use a more stringent cutoff score for certain cancer types or drugs.

If we succeed with the final retrospective validation step, then our putative DRP® companion diagnostic is ready for submission as an IDE to the FDA and, if approved, for use with actual patients in clinical trials. Depending on the outcomes of our clinical trials, a PMA application may be made with the FDA and, if approved, our DRP® companion diagnostic may be used with an approved drug in cancer therapy. The following image shows how to use a drug-specific DRP® companion diagnostic, in practice, to test whether a patient will or will not respond to a given cancer drug:



For example, we may receive at our diagnostic laboratory (or a partner diagnostic laboratory), a biopsy sample from a hospital or cancer center where a patient is being treated. Often, this biopsy sample is formalin-fixed paraffin-embedded (FFPE). Generally, we prefer a recent biopsy to an older (*e.g.* diagnostic) biopsy, since tumors may change, at the molecular level, with time and after therapy. Gene expression in tumor cells from the biopsy is determined in the same manner as in the cell lines previously described above. The expression levels of the relevant biomarkers (that comprise the DRP® companion diagnostic) in the patient's tumor are compared to the DRP® reference in order to assess how closely the patient's biomarker expression levels match the reference. We then apply the relevant DRP® score cutoff (e.g. 50%) for that drug to determine whether the patient has a high enough DRP® score to be identified as a likely responder for the drug.

Our DRP® platform has been validated by us using retrospective observational studies in 35 clinical trials that were conducted or sponsored by other companies. The FDA considers a retrospective observational study to be one in which the study identifies the population and determines the exposure/treatment from historical data (i.e. data generated prior to the initiation of the study) with the variables and outcomes of interest determined at the time the study is designed. *See, Framework for FDA's Real-World Evidence Program*, page 6 (December 2018), *https://www.fda.gov/media/120060/download*. The FDA has accepted our retrospective validation in support of two IDE applications to conduct clinical trials, one with respect to LiPlaCis® and one with respect to stenoparib. We believe our DRP® platform has successfully generated drug-specific putative DRP® companion diagnostics for a broad range of cancer drugs and therapeutic candidates with different mechanisms-of-action (e.g. kinase inhibitors, chemotherapeutics, HDAC inhibitors, PARP inhibitors, hormone receptor inhibitors, etc.) and across both solid and hematological cancers. Although none of our putative DRP® companion diagnostics have yet been approved by the FDA for marketing, the following graphic illustrates some retrospective validations we have conducted (a strong clinical impact suggests that use of the putative DRP® companion diagnostic may result in a 3X to 5X increase in therapeutic benefit for DRP®-selected patients, while a moderate clinical impact suggests that the DRP® companion diagnostic may provide a 2X increase in therapeutic benefit):



While these retrospective observational studies validate the ability of the DRP® platform to predict likely responders, few of these retrospective studies meet the criteria for proof of efficacy and safety required by the FDA. Usually, the FDA requires that the companion diagnostic be used in a sufficiently powered, prospectively enrolled phase III clinical trial before a PMA may be approved.

Although we believe our DRP® platform is very robust and retrospectively validated, we are not always successful in discovering a putative DRP® companion diagnostic in all cases. Generally, the limited number of failures we have encountered have been with cancer drugs that have a mechanism-of-action that is not directly cytotoxic to cancer cells such as angiogenesis inhibitors that interfere with new blood vessel development in the tumor microenvironment. Additionally, we have experienced some failures to develop a putative DRP® companion diagnostic for a given drug or therapeutic candidate when biopsy materials are too old, or when too many intervening treatments have taken place from the time of original biopsy to current treatment.

Our DRP® companion diagnostics have been patented for more than 70 anticancer agents across a broad range of cancer drugs. Studies involving our DRP® platform, and resulting putative DRP® companion diagnostics, have also been extensively published in peer reviewed literature and presented at major oncology conferences.

Advantages Over Other Biomarker Approaches

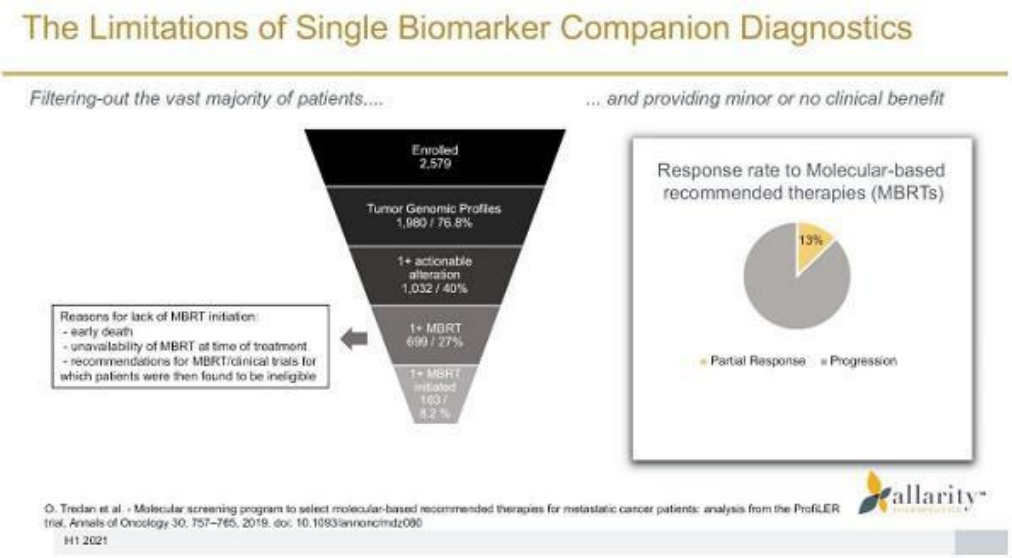
The realization of personalized medicine in cancer care has been hampered, in part, due to the general lack of FDA approved companion diagnostics to select and treat those cancer patients most likely to respond to a given drug (while avoiding treatment of those patients likely to not respond). This lack of suitable companion diagnostics we believe has largely resulted from an outdated and overly simplistic view of cancer, which fails to adequately address the great complexity of individual tumor responsiveness to a given drug or therapeutic candidate. Accordingly, historic and competitive companion diagnostic approaches mostly rely on a "knowledge-driven" approach that focus only on single biomarkers — and not on more informative and reliable, complex biomarker signatures.

Examples of competitive approaches and technologies and their shortcomings are:

- ***Gene Mutation Sequencing***. A number of gene mutations have been identified that alter the expressed protein or enzyme in such a way to preclude drug binding. Such mutations are common in kinases and can lead to failure of a drug to inhibit its target. Modern "Next Gen Sequencing" (NGS) of such genetic mutations is one current approach to identify patients who may or may not respond to a given cancer drug. NGS approaches have been commercialized by companies like Foundation Medicine and are also increasingly being used by large cancer centers with their own NGS capabilities. We believe this approach is largely limited by failing to address complex tumor biology and mechanisms of drug response/resistance, much of which is currently unknown, and, accordingly, can only partially identify patient therapeutic response if it is linked to a single gene mutation. This approach is also limited to drugs that target proteins or enzymes that have mutations and is thus not suitable for predicting response to drugs such as chemotherapeutics.

- ***Drug Target Expression Analysis***. This approach uses the level of expression of the actual drug target itself as a biomarker for whether a patient will (or will not) respond to a given drug. A common example is expression of the cell surface receptor tyrosine kinase HER2 used as a companion diagnostic for the HER2-targeting cancer drug Herceptin® for the treatment of breast cancer. We believe this approach is also largely limited by failing to address complex tumor biology and mechanisms of drug response/resistance, much of which is currently unknown. Indeed, many patients who are HER2 positive do not respond well to drugs targeting this receptor and/or patients that initially respond become resistant, indicating other, more complex underlying tumor biology.

- ***"Artificial Intelligence" (AI) or "Machine Learning" (ML) Approaches***. While there are many companies, including in the companion diagnostics space, currently employing technologies that leverage AI or ML, we believe these computer-based technologies are largely limited to the identification and/or design of potential new drug structures. Currently, we are not aware of any retrospectively or clinically validated, published, or approved companion diagnostic created by any AI-based or ML-based approach.



In contrast to other alternative companion diagnostics technologies, we believe our DRP® platform enjoys several unique competitive advantages:

- ***Broadly Applicable***. We believe our DRP® platform can successfully generate a drug-specific companion diagnostic for most cancer drug types, including DNA damaging agents, standard chemotherapeutics, targeted kinase inhibitors and epigenetic enzyme inhibitors.

- ***Retrospectively Validated***. The ability of the DRP® platform to generate reliable and accurate predictive DRP® companion diagnostics has been retrospectively validated in more than 35 clinical trials and 1 prospective clinical trial.

- ***Extensively Published***. Studies of our DRP® platform and putative companion diagnostics have been extensively published in peer-reviewed literature, including publications such as the British Journal of Cancer, Journal of the National Cancer Institute, Plos One, and Breast Cancer Research and Treatment, and have been presented at major oncology conferences, including ASCO, ESMO, and EACR.

- ***Accepted for Use in Clinical Trials by Regulatory Agencies.*** Although none of our putative DRP® companion diagnostics has yet been approved by a regulatory agency for marketing, the U.S. FDA has previously granted 2 IDE applications approving the use of DRP® companion diagnostics for both stenoparib and LiPlaCis® in clinical trials. The Company previously filed a Pre-Market Approval (PMA) application, with the FDA, for the approval and use of the Dovitinib-DRP® companion diagnostic as a marketed companion diagnostic for dovitinib in mRCC. In February 2022 the FDA issued a RTF letter on review of this PMA, largely based on the FDA's issued RTF letter on the related NDA. Separately, the stenoparib, IXEMPRA® and LiPlaCis® DRP® companion diagnostics have been accepted for use in clinical trials by national regulatory agencies in the U.S. and/or Europe.

- ***Trusted by Clinicians***. Prominent oncologists at leading cancer centers where we were conducting our DRP®-guided clinical trials, including Guy's Hospital (London, England), and Rigshospitalet (Copenhagen, Denmark), have used our putative DRP® companion diagnostics to select and treat likely responder patients and improve patient outcomes in a personalized medicine approach in such trials.

Overview of Stenoparib, our Novel Dual PARP/ Tankyrase Inhibitor

Stenoparib's Mechanism of Action

PARP is an enzyme discovered more than 40 years ago that produces large, branched chains of poly (ADP) ribose (PAR) from NAD. In humans, there are 17 members of the PARP gene family, but most of these are poorly characterized. Of the 17 PARP family members, only PARP1 and PARP 2 are known to be involved in DNA repair. PARP is an abundant nuclear enzyme that is activated by DNA strand breaks to synthesize poly (ADP-ribose) from NAD. The main function of PARP is the maintenance of genomic integrity by facilitating DNA repair through the BER pathway. BER is one mechanism by which cancer cells counteract the DNA damage elicited by cytotoxic agents or radiation and thus develop resistance to chemo-or radiation therapies. PARP inhibition may provide a novel mechanism to sensitize refractory tumors to chemotherapy and radiotherapy.

PARP inhibition has shown anti-tumor activity in homologous DNA repair-defective tumors, such as those with BRCA1 or BRCA2 mutations. Also, it is well established that cells deficient in homologous recombination are particularly sensitive to DNA-crosslinking agents, including the platinum salts (cisplatin and carboplatin) as their BRCA-selective effects are mediated by a similar mechanism to that of PARP inhibitors. Therefore, as platinum salts are frequently used for the treatment of ovarian cancer, including some individuals with BRCA1 or BRCA2 mutations, the combination with PARP inhibitors and DNA agents is an interesting combination that should be explored in clinical trials.

As used in this report, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that our therapeutic candidate Stenoparib may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for our therapeutic candidate Stenoparib or our putative Stenoparib-DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate or companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

Stenoparib is a potent inhibitor of both PARP1 and PARP2 enzymes, as demonstrated in both *in vitro* and *in vivo* studies. Development of stenoparib as single agent and in combination is supported by preclinical studies. Stenoparib inhibited proliferation in subsets of cells in cell line panels derived from a variety of tumors. Stenoparib, administered as a monotherapy, demonstrated potent tumor growth inhibition in several animal models with tumors featuring underlying defects in DNA repair, including BRCA mutant breast cancer. In addition, stenoparib demonstrated *in vivo* activity as a single agent in models of B cell lymphoma and AML.

In addition to being a potent PARP1/2 inhibitor, stenoparib also inhibits PARP5a/5b, otherwise known as tankyrase1 and 2 (TNKS1 and 2), important in maintaining chromosomal telomerase integrity and in regulating the canonical Wnt/Beta-catenin signaling. In colon cancer cell lines, stenoparib inhibited Wnt/Beta-catenin signaling, likely reflecting TNKS inhibition. Consistent with this possibility, stenoparib stabilized axin and TNKS proteins resulting in Beta-catenin de-stabilization and significantly altered expression of Wnt target genes. This indicates a potential for treating several cancers where aberrant activation of Wnt/Beta-catenin signaling can be part of the carcinogenesis and tumor progression.

Temozolomide (TMZ) is a chemotherapeutic agent with an activity that can be enhanced by PARP inhibition. PARP inhibition has also been shown to overcome resistance of cells to TMZ. Potentiation of TMZ activity was observed in orthotopic models of melanoma and glioblastoma. In xenograft models, stenoparib inhibition of PARP was observed in tumor tissue by using the PARP pharmacodynamic assay to measure PAR levels.

The predictive biomarker Ataxia-Telangiectasis Mutated (ATM) was selected for use in B cell lymphoma by demonstrating that stenoparib sensitivity was increased through ATM loss in these cells. Certain hematological indications are known to up-regulate P-glycoprotein (P-gp), which is implicated in the development of multidrug resistance leading to therapeutic failure and poor outcome. Stenoparib activity is not affected by P-gp over-expression, thus offering a potential advantage in the clinic.

Pre-Clinical Studies

PARP utilizes nicotinamide adenine dinucleotide (NAD) as substrate to catalyze the polymerization and transfer of poly (ADP-ribose) (PAR) to acceptor proteins. The posttranslational modification through addition of PAR results in modulation of target protein function. Stenoparib is a nicotinamide mimetic, competitive PARP inhibitor that inhibits PARP1 and PARP2 equipotently.

In cell-based assays, stenoparib potently inhibited proliferation of the BRCA1 mutant human breast cancer cell line MDA-MB-436. Additionally, stenoparib inhibited proliferation in the human hematologic cell lines: SR (B cell lymphoma) and MV-4-11-luc2/AcGFP (acute myeloid leukemia (AML)). In the murine leukemia cell line P388, P-glycoprotein (P-gp) overexpression had very little impact on inhibition of proliferation by stenoparib.

Oral administration of stenoparib for 28 days significantly inhibited tumor growth *in vivo* in the subcutaneous MDA-MB-436 xenograft model without any significant body weight loss. A dose- responsive pharmacodynamic effect on PARP activity in MDA-MB-436 xenograft tumor tissue was observed following administration of a single stenoparib dose. The decrease in PARP activity was sustained over several hours. These results demonstrate monotherapy activity of stenoparib in a BRCA mutant breast cancer model. Single agent activity was also observed in the AML MV-4-11-luc2/AcGFP survival model. Treatment with stenoparib resulted in decreased tumor burden as measured by luciferase signal, and reduction in disease translated to a statistically significant survival benefit.

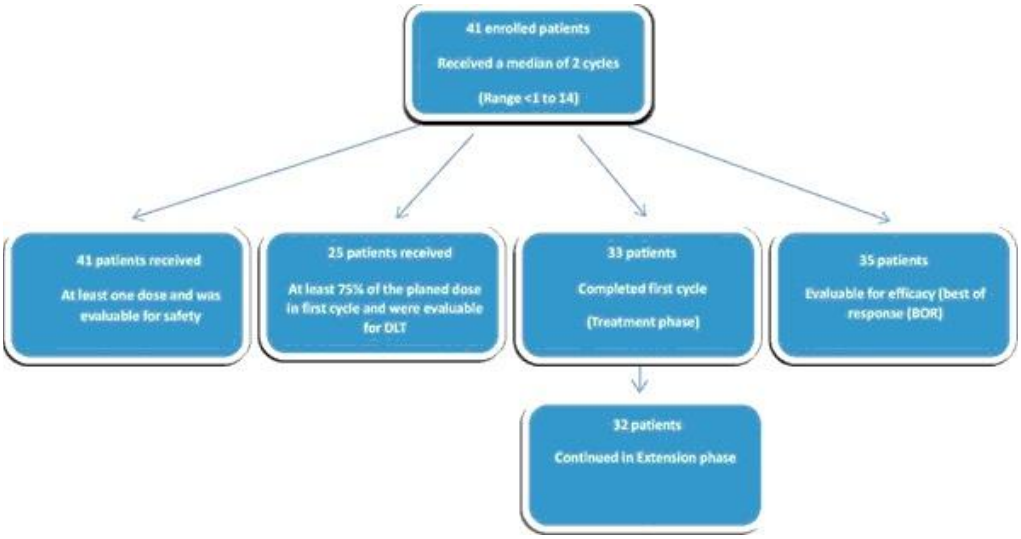
In addition to activity as monotherapy, stenoparib demonstrated potentiation of the anti-tumor effects of TMZ, eribulin mesylate (E7389) and carboplatin. In intracranial survival models of melanoma (murine melanoma B16 cell line) and glioblastoma (human glioblastoma multiforme SJGBM2 cell line), the addition of stenoparib to TMZ resulted in a significantly increased survival benefit versus that derived from TMZ alone.

Prior Clinical Trials

The initial planned first-in-human study of stenoparib (conducted by Eisai, Inc.) was an open-label, multi center, Phase 1 study of PARP Inhibitor stenoparib (formerly E7449) as single agent in subjects with advanced solid tumors or with B-cell malignancies and in combination with TMZ or with Carboplatin and Paclitaxel in Subjects with Advanced Solid Tumors. The first part (Phase 1) of the study started on January 31, 2012, and was completed with the last patient visit July 14, 2015. Further clinical evaluation was stopped, as it was decided to stop the clinical development for the reasons described below. Preliminary data after treating the first 28 patients have been presented at ESMO conference 2014. The final data including the retrospective/prospective Stenoparib-DRP® selection results were presented at ASCO 2018.

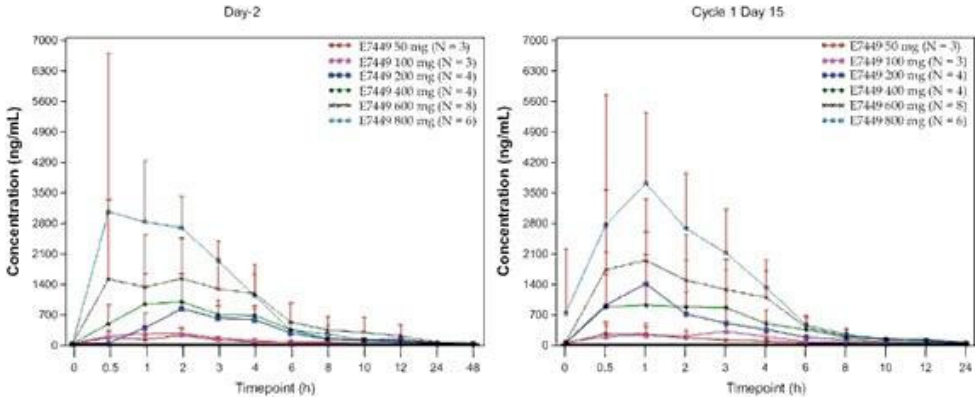
The study was conducted as Phase 1 single-agent arm (Arm 1) with standard 3+3 dose escalation. During dose escalation, sequential cohorts of 3 to 6 subjects (dose escalation cohorts) were administered increasing doses of 50 mg, 100 mg, 200 mg, 400 mg, 600 mg, and 800 mg (Table 5-1). 41 subjects were enrolled and 33 completed the 'Treatment phase' (received first cycle of treatment) while 8 subjects discontinued. 32 subjects continued in the 'Dose Extension Phase'. During the Dose Extension Phase, the primary reason for discontinuation of study treatment was disease progression (27 subjects due to objective disease progression, which was defined as treatment completion). Two subjects in the 600 mg dose group discontinued study treatment due to AEs, with AE being the primary reason for discontinuation as recorded from the disposition page of the Case Report Form (CRF).

All 41 subjects received at least 1 dose of stenoparib and were included in the safety, PK, and pharmacodynamics analyses. 12 subjects who received the 600 mg dose of stenoparib in both fed and fasted states were analyzed for food effect.



After a single or multiple oral dose, stenoparib was moderately well absorbed with tmax ranging from 0.5 to 4 hours across subjects and dose groups. The elimination half-life was approximately 8 hours with less than 1.5% of the administered dose recovered in urine. Accumulation based on AUC was minimal (less than 1.2 fold) upon 15 days of dosing across the range of doses.

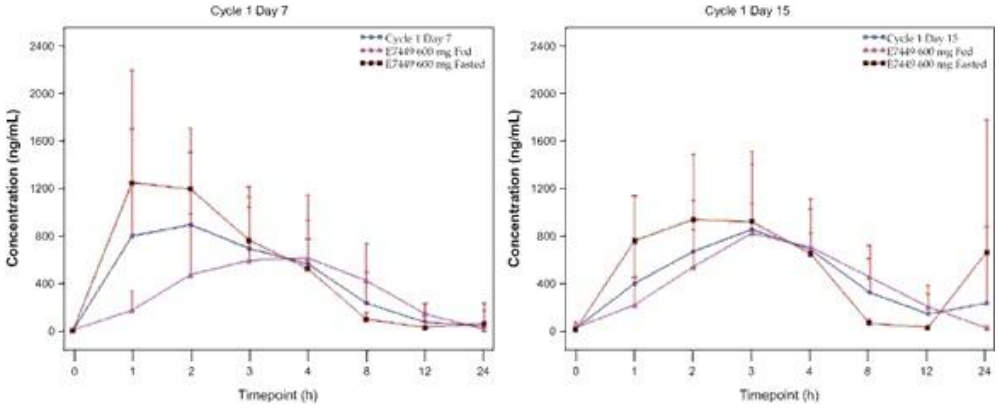
Stenoparib exposure (both Cmax and AUC) appeared to be approximately dose proportional following single or multiple oral doses between 50 mg and 800 mg, with slight deviation at the 400 mg and 600 mg doses. At the 600 mg dose, food delayed stenoparib absorption as evidenced by a shift in tmax by 2 hours, reduced Cmax by 60%, and increased AUC by 10%. The interpatient pharmacokinetic variability is large both with and without food. Thus, the effect of food decreases Cmax, and increases AUC.



The above figure shows a Linear Plot of Mean (+SD) E7449 plasma concentration versus nominal time (hours) by treatment fasting and after food intake.

Dose dependent inhibition of PARP activity, as demonstrated by percent change in PAR levels, was observed. Maximal inhibition of PARP activity was observed at the MTD dose (600 mg) of single agent stenoparib. Evaluation of PAR levels at the MTD dose of stenoparib (600 mg) in the food effect cohort demonstrated that PAR levels show maximal decrease at 2 to 4 hours post-dose with up to 90% inhibition in PAR levels (from baseline) observed. Sustained PARP inhibition was observed with a 70% or greater decrease in PAR levels observed at 24 hours post-dose. Greater decrease in PAR levels was observed with increasing plasma concentration of stenoparib and with the maximal inhibition observed corresponding to the peak plasma concentration in measurements obtained at Day-2 and Cycle 1 Day 15. A greater decrease in PAR levels was observed with a corresponding higher Cmax when stenoparib was administered without food than when administered with food. No significant changes in percent DNA in tail were observed.

In the finalized Phase 1 study, the majority of subjects (35/41; 85.4%) received up to 8 cycles of treatment with 26 subjects (63.4%) who received up to 2 cycles (<1 cycle = 7, 1 cycle = 5, and 2 cycles = 14); mean number of treatment cycles overall were 3.8 (median = 2 cycles, range: 0 i.e. <1 to 14). The overall median duration of treatment for all dose groups was 57 days (range: 1 to 392 days) with an overall median dose intensity of 11% (range: 1% to 111%) in terms of percentage of planned dose.



In the completed Phase 1 study the following safety results were reported:

- Dose Limiting Toxicities (DLTs) were reported in 5 of the 25 DLT evaluable subjects, 4 of these occurred at the 800 mg QD dose (1 Grade 3 fatigue and 3 Grade 2 fatigue resulting in administration of less than 75% of the planned dosage of stenoparib) and 1 occurred at the 600 mg QD dose (Grade 3 anaphylactic reaction). Based on assessment of DLTs, the Maximum Tolerated Dose (MTD) and Recommended Phase 2 Dose (RP2D) of single agent stenoparib treatment was 600 mg administered orally once daily (QD) in 28-day cycles.

- The mean number of treatment cycles received by the 41 subjects treated at the different dose levels of stenoparib was 3.8 (median = 2 cycles, range: <1 to 14). The overall median duration of treatment for all dose groups was 57 days (range: 1 to 392 days).

- No deaths due to AEs were reported during the study. Nonfatal Severe Adverse Events (SAEs) were reported in 58.5% subjects overall. The majority of SAEs were considered not related to stenoparib treatment and were reported in not more than 1 subject overall; SAEs reported in more than 2 subjects overall were fatigue (n=3) and lower respiratory tract infection (n=3). Treatment related SAEs included fatigue (n=3), anemia (n=1), anaphylactic reaction (n=1), drug hypersensitivity (n=1), depression (n=1), pyrexia (n=1), and transaminases increased (n=1).

- Treatment Emergent Adverse Events (TEAEs) occurred in all study subjects. The most frequently reported (>30% of subjects overall) TEAEs were fatigue, chromaturia, decreased appetite, nausea, diarrhea, constipation, and vomiting. The majority of TEAEs were reported to be Grade 1 or 2 in severity. Overall, Grade 3 events were reported in 27 subjects (65.9%) and the most frequently reported Grade 3 event was fatigue (n=7, 17.1%). A single Grade 4 AE of non-treatment-related hypokalemia was reported in a subject in the 200 mg dose group. No Grade 5 (fatal) events were reported. (Table 5-3)

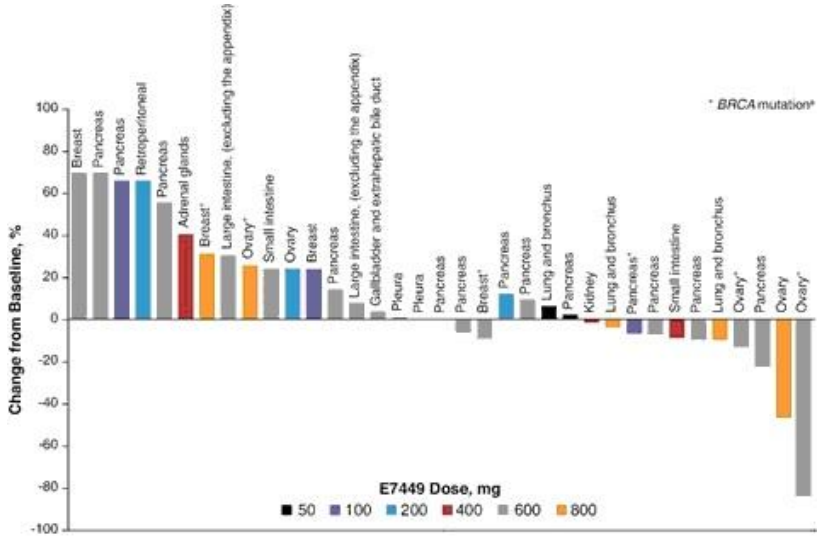
- The most common treatment-related TEAE was fatigue (63%), followed by chromaturia (49%), nausea (34%), diarrhea (29%), and maculo-papular rash (27%). The majority of treatment-related AEs were Grade 1 or 2 in severity. With the exception of treatment-related fatigue that was reported to be Grade 3 in severity for 4 subjects (2 subjects each in the 600 mg and 800 mg dose groups), all other Grade 3 treatment-related events were reported in not more than 2 subjects overall (Table 5-4).

- The study treatment was discontinued due to AEs in 17% subjects (1/3 subjects in 50 mg, 4/21 subjects in 600 mg, and 2/6 subjects in 800 mg dose groups). The events leading to treatment discontinuation included fatigue (n=3), diarrhea (n=2), muscular weakness (n=2), nausea (n=1), photosensitivity reaction (n=1), decreased appetite (n=1), paresthesia (n=1), and anaphylactic reaction (n=1). A total of 24 of 41 subjects (59%) required dose interruptions to manage treatment emergent toxicity. Dose reductions due to AEs were required in 14.6% subjects overall (1/4 subjects in 400 mg, 2/21 subjects in 600 mg, and 3/6 subjects in 800 mg dose groups).

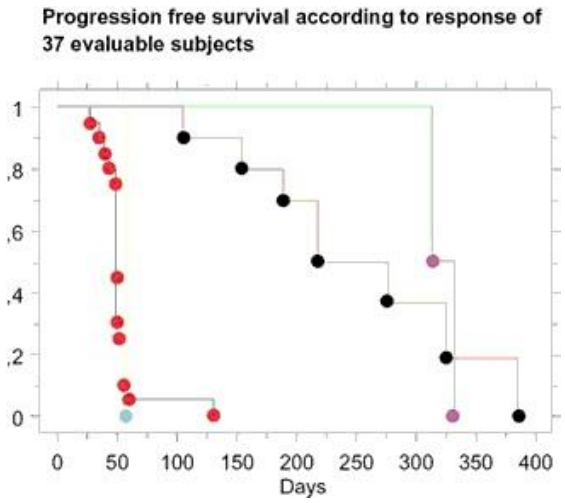
- Skin rash was considered as an event of special interest for stenoparib. Overall, 41.5% experienced AEs of skin rash with the highest incidence observed in the 800 mg dose group (66.7%) followed by the 600 mg dose group (47.6%). No serious events of skin rash were reported. All but 1 event of Grade 3 erythematous rash reported with the 600 mg dose group.

Preliminary anti-cancer activity assessment was a secondary objective of the Phase 1 study. Of the total 41 subjects who received single agent stenoparib treatment, best overall response (BOR) could not be assessed for 6 subjects including 5 subjects who discontinued study treatment prior to the first posttreatment tumor evaluation and 1 subject who did not have any target lesion (i.e., measurable disease). None of the 35 subjects assessed had a BOR of Complete Response (CR) based on investigator assessment using RECIST 1.1. The overall objective response rate (ORR; CR + Partial Response or PR) was 4.9% (n=2) with 2 PR out of 41 (both in ovarian cancer), and 31.7% Stable Disease (SD) (13 out of 41), and disease control rate lasting more than 23 weeks was 24.4% (CR+PR+SD: N=10). Both PRs were predicted by the DRP® for stenoparib after analyzing biopsies from 13 of the patients. A waterfall plot of the individual responses of 35 subjects from the safety cohort is presented below:

Anti-cancer activity according to dose groups



PFS for the whole population was 55 days. A Kaplan Meier plot of progression free survival of subjects with PR (green line), SD (orange line), NE (yellow line) and PD (blue line) is below:



The study was published in the British Journal of Cancer in 2020. It concluded that the drug stenoparib "showed good tolerability, promising antitumor activity and significant concentration-dependent PARP inhibition," and that "The results support further clinical investigation." Nevertheless, Eisai decided to pursue other priorities and for undisclosed reasons offered the therapeutic candidate to us because we had developed a Stenoparib-DRP® response predictor that could identify the responsive patients.

DRP®-Guided Phase 2 Trials

We have previously conducted an open label, single arm Phase 2 study to investigate the tolerability and anti-cancer activity of stenoparib in patients with metastatic breast cancer. Patients were selected by having a Stenoparib-DRP® score of >80%. Stenoparib was administered as a once daily oral dose of 600 mg in 21-day cycles (study SMR-3475/2X-1001). The study was initiated in June 2018 and discontinued in June 2020 due to inconclusive results. Fourteen patients were enrolled and received at least 1 dose of stenoparib. The median of number of previous chemotherapies were 6. There were 3 patients with 'stable disease' after receiving the treatment, with 1 patient maintaining stable disease for more than 26 weeks. The overall Clinical Benefit Rate (CBR) in the evaluable population was 9.1%, Progression Free Survival (PFS) was 6 weeks, and Overall Survival (OS) was 8 months. The most common Adverse Event (AE) was Fatigue (n = 11; 79%), the second most common AE was decreased appetite and nausea, respectively (n = 8; 57%). There were 8 Severe AEs (SAEs) reported by 5 patients, 6 events were unrelated, 1 was unlikely to be related, and 1 event (urinary tract infection) was possibly related to the treatment. The data from this mBC trial suggest that a diagnostic biopsy cannot be used for predicting likelihood of drug response, using the Stenoparib-DRP® companion diagnostic, in heavily pre-treated mBC patients, and that newer biopsies are needed. By terminating the mBC study, Allarity decided to focus on advancing stenoparib in indications with a higher likelihood of success, including ovarian and pancreatic cancer.

We are currently conducting a DRP®-guided Phase 2, open label, single arm study to investigate the tolerability and anti-cancer activity of stenoparib in patients with advanced, recurrent ovarian cancer. The protocol (2X-1002) addresses unmet medical needs in ovarian cancer patients that have progressed on previous PARPi therapy without requiring repeat platinum treatment and in selecting both Homologous Repair (HR) proficient and HR deficient patients/tumors with high likelihood of responding. The primary endpoint is Overall Response Rate (ORR) as determined by RECIST 1.1. Secondary endpoints are CBR, PFS and OS. This study is being conducted at Guy's Hospital (London, England), in addition to other trials sites in the U.S. and Europe. Patients are selected by using the Stenoparib-DRP® with a score of >50%. Stenoparib is currently administered twice daily (200 mg in the morning plus 400 mg in the evening for a total oral dose of 600 mg) in a 28-days cycle (study 2X-1002). The study was initiated in April 2019 using a single daily dose of 600 mg. 10 subjects that were required to be enrolled independent of DRP® score have received at least 1 dose of stenoparib and are included in the safety SAE reporting. Stenoparib-DRP®-selected patients commenced enrollment in June 2021. The delay in enrolling Stenoparib-DRP®- selected patients has mainly been due to COVID-19 pandemic issues. Enrollment on the twice daily dosing regimen described above began in Q2 2023. Since the Phase 2 studies currently are ongoing, anti-cancer activity data from these are too early to report from the full study. However, as of the 05 December 2023 press release, the current enrollment guided by DRP® is showing promising emerging clinical benefit in evaluable patients, including one CR.

Overview of Ovarian Cancer

Ovarian Cancer (OC) is a lethal disease with a 5-year survival rate of 20-30% for advanced OC. It is the second leading cause of cancer related deaths in women. A large proportion of patients with OC are diagnosed at an advanced tumor stage. The outcome after chemotherapy for advanced OC becomes poorer and poorer each time a new treatment is introduced following progression on the previous treatment. Approximately 14,000 OC patients die each year due to disease progression.

Treatment of OC (as well as breast cancer (BC)) advanced when the genes BRCA1 and BRCA2 were cloned in the early 1990s, allowing identification of high-risk individuals. These genes encode proteins that are involved in DNA homologous recombination (HR). Patients harboring germline BRCA1/2 mutations carry a defective copy of the gene in every cell, which increases the likelihood of cancer developing if the remaining copy becomes defective through somatic mutation or epigenetic inactivation. However, there are also patients with germline mutations in other HR pathway genes and patients who do not carry an inherited germline mutation but have tumors with sporadic HRD mutations. Data from the Cancer Genome Atlas (TCGA) demonstrates that approximately fifty percent of high grade serous ovarian cancers have aberrations in HR repair.

Epidemiological studies have shown an association between germline BRCA1/2 (gBRCA1/2) mutations and the development of OC, BC, and to a lesser extent pancreatic and endometrial cancers. Mutation frequencies are estimated to be approximately 15-20% for those diagnosed with OC and 5% for those diagnosed with BC (15). In a recent publication it was shown that for BRCA1 and 2 carriers, cumulative risk for BC by age 80 was 72% and 69%, respectively. For OC, cumulative risk was 44% and 17%, respectively.

The peak incidence of BC occurred in the 41-50-year age group (28.3 per 1000 person-years) for BRCA1 and in the 51-60-year group (30.6 per 1000) for BRCA2 mutation carriers. The incidence of OC was 3.6 times higher for BRCA1 than BRCA2 carriers, with the peak incidence of cancer occurring regardless of mutation type among women in the 61-70-year age group (29.4 per 1,000 in BRCA1 carriers). For BRCA1 and 2 carriers, BC risk increased with the number of first- and second- degree relatives with breast cancer. In contrast, OC risk did not vary with respect to family history of this disease. DNA repair pathways involving BRCA1/2 engage in single or double stranded DNA breaks, which can occur from damage caused by ultraviolet light, the generation of reactive oxygen species, ambient or therapeutic irradiation, day- to-day replication errors or chemical exposure. Cells lacking a functional BRCA1/2 are also deficient in HR and show a high-degree of chromosomal instability as well as increased sensitivity to ionizing radiation and chemotherapeutic agents that lead to double-stranded breaks.

Rationale for Targeting PARP in Ovarian Cancer

Poly (ADP-ribose) polymerases (PARPs) are a family of DNA-dependent nuclear enzymes catalyzing the transfer of ADP-ribose moieties from cellular nicotinamide-adenine-dinucleotide (NAD+) to a variety of target proteins. There are 17 PARP family member proteins identified through sequence homology of the catalytic domain. PARP1, 2 and 3 have all been implicated in DNA repair, with PARP1 being the most abundant. PARP inhibitors are designed to compete with NAD+ for the substrate binding to PARP and inhibit PARP activity. Cells containing dysfunctional BRCA1 or BRCA2 have been shown to become profoundly sensitized to the inhibition of PARP enzymatic activity, resulting in chromosomal instability, cell cycle arrest and subsequent apoptosis. PARP inhibition is thought to induce synthetic lethality, which describes a process where at least two genetic lesions that individually are not lethal become lethal when combined in the same cell. For example, cells that are deficient in HR, which is not lethal in itself, are hypersensitive to a reduction in PARP activity by PARP inhibitors. However, disruption to other proteins involved in HR DNA repair other than in BRCA may have the same effect on PARP inhibitor sensitivity.

A further important mechanism of action for PARP inhibition is the trapping of the PARP1 and PARP2 enzymes at damaged DNA causing cytotoxicity and cell death. Recent studies have revealed a more complex web of fundamental cellular processes that PARP1 is involved in crucial cell processes other than in DNA damage repair, such as chromatin remodeling and transcription or regulation of the cell cycle.

There are multiple PARP inhibitors approved for either monotherapy or maintenance therapy or both in patients with advanced OC. The effectiveness of PARP inhibitors as monotherapy or as maintenance therapy has substantially improved the progression free survival and may be promising for overall survival in OC patients. PARP inhibitors as single agents or as potential enhancers of cytotoxic agents that provoke DNA damage, such as alkylating agents and chemotherapy, have been investigated in a number of studies, including olaparib, rucaparib, niraparib, veliparib, and talazoparib, where the two latter PARPi are still under development. As of Q3 2022, PARP inhibitors were withdrawn from the market for the treatment of active, advanced ovarian cancers.

There is a current unmet need for treatment of patients with OC who have progressed on PARPi treatment. Our ongoing Phase 2 study in ovarian cancer allows for enrollment of patients previously treated with a PARPi. We intend to use our Stenoparib-DRP® to select patients from this group that will have a high likelihood of responding to our PARPi, Stenoparib.

Future Opportunities & Development Plans for Stenoparib

Overview of Pancreatic Ductal Adenocarcinoma (PDAC) & Rationale for Targeting PARP in PDAC

PDAC is the third leading cause of cancer related death in the United States (2018). Initial presentation of the disease is typically with metastasis, and the overall 5-year survival for all stages combined is 8%. Molecular analysis has revealed four subtypes of PDAC giving clinicians further insight into treating this deadly disease. One subtype that has been elucidated and termed “unstable” is significant for the presence of DNA damage repair deficiency and can be targeted by several old and emerging therapies. One such therapy that may be considered are PARP inhibitors.

There have been reports of responses seen to PARP inhibitors in individuals with pancreatic cancer, and there are clinical trials currently (NCT03140670, NCT02184195, NCT01585805) for this patient population. One PARPi (olaparib) was approved by the FDA in December 2019 for the treatment of BRCA1/2 mutated PDAC. Due to the relatively common DNA repair pathway mutations in PDAC tumors, PARP inhibition may be a potential therapeutic option in individuals with advanced PDAC with the HRD phenotype.

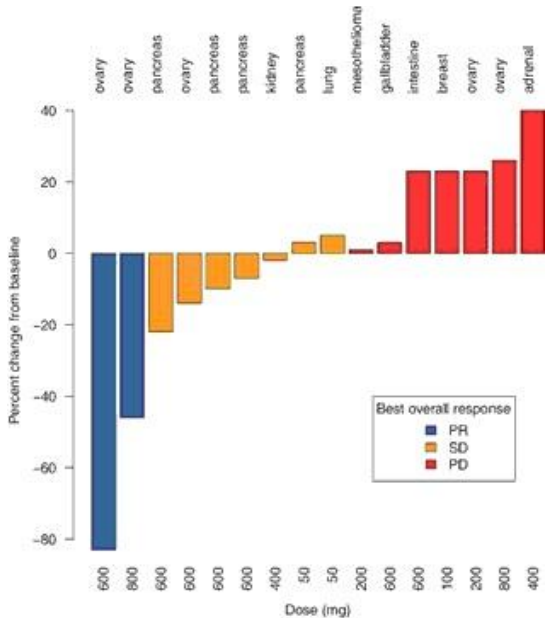
DRP® Companion Diagnostic for Stenoparib

We are developing stenoparib together with its validated DRP® companion diagnostic, which enables us to select the patients most likely to respond to the drug in our clinical trials. An IDE for our Stenoparib-DRP® was granted by the FDA (G180165) in 2018. The Stenoparib-DRP®, which comprises 414 expressed genes, was initially developed using a panel of 61 cancer cell lines (provided by Eisai) treated with stenoparib. This putative DRP® contains biomarkers that reflect the mechanism of action of PARP and Tankyrase inhibition by stenoparib, as well as capturing much unknown tumor biology, and is largely independent of BRCA mutation.

The putative Stenoparib-DRP®, developed through our DRP® platform using gene expression data from cancer cell line testing data, was retrospectively tested using biopsy materials from the Phase 1 trial of the drug (formerly E7449), sponsored by Eisai, that was conducted in the United Kingdom (UK) from 2012-2015 (clinicaltrial.gov number NCT01618136). Of 41 patients enrolled in the Phase 1 study, 35 had response assessment. Of these, 2 had PR (5% ORR) and 13 had SD. Biopsies and BRCA analysis were voluntary and available from 16, and 7 patients, respectively. Of the 16 patients with biopsies, 13 passed our QC in the lab and were assayed on the Affymetrix HG-U133Plus2 array.

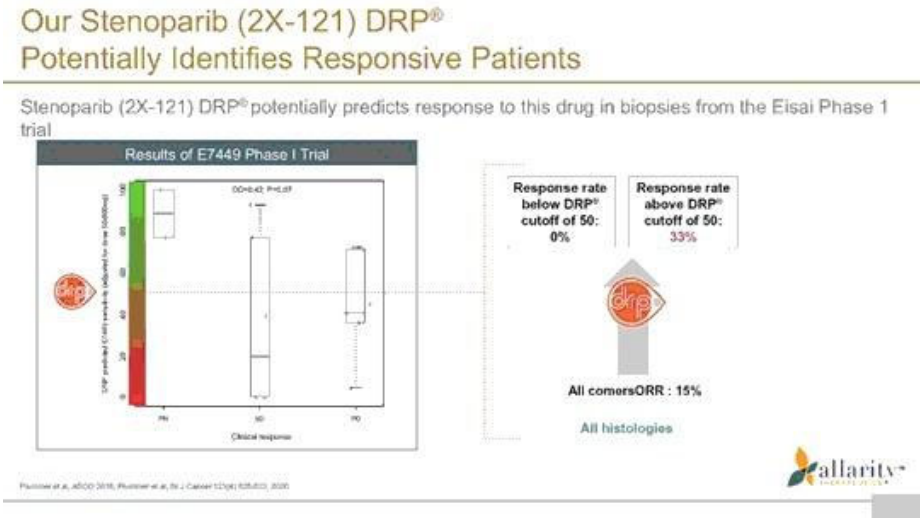
Waterfall plot of 16 Phase 1 patients for which biopsies were available

A statistical analysis plan was completed before initiation of retrospective blinded prediction of stenoparib sensitivity on the 13 samples.



Before blinded retrospective analysis of mixed histology biopsies from the Phase I trial of stenoparib, two crucial choices were made: 1) to use a reference population of 819 breast cancer biopsies, and 2) to use as cutoff the population median of the Phase 1 biopsies. Both choices turned out to be excellent, because the population median of the Phase 1 biopsies was very close to the population median of the breast cancer reference population, and when applied to the Phase 1 biopsies both medians separated the samples in identical populations with a clear difference in response rate and PFS.

It was decided that the breast cancer reference population with a cutoff of 50% would be used for the proposed Phase II trial. This has the added advantage of being the exact same parameters used for the blinded analysis of the Phase I trial. The only difference is that DRP has been locked and retrospectively validated between Phase I and proposed Phase II. The following figure shows the unblinded comparison of dose-adjusted predicted sensitivity to stenoparib and clinical response to stenoparib (the highest scoring SD patient is actually a long-term progression-free pancreatic cancer survivor (still alive at last check at 406 days, and progression-free at last evaluation at 321 days):



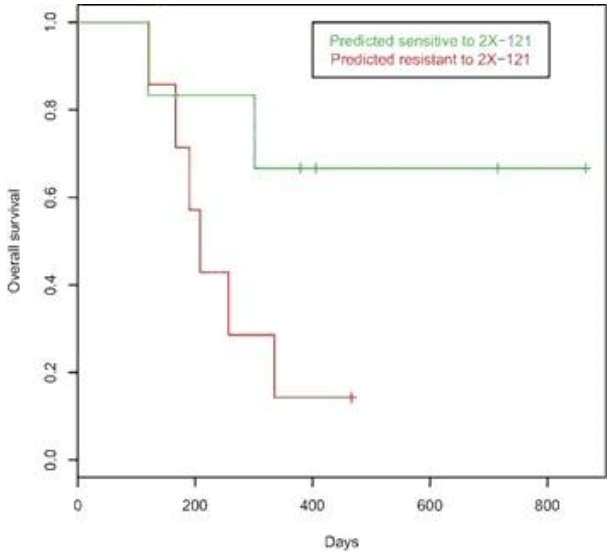
Clinical performance of the Stenoparib-DRP® at the pre-specified cutoff of 50 in ovarian cancer

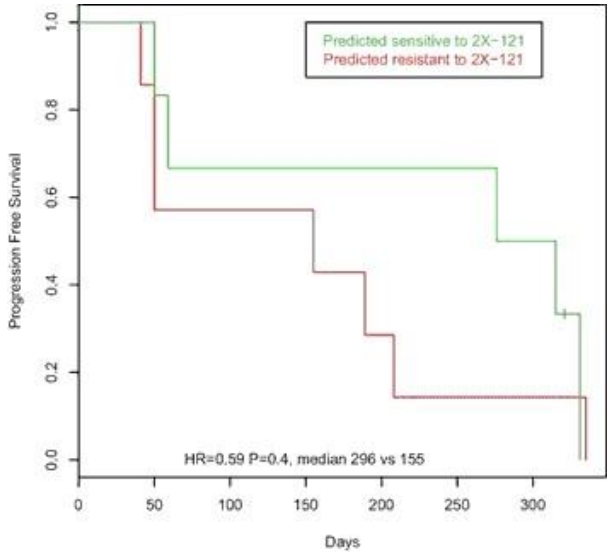
Ovarian only (N=3)	Responders (PR)	Non-responders (SD+PD)
DRP® positive (top 50%)	2	0
DRP® negative (bottom 50%)	0	1
Overall precision: 100% correct prediction		
Sensitivity: 100% of responders correctly predicted		
Specificity: 100% of non-responders correctly predicted		

Clinical performance of the Stenoparib-DRP® at the pre-specified cutoff of 50 for all histologies

All histologies (N=13)	Responders (PR)	Non-responders (SD+PD)
DRP® positive (top 50%)	2	4
DRP® negative (bottom 50%)	0	7
Overall precision: 69% correct prediction		
Sensitivity: 100% of responders correctly predicted		
Specificity: 64% of non-responders correctly predicted		

The following figures show Kaplan-Meier curves of overall survival (OS) and progression free survival (PFS) in two populations, those above a dose-adjusted cutoff of 50 (N=6), and those below a cutoff of 50 (N=7). The hazard ratio is 0.26 (P=0.04 one sided) and the median survival in the predicted resistant group (below cutoff) is 208 days. More than half of the patients remain alive in the group predicted sensitive.





Additionally, BRCA mutation status was considered, but was only available for 7 patients in the trial (NCT01618136), of which 6 are BRCA mutated. Of these 6, 1 responded to stenoparib, giving a response rate of 1/6 or 16% in the BRCA mutated population. This equals the response rate observed in the unselected 13 patients analyzed with DRP® score. Thus, BRCA mutation does not appear to be a predictor of response in this small trial.

In sum, our retrospectively tested Stenoparib-DRP® companion diagnostic correctly identifies responder patients to stenoparib and we plan use this DRP® companion diagnostic for all of our clinical programs to advance stenoparib, including our ongoing Phase 2 ovarian cancer study.

Existing PARP Inhibitors and Our Opportunity

Numerous PARP inhibitors, including Lynparza® (laparib), Rubraca® (rucaparib camsylate), Zejula® (niraparib) and Talzenna® (talazoparib tosylate) have been approved by the FDA for multiple oncology indications, including ovarian, breast, prostate, and pancreatic cancer. Sales of these FDA-approved PARP inhibitors were approximately $1.7 billion in 2019 and are forecasted to be over $7.0 billion in 2025, with Lynparza® (laparib) accounting for $1.2 billion and over $4.0 billion in the 2019 and 2025 totals, respectively.

Despite the commercial success of PARP inhibitors, broader adoption is limited by their high rates of GI and bone marrow/ myelo-toxicity, which is largely a result of off-target cell killing. Adverse grade 3–4 events from this class of drugs include anemia, thrombocytopenia, neutropenia and alopecia. Other common adverse reactions include nausea, vomiting, diarrhea, fatigue, and decreased appetite.

We believe Stenoparib is distinguished among the PARP class of drugs by the following features and advantages:

- It is a dual inhibitor of Tankyrases 1 and 2, which provides a likely dual cancer cell killing mechanism by interference with Wnt signaling pathways and chromosomal telomerase maintenance and stability.
- It lacks myelotoxicity, a common limiting adverse event among PARP inhibitors, at the established MTD.
- It is resistant to P-glycoprotein (PgP) mediated export from target cancer cells, resulting in higher accumulation of drug in target cells.
- It can cross the BBB, enabling the potential treatment of primary brain tumors, such as GBM, and brain metastases from other body tumors, such as malignant breast cancer.

Additionally, the use of our Stenoparib-DRP® companion diagnostic to identify and treat only those patients most likely to benefit from the drug (while excluding those patients unlikely to benefit from the drug), gives us a substantial advantage in increasing patient benefit rates, avoiding adverse events in patients that are not likely to benefit from our drug, and providing health economics advantages.

Furthermore, our DRP® for stenoparib identifies a broader group of potential responder patients than can be identified by the competitive biomarker approach of only assessing BRCA 1 and 2 mutation status in order to select and treat patients. The DRP® for stenoparib comprises 414 genes, including Wnt-beta-catenin and a number of DNA repair pathways, and thus is a broader assessment of the tumor responsiveness to the drug than determining mutation in one or two BRCA genes.

Other Therapeutic Programs Now De-prioritized or Terminated

The changes to Allarity senior management were instituted in December 2023. Under the leadership of the newly appointed interim CEO, Thomas Jensen, significant changes are being implemented currently to align the business with current fiscal realities and to focus company resources on Stenoparib, the company's most promising clinical asset. Given that this leadership change is so recent, the following sections for the 10K are still included for reference even though the further development of these assets is paused or terminated.

Overview of IXEMPRA® (microtubule inhibitor) - Deprioritized

Mechanisms of Action

Ixabepilone (IXEMPRA®) is a semisynthetic derivative of epothilone B, with improved in vitro metabolic stability. It is a novel antineoplastic agent that stabilizes microtubule dynamics, resulting in blockade of cancer cells in mitosis during cell division, leading to cell death. Ixabepilone induces a distinct pathway of cellular apoptosis via activation of caspase-2, whereas other tubulin agents, such as the taxanes, act via caspase-9. Ixabepilone is a poor substrate for efflux transporters such as the multidrug resistance-related protein (MRP1) and P-glycoprotein (P-gp) that are involved in drug-resistance mechanisms. Epothilones have a tubulin-binding mode distinct from that of other microtubule- stabilizing agents. Ixabepilone's tubulin-binding mode affects the microtubule dynamics of multiple ®-tubulin isoforms, including the class III isoform of ®-tubulin (®-III tubulin), the expression of which has been implicated in clinical taxane resistance. As used in this section of this report describing our therapeutic candidate IXEMPRA®, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that our therapeutic candidate IXEMPRA® may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for our therapeutic candidate IXEMPRA® or our putative IXEMPRA®-DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate or companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

Ixabepilone has anti-tumor activity in vivo against a broad spectrum of tumor types, including tumors that overexpress P-gp and are resistant to multiple agents including taxanes, anthracyclines, and vinca alkaloids. Ixabepilone demonstrated synergistic in vivo activity in combination with capecitabine. In addition to direct anti-tumor activity, ixabepilone demonstrated antiangiogenic activity in vivo.

The nonclinical pharmacokinetic (PK) studies performed with ixabepilone were directed toward the preliminary assessment of the absorption, distribution, metabolism, and excretion of the drug. Ixabepilone was (a) orally bioavailable with bioavailability ranging from 8 to 40% in mice, rats, and dogs; (b) extensively distributed extravascularly; (c) moderately bound to serum protein; (d) extensively metabolized to many metabolites and the metabolite profile was similar among species including humans; I metabolized by CYP3A4/5; (f) cleared primarily via oxidative metabolism and then mostly excreted in the feces; (g) neither a CYP inhibitor nor a CYP inducer at clinically relevant concentrations.

Pre-Clinical Studies

The results from the in vitro cytotoxicity studies against extensive panels of human-tissue specific, taxane-sensitive and taxane-resistant (including MDR, ®-III tubulin over- expression, and tubulin mutation mechanisms), cancer cell lines demonstrate that ixabepilone has potent and broad-spectrum antineoplastic activity. The effectiveness of ixabepilone in vitro is paralleled by equally broad-spectrum activity observed in vivo. Ixabepilone demonstrated a broad spectrum of in vivo anti-tumor activity in taxane- sensitive and taxane-resistant human cancer xenograft models. Less frequent dosing schedules allowed higher doses of ixabepilone to be given and performed better than the more frequent dosing schedules. Against a total of 35 human tumor xenografts grown in mice, representing a wide array of tumor types, ixabepilone demonstrated anti-tumor activities, producing 1 LCK or greater anti-cancer activity in 33 of 35 tumors. Ixabepilone demonstrated the ability to overcome drug resistance due to the Pgp-mediated multidrug resistance (MDR) phenotype in vivo, reversing the MDR resistance of 2 established MDR models: the 16C/ADR breast carcinoma models and the HCT116/VM46 human colon carcinoma model. Ixabepilone also demonstrated anti-tumor activity both in vitro and in vivo against a human tumor model that over expresses MRP1 (Pat-7), producing in vitro IC90 values of 7.4 nM (compared with 150 nM for paclitaxel) and an in vivo activity of 2.9 LCK (compared with 0.8 LCK for paclitaxel).

Ixabepilone suppresses the dynamic instability of < ®-III microtubules and< ®-II microtubules. This is in contrast to paclitaxel which had no suppressive effect on the dynamic instability of < ®-III microtubules, but suppressed the dynamic instability of < ®-II microtubules. Thus, ixabepilone should be more effective than paclitaxel at inhibiting proper formation of the mitotic spindle and disrupting mitosis in tumor cells with high expression of ®-III tubulin. On this basis, ixabepilone is expected to be more active on tumors that are resistant to paclitaxel because of over expression of ®-III tubulin.

The in vitro and in vivo cardiovascular safety pharmacology studies conducted with ixabepilone indicated that it is unlikely that ixabepilone will affect electrocardiographic parameters at anticipated plasma concentrations in patients. Ixabepilone induced drug- related clinical signs consistent with peripheral neuropathy in rodents. In a comparative study in rats, ixabepilone and paclitaxel induced peripheral neuropathy that was similar in nature and characterized by decreases in sensory and motor maximal nerve conduction velocities and reductions in sensory and compound nerve-response amplitudes. There were no ixabepilone-related CNS or respiratory findings.

The combination of ixabepilone with a number of approved anticancer therapeutic agents produced anti-tumor activities that were markedly greater than the best achievable responses from the individual single agents administered at their MTD alone. Such therapeutic synergism was observed with capecitabine, cetuximab, bevacizumab, or trastuzumab. Modest anti-cancer activity enhancement was observed when combined with irinotecan. However, no therapeutic advantage was observed when combined with gefitinib, gemcitabine, or paclitaxel).

The pharmacokinetic characteristics of ixabepilone in mice, rats, and dogs are comparable to those in humans, indicating the acceptability of those species for the toxicological assessment of ixabepilone. Serum protein binding of ixabepilone was moderate in rat, dog, and human serum.

In both animals and humans, ixabepilone was extensively metabolized via oxidative metabolism and eliminated mainly through fecal excretion. Only metabolites formed through oxidation of ixabepilone were found in animals and humans. All of the metabolites identified in humans were present in the species used in the toxicological evaluation of ixabepilone. The total amount of metabolites, as a percentage of the total radioactive dose in excreta (urine and feces), was high in all species studied. The known degradants of ixabepilone, BMS-249798, BMS-326412, and BMS-567637, were detected in plasma and excreta across species. The metabolite and degradant profiles in plasma are similar among humans, rats, and dogs, with unchanged ixabepilone being the most abundant drug-related component. Although the pharmacologic activity of individual metabolites is not known, a mixture of in vitro metabolites of ixabepilone was not active in in vitro cytotoxicity assays.

Ixabepilone is a substrate of CYP3A4 and CYP3A5. The PK of ixabepilone may be affected by the co-administration of agents that inhibit or induce CYP3A4. Ixabepilone is an inhibitor of CYP3A4, but it does not inhibit any of the other common CYP enzymes. Ixabepilone is not an inducer of CYP enzymes in vitro. Based on the efficacious plasma concentration and the in vitro inhibition and induction characteristics, ixabepilone is not expected to affect the PK of co-administered agents that are metabolized by CYP enzymes.

Nonclinical toxicity studies identified the principal target-organ, genetic, and developmental toxicities of ixabepilone. Ixabepilone principally affected tissues having rapid-cell division, including the GI, hematopoietic and lymphoid systems, and the male reproductive system. In mice and rats, peripheral neuropathy was also a prominent effect. Ixabepilone-induced toxicities were generally reversible following a 1-month, post dose recovery period, except for delayed testicular effects in rats and dogs and peripheral neuropathy in rats and mice. In rats, females were generally more severely affected than males, consistent with higher systemic exposures in females. When administered daily for 2 weeks or once every 21 days for 6 or 9 months, ixabepilone toxicity was similar to that observed in the single-dose, 5-day, and 1-month intermittent dose (QWx5) toxicity studies, with the exception of loss of bony trabeculae of the femoral growth plate in rats, which was not seen in any other studies. The increased growth-plate thickness observed in the rat is not likely to be a safety risk for the treatment of cancer in adult human populations, because in the rat, unlike humans, the growth plates do not fuse upon reaching sexual maturity.

Ixabepilone was not mutagenic in the Ames bacterial mutation assay. Ixabepilone was not clastogenic in the in vitro cytogenetics assay in primary human lymphocytes, but did increase the incidence of polyploid lymphocytes at high concentrations. However, ixabepilone was clastogenic (induction of micronuclei) in the in vivo rat micronucleus study. These findings were similar to other microtubule-stabilizing drugs and result in a benefit-risk analysis in the indicated patient population that supports the use of these drugs for a cancer indication. Ixabepilone did not affect mating or fertility in a rat reproduction study, and induced embryo-fetal toxicity in rats and rabbits only at doses that also caused maternal toxicity. Since clinical administration of ixabepilone occurs at doses associated with minimal to mild clinical side effects, administration during pregnancy may pose a risk for fetal toxicity.

The single- and repeat-dose IV toxicity studies with ixabepilone adequately predicted the clinical toxicities that were subsequently observed in humans. In both experimental animals and humans, ixabepilone toxicities were primarily manifested in the GI, hematopoietic, and peripheral nervous systems. These effects were expected and consistent with the toxicity produced by other microtubule-stabilizing anticancer drugs. In general, the nonclinical species were more sensitive to ixabepilone-induced toxicity than human subjects. In vitro, vincristine and paclitaxel were more potent than ixabepilone in inhibiting mitochondrial axonal transport in fetal dorsal root ganglion culture, whereas in mice and rats, paclitaxel and ixabepilone induced axonal degeneration or decreases in nerve conduction velocities that were similar in nature and severity. Based on the intended use of ixabepilone in treating advanced breast cancer and other solid tumors, the scope and results of the nonclinical pharmacology, pharmacokinetics, toxicity, and exposure studies support the continuous IV administration of ixabepilone on a once every 21-day cycle in this patient population.

Prior Clinical Trials

IXEMPRA® was originally developed through Phase 3 clinical trials and brought to market by Bristol-Myers Squibb (BMS). In Phase 1 clinical trials of ixabepilone as monotherapy, objective responses were demonstrated in a variety of tumor types, including breast, colon, head and neck, ovarian, endometrial, vulvar, and peritoneal cancers, melanoma, and non-Hodgkin's lymphoma.

Dose-limiting toxicities observed in Phase 1 clinical trials of ixabepilone as monotherapy included sensory neuropathy, neutropenia, myalgia, and fatigue. Adverse events (AEs) reported in Phase 1 studies in which ixabepilone was used in combination with other chemotherapy agents (*e.g.*, carboplatin [CA163007], doxorubicin [CA163008], and irinotecan [CA163025]) were similar qualitatively and in frequency to that observed in monotherapy studies; no toxicities unique to combination therapies were reported.

The PK of ixabepilone are linear, based on consistent total body clearance and apparent terminal elimination half-life across doses from 15 mg/m^2 to 57 mg/m^2. The coadministration of ketoconazole increases ixabepilone exposure in patients. Ketoconazole or other potent CYP3A4 inhibitors such as itraconazole, clarithromycin, atazanavir, nefazodone, saquinavir, telithromycin, ritonavir, amprenavir, indinavir, nelfinavir, delavirdine, or voriconazole should be avoided. If alternative treatment cannot be administered, a dose adjustment should be considered, and patients should be monitored closely for acute toxicities. Pharmacokinetics results indicate that exposure to ixabepilone is increased by 22%, 30%, and 81% in patients with mild, moderate, or severe hepatic dysfunction, respectively. After coadministration of ixabepilone and capecitabine, PK differences are minor and are not expected to affect the toleration profile or anti-cancer activity of either ixabepilone or capecitabine.

In a Phase 1/2 clinical trial (CA163031) evaluating ixabepilone in combination with capecitabine for the treatment of metastatic breast cancer (MBC), common toxicities included fatigue, nausea, hand-foot syndrome, and sensory neuropathy.

Phase 2 clinical trials demonstrated the activity of ixabepilone in advanced breast cancer, non- small cell, small-cell lung cancers, prostate cancer, gastric, and other malignancies. The most notable toxicities reported in Phase 2 trials of ixabepilone as monotherapy are peripheral neuropathy, neutropenia, myalgia, arthralgia, alopecia, and fatigue. The peripheral neuropathy has been predominantly sensory, cumulative in nature, and reversible upon discontinuation of ixabepilone.

In a large, international Phase 3 clinical trial (CA16304612) in patients with taxane-resistant and anthracycline-pre-treated or resistant metastatic or locally advanced breast cancer, ixabepilone in combination with capecitabine resulted in a statistically significant improvement in progression-free survival (PFS) and response rate (RR) compared to capecitabine monotherapy, per the independent radiology review committee (IRRC). Another similar, large, multicenter, international randomized, Phase 3 clinical trial (CA16304813) compared ixabepilone in combination with capecitabine to capecitabine alone in patients with metastatic or locally advanced breast cancer previously treated with anthracyclines and taxanes. CA163048, in which OS was the primary endpoint, demonstrated statistically significant and clinically meaningful superiority in PFS and improved RR over capecitabine alone that translated into a modest improvement in overall survival (OS) favoring the combination which did not meet statistical significance. These studies were conducted in 29 countries, with more than 300 clinical investigators and over 1,200 treated patients. The studies included dozens of trial sites spread throughout European countries.

Based on the Phase 3 clinical trials, ixabepilone was approved by the FDA in 2007 for the treatment of metastatic breast cancer in the following settings:

- In combination with capecitabine for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline and a taxane.

- As monotherapy for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline, a taxane, and capecitabine.

Despite the positive Phase 3 clinical trial results leading to approval of Ixabepilone in the U.S., the drug has not yet been approved in Europe, due to the EMA's determination of insufficient risk-benefit for Ixabepilone under the European socialized medicine pricing structure. Subsequently, IXEMPRA® was out-licensed to us to pursue approval in Europe using our IXEMPRA®-DRP®-selected patient population in order to show statistical significance in further clinical trials that the therapeutic candidate has sufficient risk-benefit under European standards to support a pricing structure that would be appropriate.

As of March 2009, more than 3,144 patients have been treated with ixabepilone in BMS- sponsored Phase 1, 2, and 3 clinical trials. In addition, the Cancer Therapy Evaluation Program (CTEP) program of the U.S. National Cancer Institute (NCI) independently conducted a number of clinical studies. These studies demonstrated the activity of ixabepilone in a variety of tumor types, including breast, hormone-refractory prostate, pancreatic, renal cell, non-small cell and small-cell lung cancers, and non-Hodgkin's lymphoma.

DRP®-Guided Phase 2 Clinical Trial

We are currently conducting a DRP®-guided, Phase 2, open label, single arm clinical trial — in Europe — to investigate the toleration and anti-cancer activity of IXEMPRA® as monotherapy in patients with metastatic or locally advanced breast cancer after failure of an anthracycline, a taxane, and capecitabine. This clinical trial, with an enrollment target of 60 IXEMPRA®-DRP®-selected patients, is being conducted at numerous sites in Europe, including Belgium, England, Finland, Poland and Germany. Patients are selected by using the putative IXEMPRA®-DRP® companion diagnostic at a cut-off score of 67%, and IXEMPRA® is administered at 40 mg/m^2 infused intravenously over 3 hours every 3 weeks (in accordance with the U.S. label of the drug). Dose reduction is required in certain patients with elevated AST, ALT, or bilirubin. The trial was initiated in April 2021. Thus far, several DRP®-selected patients have been enrolled and dosed in the trial, despite delays resulting from the ongoing COVID-19 pandemic. The clinical trial's goal is to provide a superior clinical benefit to DRP®-selected patients receiving IXEMPRA®, as compared to historical clinical data from breast cancer patients treated with IXEMPRA® but not selected with the putative DRP® companion diagnostic for the drug. Since the Phase 2 clinical trials currently are ongoing, data from these trials is not yet available to report. We have entered into a cost sharing arrangement with Smerud Medical Research International, our CRO for the Phase 2 clinical trial, where Smerud has agreed to accept a single digit share of any proceeds we generate from the commercialization or disposition of IXEMPRA® in exchange for the anticipated costs our CRO would incur in conducting the Phase 2 clinical trial up to an agreed upon maximum amount of costs incurred.

Overview of Metastatic Breast Cancer

Breast cancer is the most frequent malignancy in women worldwide, and the second most common cancer worldwide, with an estimated 1.8 million new diagnoses per year. In the U.S., breast cancer has the highest prevalence among all cancers. The Surveillance, Epidemiology, and End Results ("SEER") Program at National Cancer Institute estimates that in 2020, there will be 276,000 new cases of breast cancer in the U.S. alone, and more than 40,000 deaths. Treatment options for breast cancer depend on many factors, including the stage of cancer. Breast cancer is a heterogeneous disease which is grouped into several clinical subtypes based on the expression of three proteins: ER, progesterone receptor ("PR") and HER2. Both ER and PR are hormone receptors, and tumors that express either of these receptors are referred to as hormone receptor-positive. The American Cancer Society estimates that approximately 75-80% of all breast cancers express estrogen receptor ("ER+") highlighting the central role of ER signaling in driving a large majority of breast cancer. Although early-stage non-metastatic disease is curable in approximately 70-80% of patients, advanced breast cancer with distant organ metastases is considered incurable with currently available therapies. Advanced breast cancer comprises inoperable locally advanced breast cancer, which has not spread to distant organs, and metastatic (stage IV) breast cancer; common sites of spread are bone, lungs, liver, and brain. Currently, it is a treatable but virtually incurable disease, with metastases including to the brain being the cause of death in almost all patients, and a median overall survival of two to three years. Patients with metastatic breast cancer receive treatments that aim to relieve their symptoms and to prolong quality-adjusted life expectancy.

Treatment often continues until the cancer starts growing again or until side effects become unacceptable. If this happens, other drugs might be tried. The types of drugs used for stage IV (metastatic) breast cancer depend on the hormone receptor status and the HER2 status of the cancer. Women with hormone receptor-positive (estrogen receptor-positive or progesterone receptor-positive) cancers are often treated first with hormone therapy (tamoxifen or an aromatase inhibitor). This may be combined with a targeted drug such as a CDK4/6 inhibitor, everolimus or a PI3K inhibitor. Women who haven't yet gone through menopause are often treated with tamoxifen or with medicines that keep the ovaries from making hormones along with other drugs. Because hormone therapy can take months to work, chemo is often the first treatment for patients with serious problems from their cancer spread, such as breathing problems. Chemotherapy is the main treatment for women with hormone receptor-negative (ER-negative and PR-negative) cancers. These breast cancers are either HER2 positive or triple negative.

Trastuzumab (Herceptin®) may help women with HER2-positive cancers live longer if it's given along with chemo or with other medications such as hormonal therapy or other anti-HER2 drugs. Pertuzumab (Perjeta®), another targeted drug, might be added as well. Other options might include targeted drugs such as lapatinib (which may be given with certain chemo drugs or hormone therapy) or ado-trastuzumab emtansine (Kadcyla®). For HER2-negative patients, treatment depends on specific gene mutation status. Women who have a BRCA mutation are typically treated with chemotherapy (and hormone therapy, if the cancer is hormone receptor-positive). An option after getting chemotherapy is treatment with a PARP inhibitor, such as olaparib or talazoparib. Women who have a PIK3CA mutation are typically treated with alpelisib, a targeted PI3K inhibitor that can be used along with fulvestrant to treat postmenopausal women with advanced hormone receptor positive breast cancer.

For women that have triple-negative breast cancer (TNBC) — HER2 negative, ER negative, and PR negative — the immunotherapy dug atezolizumab (Tecentriq®) if often used, along with albumin-bound paclitaxel (Abraxane®) in patients with advanced triple-negative breast cancer with tumors expressing the PD-L1 protein (which is expressed is about 20% of triple-negative breast cancers.) For women with TNBC and a BRCA mutation whose cancer no longer responds to common breast cancer chemo drugs, platinum drugs (like cisplatin or carboplatin) may be considered.

According to the current estimates, the global therapeutics market for treatment of breast cancer was valued at over $19 billion in 2018 and is expected to reach over $40 billion by the year 2026, at a CAGR of 10.6%. By way of example, in 2019, worldwide sales for endocrine and targeted therapies treating ER+ breast cancer patients totaled $9.6 billion. Given the incidence rate and cost of treatment, by 2027 the market size for adjuvant therapy, first line treatments and second line treatments could total $25 billion, $8 billion and $4 billion, respectively. Accordingly, the potential market for treatment of mBC, including treatment of brain metastases (for which there is currently no approved therapy) is large and growing.

Rationale for Targeting Microtubules in mBC

IXEMPRA® is approved and on market in the U.S. as third- or fourth-line treatment of metastatic breast cancer in the following settings:

- In combination with capecitabine for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline and a taxane.

- As monotherapy for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline, a taxane, and capecitabine.

Accordingly, the clinical benefit of IXEMPRA®, a microtubule inhibitor, in these patient groups is already established. We seek to gain approval of this drug in Europe, for the same mBC patient groups, in connection with our putative IXEMPRA®-DRP® companion diagnostic, used to select and treat the most likely responder patients for the drug, in order to yield a superior therapeutic benefit in selected patients. Further, use of our putative DRP® companion diagnostic is expected to provide an improved benefit versus risk ratio, which we believe should support an EMA approval. IXEMPRA® was previously rejected by the EMA on basis of the risk versus benefit ratio.

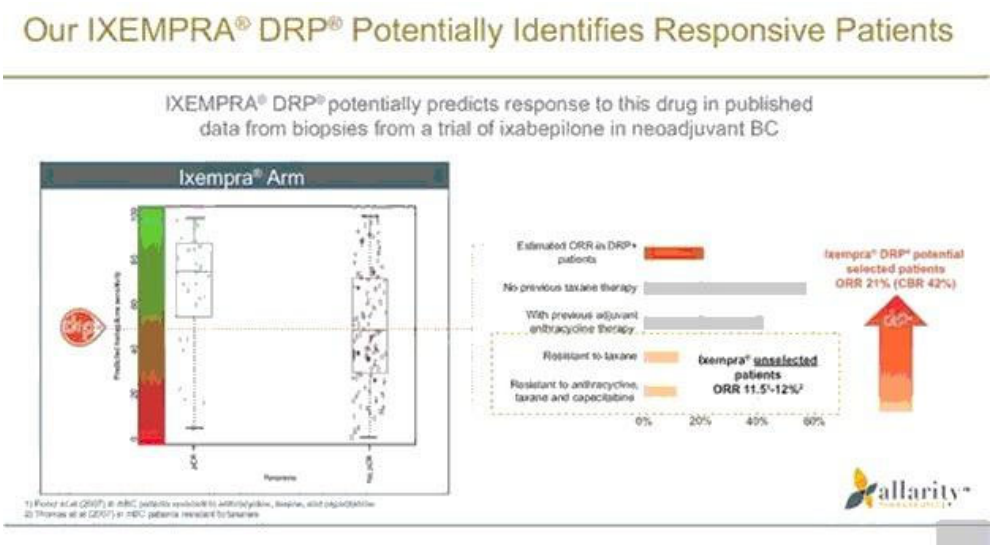
Future Opportunities & Development Plans for IXEMPRA®

Potential Development for Neoadjuvant mBC Setting

Since the retrospective validation of the IXEMPRA®-DRP® companion diagnostic showed a 58% increase in complete remission of patients treated with IXEMPRA® (see below) as adjuvant therapy, there is a potential to expand the IXEMPRA® drug plus a DRP® companion diagnostic combination to this setting as an attractive alternative to the commonly used paclitaxel. The neoadjuvant mBC setting is a substantially larger market opportunity than the third- or fourth-line mBC setting.

DRP® Companion Diagnostic for IXEMPRA®

We are developing IXEMPRA® together with its retrospectively validated DRP® companion diagnostic, which we believe enables us to select the patients most likely to respond to the drug in our clinical trials. Our Phase 2 clinical trial protocol, including use of the putative IXEMPRA®-DRP® companion diagnostic is in process of being approved by the regulatory agencies in the countries where we are conducting the clinical trial, and is already approved for use in clinical trials in Belgium, Finland, UK and Poland. The putative IXEMPRA-DRP® companion diagnostic, which comprises 198 expressed genes, was initially retrospectively validated using gene expression data from patient biopsies in the prior Phase 2 clinical trial of ixabepilone in neoadjuvant breast cancer setting that was conducted by BMS (NCT00455533). In retrospective analysis of this trial, patients selected with our putative IXEMPRA®-DRP® companion diagnostic was observed to have a 58% increase in complete remission when compared to randomly selected patients treated with ixabepilone.



In sum, we believe our retrospectively validated putative IXEMPRA®-DRP® companion diagnostic accurately and reliably identifies responder patients to this drug, and we plan to use this DRP® companion diagnostic for all of our clinical programs to advance IXEMPRA®, including our ongoing Phase 2 clinical trial for mBC.

Existing Microtubule Inhibitors & Our Opportunity

A number of microtubule inhibitors are approved and on market for the treatment of multiple cancer types. These approved drugs include docetaxel (Taxotere®), eribulin (Halaven®), ixabepilone (IXEMPRA®), paclitaxel (Taxol®, Abraxane®), and vinorelbine (Navelbine®). Docetaxel, paclitaxel, and albumin-bound paclitaxel are also called taxanes. Currently marketed microtubule inhibitors have generated several $billions of sales in the past few years. For example, sales of Halaven® (Eisai) alone were about $400 million in 2019, and sales of vinorelbine exceeded $110 million in 2018. The following table (2019) summarizes many of the approved microtubule inhibitors:

Drug	Main indications	Dose	Combinations
Vinblastine 1961*	Hodgkin's disease, non-Hodgkin lymphoma, histiocytic lymphoma, mycosis fungoides, testis, Kaposi's sarcoma, choriocarcinoma, breast, kidney	3.7 mg/m^2 – 18.5 mg/m^2	Monotherapy, mechlorethamine, doxorubicin, vincristine, bleomycin, etoposide, dacarbazine, brentuximab, cisplatin, ifosfamide, methotrexate, mitomycine
Vincristine 1963*	Leukemias, lymphomas, myeloma, breast, lung, head & neck, sarcomas, Wilms' tumor, neuroblastoma, retinoblastoma, medulloblastoma,	0.8 mg/m^2 – 2 mg	Monotherapy, doxorubicin, carboplatin mechlorethamine, vinblastine, bleomycin, etoposide, cyclophosphamide, procarbazine, topotecan, dactinomycin, leucovorin, actinomycin D
Vindesine 1982***	ALL, CML, melanoma, breast	3 mg/m^2 – 4 mg/m^2	Monotherapy, cisplatin
Vinorelbine 1994*	NSCLC, Hodgkin's disease, non-Hodgkin lymphoma, rhabdomyosarcoma, Wilm's tumor, neuroblastoma	25 mg/m^2 – 30 mg/m^2	Monotherapy, cisplatin
Vinflunine 2009**	Urothelial carcinoma	280 mg/m^2 – 320 mg/m^2	Monotherapy
Vincristine Liposomal 2012*	Philadelphia chromosome-negative ALL	2.25 mg/m^2	Monotherapy
Paclitaxel 1992*	Ovarian, breast, lung, gastric, Kaposi's sarcoma	100 mg/m^2 – 210 mg/m^2	Monotherapy, cisplatin, doxorubicin
Docetaxel 1996*	Breast, lung, prostate, gastric, head & neck	75 mg/m^2 – 100 mg/m^2	Monotherapy, cyclophosphamide, cisplatin, 5-fluorouracil
Nab-Paclitaxel 2005*	Breast, lung, pancreas	100 mg/m^2 – 260 mg/m^2	Monotherapy, carboplatin, gemcitabine
Cabazitaxel 2010*	Prostate	20 mg/m^2 – 25 mg/m^2	Monotherapy
lxabepilone 2007*	Breast	40 mg/m^2	Capecitabine

Anti-tubulin agents first approved by FDA (*), EMA (**) or in other countries (***). ALL: acute lymphoblastic leukemia; CML: chronic myelogenous leukemia; NSCLC: non-small-cell lung carcinoma

According to the National Comprehensive Cancer Network (NCCN) guidelines for treatment of metastatic breast cancer, in the second line metastatic breast cancer (mBC) setting, for patients who are HER2 negative, ixabepilone in combination with capecitabine is a therapeutic option, along with other microtubule inhibitors, such as eribulin, cyclophosphamide, docetaxel, and epirubicin. The choice of a particular microtubule therapeutic is made by the treating oncologist, and the current lack of suitable companion diagnostics to guide therapy selection has hampered the introduction of personalized medicine to this patient group. Our current clinical program for ixabepilone in metastatic breast cancer is focused on a third-line monotherapy in patients selected with the IXEMPRA®-DRP® companion diagnostic.

Despite the success of microtubule inhibitors as a class in the treatment of cancer, the expanded use of these drugs has been limited by certain toxicities, that include neutropenia and neurotoxicity, and the development of tumor resistance to the drugs after long-term use. For example, primary resistance to taxanes is a critical factor for disease progression. More than one-third of patients with metastatic breast cancer do not respond to first-line anthracyclines or taxanes. Taxane resistance rates of up to 55% in anthracycline-pre-treated patients and up to one-third in anthracycline-naive patients have been reported. Second-line, the same spectrum of outcomes can be expected.

Drug resistance is attributed to heterogeneity of tumors. Each patient has his/her own tumor with different characteristics and therefore different therapy outcomes. The variabilities include but are not limited to different genetic, epigenetic, transcriptomic and proteomic properties. The genotypic changes include mutations, gene amplifications, deletions, chromosomal rearrangements, transpositions of the genetic elements, translocations and microRNA alterations. Genomic instability generates a great level of intercellular genetic heterogeneity in cancer.

We believe that our microtubule inhibitor, IXEMPRA®, together with its DRP® companion diagnostic, can overcome many of the limitations of current microtubule inhibitors and has the potential to be a leading drug in its class that can succeed and compete in the marketplace for the treatment of mBC, and potentially other indications. The use of the IXEMPRA®-DRP® companion diagnostic to select and treat only those mBC patients most likely to respond to the drug (while excluding treatment of likely non-responders) can mitigate toxicity events in non-responder patients, while increasing therapeutic benefit in the identified responder patient population. The success of our IXEMPRA® program will establish the ability of our DRP® platform to expand oncology markets for approved cancer therapeutics through a personalized medicine approach using DRP® companion diagnostics.

Outlicensed or Partnered Programs

The following programs have been outlicensed or are part of business development deals and do not require the heavy resource commitment from Allarity. The development of these assets is largely the responsibility of the partner with limited support from Allarity to enable the DRP® companion diagnostic for each asset. The new leadership instituted in December 2023 is currently evaluating each of these programs. These remain in the 10K for reference as critical decisions about these programs have not yet been finalized.

Overview of our DRP® companion diagnostic for LiPlaCis® (targeted, liposomal cisplatin)

Mechanisms of Action

Cisplatin (or cisplatinum or *cis*-diamminedichloroplatinum (II)) is a chemotherapeutic drug that has been used, since the 1970s, in the treatment of various types of human cancers such as ovarian, lung, head and neck, testicular and bladder. Cisplatin has demonstrated anti-cancer activity against various types of cancers such as germ cell tumors, sarcomas, carcinomas as well as lymphomas. The mechanism of action of cisplatin has been associated with ability to crosslink with the urine bases on the DNA to form DNA adducts, preventing repair of the DNA leading to DNA damage and subsequently induces apoptosis (programmed cell death) within cancer cells. However, the drug exhibits certain level of resistance including increased repair of the damaged DNA, reduction in the accumulation of the drug intracellular and cytosolic inactivation of cisplatin.

The drug is also characterized by various toxic side effects including nausea, nephrotoxicity, cardiotoxicity, hepatotoxicity and neurotoxicity. Due to various side effects as well as drug resistance, other anti-cancer drugs that contain platinum such as carboplatin and oxaliplatin, among others, have been used in combination with cisplatin in chemotherapeutic treatment of cancer. In addition to the cytotoxic effects, cisplatin has immunosuppressive and radio-sensitizing properties. As used in this section of this report describing our therapeutic candidate LiPlaCis®, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that our therapeutic candidate LiPlaCis® may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for our therapeutic candidate LiPlaCis® or our putative Cisplatin-DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate or companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

LiPlaCis® is a novel, targeted liposomal formulation of the anti-cancer drug cisplatin. Liposomes are closed spherical vesicles, having an interior aqueous space entrapped by a bilayer lipid membrane. LiPlaCis® liposomes have cisplatin encapsulated in the interior aqueous space of the liposomes and the bilayer membrane is constituted by 3 phospholipids. The use of liposomes as drug carriers has been limited due to the rapid clearance of these carriers from the blood stream by the reticuloendothelial system. The addition of polyethylenglycol (PEG) polymers to the surface of the liposomes leads to reduced clearance rates. As a result, the use of liposomes is now recognized as a promising strategy for tumor-targeted drug delivery. Due to the leaky tumor vasculature and the incomplete lymphatic drainage system of tumors, long circulatory liposomes may be preferentially trapped and therefore accumulate in cancer tissues. The preferential entrapment and accumulation of the liposomes in the cancer tissue is also known as the enhanced permeability and retention effect (EPR-effect). Because of the trapping of liposomes, significantly more drug substance is present at the site of the tumor compared to administration of plain drug products.

However, it has also been realized that the degradation of liposomes and release of the encapsulated drug(s) after the liposomes accumulate in the tumor are critical elements to the success of liposomal drug delivery. This is the case for hydrophilic drugs such as cisplatin, which do not readily diffuse across the liposomal membrane. Such hydrophilic drugs require that tumor-specific degradation of the liposomal carrier takes place before the drug can be released and exert its cytotoxic action on the cancer cells. In fact, the absence of a trigger mechanism in the tumor tissue was proposed as the explanation for the lack of anti-tumor activity in clinical trials using cisplatin containing Stealth® liposomes (SPI-077) (PEGylated liposomes). In these studies, a high level of cisplatin was found in the tumor tissue inside the liposomes, but it was not bioavailable.

LiPlaCis® includes a tumor-specific targeting mechanism on the surface of its liposomes, which triggers the release of cisplatin specifically in tumor tissue. Secretory sPLA2 is a small secreted and phospholipid-degrading enzyme, which is overexpressed in cancer tissue compared to normal tissue. Until now, 10 catalytically active isoforms of sPLA2 have been identified, of which the Group II sPLA2 isoform seems to be the most predominant form in cancer. In normal tissue, Group II sPLA2 has been found to be expressed in cartilage, digestive tract (stomach, duodenum, jejunum, ileum and colon), and in prostate-, parotid- and lacrimal glands. This enzyme breaks down the LiPlaCis® once it accumulates in the cancer tissue due to the EPR-effect. The lipid composition of the LiPlaCis® is designed to be specifically susceptible to degradation by sPLA2. This leads to tumor-specific release of the encapsulated drug substance in the target tissue. sPLA2 has shown to be overexpressed in a wide range of tumors such as stomach, breast, gastric, liver, lung and pancreatic cancers. It has been shown that sPLA2 expression is increased with advancing stage of cancer disease and that enhanced expression of sPLA2 may be related to tumor progression.

LiPlaCis® enables the targeted transport of high concentrations of encapsulated anti-cancer drugs to cancer tissue. After IV administration, LiPlaCis® will naturally extravasate and accumulate in the extracellular space of the tumor tissue. The secretion of sPLA2 into the extracellular space of the cancer tissue provides further support to the overall concept of achieving a tumor-specific degradation of the LiPlaCis® after extravasation. The targeted delivery of cisplatin to tumors that is achieved by LiPlaCis® has the benefits of transporting this mutagenic and toxic chemotherapeutic to cancer cells while avoiding exposure to healthy cells. The tumor-specific degradation of the liposomal drug carriers by overexpressed sPLA2 offers a novel way to achieve a targeted and triggered release of the encapsulated drugs in the cancer tissue without any prior knowledge of the position and size of the tumor, *e.g.* undetected metastases.

DRP® Companion Diagnostic for LiPlaCis®

LiPlaCis® is being clinically developed by Chosa ApS together with our prospectively validated DRP® companion diagnostic for cisplatin, which enables Chosa to select the patients most likely to respond to the drug in their clinical trials. In August 2019, the FDA approved our IDE application for use of our Cisplatin-DRP® companion diagnostic in a planned pivotal Phase 3 clinical trial of LiPlaCis® in mBC. In June 2019, we announced that the FDA had provided feedback on our pending IND application and proposed pivotal Phase 3 clinical trial in mBC using the Cisplatin-DRP®. The Cisplatin-DRP®, which comprises 205 expressed genes, was initially developed using gene expression data from the National Cancer Institute NCI60 panel of cancer cell lines. We have out-licensed our putative Cisplatin-DRP® companion diagnostic to Chosa as described above.

Our putative Cisplatin-DRP® companion diagnostic was retrospectively validated in two non-small cell lung cancer (NSCLC) cohorts. Molecular prediction of adjuvant cisplatin anti-cancer activity in NSCLC showed a significant prediction at 3-year survival from surgery in univariate (HR = 0.138 (95% CI:0.035 – 0.537), p = 0.004) and multivariate analysis (HR = 0.14 (95% CI:0.030 – 0.6), p = 0.0081).

In sum, we believe our retrospectively and prospectively validated putative LiPlaCis®-DRP® companion diagnostic accurately and reliably identifies responder patients to LiPlaCis®, and we plan to use this DRP® companion diagnostic for all of our clinical programs to advance LiPlaCis®, including the planned, expanded Phase 2 clinical trial for mBC being advanced by our licensee, Chosa ApS.

Overview of 2X-111 (targeted, liposomal doxorubicin)

Mechanisms of Action

2X-111 is an advanced, targeted liposomal formulation of doxorubicin, one of the world's most widely used chemotherapies. The specific 2X-111 formulation, which exploits a unique, glutathione enhanced PEG-liposomal delivery system, allows the drug to cross the BBB, thereby enabling the treatment of primary brain tumors, such as GBM, and secondary brain tumors that originated from cancers outside the brain, such as metastatic breast cancer.

Doxorubicin is a type of chemotherapy drug called an anthracycline. It slows or stops the growth of cancer cells by blocking an enzyme called topo isomerase 2, which is necessary for DNA replication. Topo isomerase 2 is an enzyme that cuts both strands of the DNA helix simultaneously in order to manage DNA tangles and supercoils. Cancer cells need this enzyme to divide and grow. Doxorubicin is approved and in use for a number of cancer types, including breast cancer, bladder cancer, Kaposi's sarcoma, lymphoma, and acute lymphocytic leukemia. It is often used together with other chemotherapy agents.

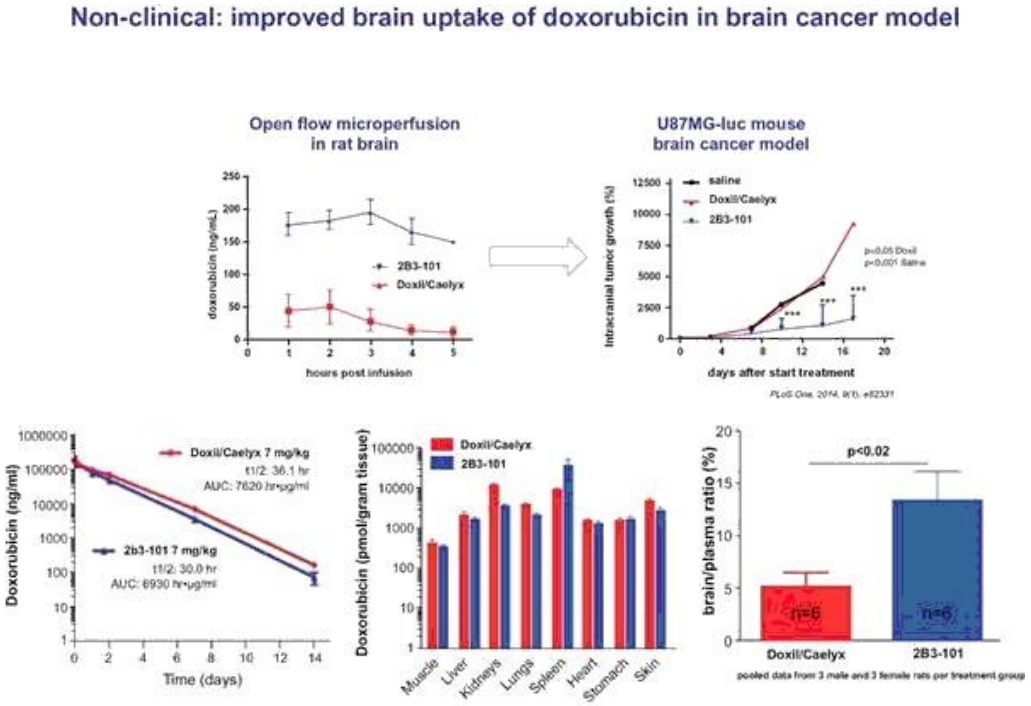
Liposomes are closed spherical vesicles, having an interior aqueous space entrapped by a bilayer lipid membrane. 2X-111 liposomes have doxorubicin encapsulated in the interior aqueous space of the liposomes and the bilayer membrane is constituted by 3 phospholipids. The use of liposomes as drug carriers has been limited due to the rapid clearance of these carriers from the blood stream by the reticuloendothelial system. The addition of polyethylenglycol (PEG) polymers to the surface of the liposomes leads to reduced clearance rates. As a result, the use of liposomes is now recognized as a promising strategy for tumor-targeted drug delivery. Due to the leaky tumor vasculature and the incomplete lymphatic drainage system of tumors, long circulatory liposomes may be preferentially trapped and therefore accumulate in cancer tissues. The preferential entrapment and accumulation of the liposomes in the cIncer tissue is also known as the enhanced permeability and retention effect (EPR-effect). As a consequence of the trapping of liposomes, significantly more drug substance is present at the site of the tumor compared to administration of plain drug products.

Most PEG-liposomal cancer drugs cannot pass the BBB and therefore cannot be used for treatment of primary or secondary brain tumors. The delicate metabolic homeostasis of the central nervous system is largely maintained by the BBB, which plays a key role in excluding potentially neurotoxic and exogenous compounds from the brain, while still allowing the penetration and uptake of essential nutrients. Many potentially highly efficacious anticancer drugs are currently not available to treat brain tumors because they do not adequately cross the BBB, and therefore do not reach the brain.

Glutathione is an endogenous tri-peptide with antioxidant-like properties in the brain and its active (sodium-dependent) transport receptor is highly expressed on the BBB. The unique 2X-111 glutathione-modified PEG-liposome enables transport of encapsulated drugs, such as doxorubicin past the BBB, enhancing the delivery of such drugs to the brain. As used in this section of this report describing our therapeutic candidate 2X-111, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that our therapeutic candidate 2X-111 may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for our therapeutic candidate 2X-111® or our putative Doxorubicin-DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate or companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

Pre-Clinical Studies

Preclinical studies have been performed in order to determine the anti-cancer activity and toleration of 2X-111 both systemically and in the CNS prior to the start of the human clinical trials. 2X-111 showed significantly better tumor growth inhibition and survival benefit in rodents with brain tumors as compared to normal PEGylated liposomal doxorubicin (Caelyx®/Doxil®). In a systemic breast cancer animal model, the tumor suppression was equal between 2X-111 and Caelyx®/Doxil®. Moreover, compared to Caelyx®/Doxil®, enhanced doxorubicin delivery by 2X-111 across the BBB was observed, with a favorable pharmacokinetic and safety profile in animal models. The following graphs represent some of the preclinical observations:



Prior Clinical Trials

2X-111 (formerly 2B3-101) was previously evaluated in Phase I/IIa, multi-center, open-label, dose-escalation clinical trial sponsored by 2-BBB Medicines, B.V. (NCT01818713; NCT01386580). Dieta Brandsma, MD, PhD, Division of Neuro-Oncology, Netherlands Cancer Institute in Amsterdam was the Coordinating Investigator. There were numerous trial sites in the Netherlands, Belgium, and France.

The purpose of this study was the determination of safety, tolerability, and PK of 2X-111 both as single agent and in combination with trastuzumab. Furthermore, the study aimed to explore the preliminary anti-tumor activity of 2X-111 as single agent in patients with solid tumors and brain metastases or recurrent malignant glioma, as well as in patients with various forms of breast cancer in combination with trastuzumab in Her2+ breast cancer patients with brain metastases. The study was performed in two phases: a dose escalation phase following a standard "3+3" design to determine dose-limiting toxicities (DLT) and a safe dose (MTD) of 2X-111, followed by four expanded study arms where patients were treated at the MTD to confirm the Recommended Phase II Dose (RP2D).

84 patients were enrolled in this study, including 37 in the dose escalation phase and an additional 47 patients in the expansion safety cohorts. Only patients who meet all the inclusion and exclusion criteria were enrolled. Two populations were used to analyze the study data including:

- Safety: Patients who received at least one dose of 2X-111 were evaluable for safety analysis.
- Intention to Treat (ITT): All patients in the Safety Population who have received at least one dose of trial medication were evaluable for ITT analysis.

To be eligible to participate in this study, candidates must have met the following eligibility criteria:

1. Patients with pathologically confirmed diagnosis of advanced, recurrent solid tumors and unequivocal evidence of brain metastases that were refractory to standard therapy or for whom no standard therapy existed or with unequivocal evidence of newly diagnosed untreated brain metastases and controlled extra cranial disease, which per the multi-disciplinary team decision did not require immediate radiotherapy, surgery, or standard systemic chemotherapy. Brain metastases may have been stable, progressive, symptomatic or asymptomatic brain metastasis/es. Stable or decreasing doses of steroids (e.g. dexamethasone) for a minimum of 7 days prior to baseline MRI or non-enzyme inducing antiepileptic drugs were allowed.

2. Patients with pathology confirmed diagnosis of advanced, recurrent primary malignant (grade III and IV) glioma that were refractory to standard therapy or for whom no standard therapy existed. Stable or decreasing doses of steroids (e.g. dexamethasone) for a minimum of 7 days prior to baseline MRI or non-enzyme inducing antiepileptic drugs were allowed.

2X-111 in combination with trastuzumab dose-escalation phase:

3. Patients with histologically-confirmed Her2+ (IHC 3+ or fluorescence in situ hybridization [FISH] amplified; by clinical assay on either primary or metastatic tumor) adenocarcinoma of the breast with unequivocal evidence of brain metastases that were refractory to standard therapy or for whom no standard therapy exist or with unequivocal evidence of newly diagnosed untreated brain metastases and controlled extra cranial disease, which per the multi-disciplinary team decision did not require immediate radiotherapy, surgery, or standard systemic chemotherapy could be included to this escalation phase as well.

Breast cancer brain metastases study arm of the expansion phase:

4. Patients with pathologically confirmed diagnosis of advanced, recurrent breast cancer with at least one progressive and/or new metastatic brain lesion, that were refractory to standard therapy or for whom no standard therapy exists. Stable or decreasing dosages of steroids (e.g. dexamethasone) for 7 days prior to baseline MRI and/or non-enzyme inducing antiepileptic drugs were allowed.

5. Patients with pathologically confirmed diagnosis of advanced breast cancer with newly diagnosed, untreated, brain metastases and controlled extracranial disease, which per the multi-disciplinary team decision do not require immediate radiotherapy, surgery, or standard systemic chemotherapy.

6. Once the MTD of 2B3-101 with trastuzumab has been determined, patients with histologically-confirmed Her2+ (IHC 3+ or fluorescence in situ hybridization [FISH] amplified; by clinical assay on either primary or metastatic tumor) adenocarcinoma of the breast with at least one progressive and/or new metastatic brain lesion, that were refractory to standard therapy or for which no standard therapy exist or with unequivocal evidence of newly diagnosed untreated brain metastases and controlled extra cranial disease, which per the multi-disciplinary team decision do not require immediate radiotherapy, surgery, or standard systemic chemotherapy, could be included to this expansion phase as well.

SCLC brain metastases study arm of the expansion phase:

7. Patients with pathologically confirmed diagnosis of advanced, recurrent SCLC with at least one progressive and/or new metastatic brain lesion, that were refractory to standard therapy or for whom no standard therapy exists. Stable or decreasing dosages of steroids (e.g. dexmethasone) for 7 days prior to baseline MRI and/or use of non-enzyme inducing antiepileptic drugs were allowed.

8. Patients with pathologically confirmed diagnosis of advanced SCLC with newly diagnosed, untreated, brain metastases and controlled extra cranial disease, which per the multi-disciplinary team decision do not require immediate radiotherapy, surgery, or standard systemic chemotherapy.

Melanoma brain metastases study arm of the expansion phase:

9. Patients with pathologically confirmed diagnosis of advanced, recurrent melanoma with at least one progressive and/or new metastatic brain lesion, that were refractory to standard therapy or for whom no standard therapy exists. Stable or decreasing dosages of steroids (e.g. dexamethasone) for 7 days prior to baseline MRI and/or use of non-enzyme inducing antiepileptic drugs were allowed.

10. Patients with pathologically confirmed diagnosis of advanced melanoma with newly diagnosed, untreated, brain metastases and controlled extra cranial disease, which per the multi-disciplinary team decision do not require immediate radiotherapy, surgery, or standard systemic chemotherapy.

Recurrent malignant glioma study arm of the expansion phase:

11. Patients with histologically proven glioma grade IV, which were progressive following first line treatment with surgery or biopsy followed by fractionated radiotherapy with concurrent temozolomide as chemotherapy.

12. Patients with recurrent histologically confirmed malignant (WHO grade III and IV) glioma or histologically confirmed low-grade (WHO grade II) glioma with radiographic evidence of malignant transformation by MRI, that were refractory to standard therapy, or for whom no standard therapy exists or did not require immediate standard therapy per the multi- disciplinary team decision.

13. Patients in both groups should have stable and decreasing dosage of steroids (e.g. dexamethasone) for a minimum of 7 days prior to baseline MRI. Non-enzyme inducing antiepileptic drugs are allowed.

In the single agent dose-escalation phase, patients eligible for the study were assigned to a dose level cohort. The starting dose was 5 mg/m^2, which was equal to 1/10 of the human equivalent dose of the LD10 of 2X-111 in rats. Dose levels for subsequent cohorts were 10, 20, 30 mg/m^2 and steps of 10 mg/m^2 thereafter. Patients received a single IV dose of 2X-111 on day 1 of each cycle. To minimize the risk of infusion reactions 5% of the total dose of 2B3-101 (in mg) was infused slowly over the first 30 minutes. If tolerated, the infusion was completed over the next hour for a total infusion time of 90 minutes. Each treatment cycle consisted of 21 days.

In the combination with trastuzumab dose-escalation phase, patients were assigned to a 2X-111 dose level cohort. The starting dose of 2X-111 was 40 mg/m^2 every 3 weeks. This dose has been selected based upon safety information from patients treated with 2X-111 at this dose level, as well as upon previous treatment with PEGylated liposomal doxorubicin in combinations trastuzumab.

In both cases, dose-escalation was conducted in steps of 10 mg/m^2 up to the MTD level determined for 2X-111 as single agent. The trastuzumab dose remained fixed to a loading dose of 8 mg/kg at day 1 and 6 mg/kg every 3 weeks at the subsequent cycles throughout the determination of the MTD. All patients received a single IV dose of 2X-111 on day 1 of each cycle. To minimize the risk of infusion reactions 5% of the total dose of 2X-111 (in mg) was infused slowly over the first 30 minutes. If 2X-111 was well tolerated, the remaining 95% of the infusion thereafter were administered over the next 60 min, resulting in a total infusion time of 90 minutes. The infusion of trastuzumab followed 30 minutes after the completion of the 2B3-101 infusion.

In the breast cancer brain metastases study arm of the expansion phase, each treatment cycle equally also consisted of 21 days. On day 1 of each cycle patients received a single IV 50 mg/m^2 dose of 2X-111 as single agent, or a dose of 2X-111 at the MTD of 2B3-101 in combination with trastuzumab (if different). To minimize the risk of infusion reactions 5% of the total dose (in mg) was infused slowly over the first 30 minutes. If 2X-111 was well tolerated, the remaining 95% of the infusion was thereafter administered over the next 60 minutes, resulting in a total infusion time of 90 minutes. A trastuzumab infusion followed 30 minutes after the completion of the 2X-111 infusion, if applicable. Each treatment cycle consisted of 21 days.

In the SCLC brain metastases study arm of the expansion phase, each treatment cycle also consisted of 21 days. Patients received a single IV 50 mg/m^2 dose of 2X-111 on day 1 of each cycle. To minimize the risk of infusion reactions 5% of the total dose of 2X-111 (in mg) was infused slowly over the first 30 minutes. If tolerated, the infusion was then completed over the next hour for a total infusion time of 90 minutes. Each treatment cycle consisted of 21 days.

In the melanoma brain metastases study arm of the expansion phase, each treatment cycle also consisted of 21 days. Patients received a single IV 50 mg/m^2 dose of 2X-111 on day 1 of each cycle. To minimize the risk of infusion reactions 5% of the total dose of 2X-111 (in mg) was infused slowly over the first 30 minutes. If tolerated, the infusion was completed over the next hour for a total infusion time of 90 minutes. Each treatment cycle consisted of 21 days.

In the recurrent malignant glioma study arm of the expansion phase, each treatment cycle consists of 28 days. Patients received a single IV 60 mg/m^2 dose of 2X-111 on day 1 of each cycle. To minimize the risk of infusion reactions 5% of the total dose of 2X-111 (in mg) was infused slowly over the first 30 minutes. If tolerated, the infusion was completed over the next hour for a total infusion time of 90 minutes. Each treatment cycle consisted of 28 days.

Infusion or hypersensitivity reactions were expected with the first or subsequent dose of 2X-111 and/or trastuzumab. In case of an infusion reaction, it was recommended to follow the below infusion scheme not only for the continued infusion but also for all future infusions with 2X-111 in the patients that experience such a reaction:

- (Re)-start the 2X-111 infusion with 10 mL/hour for the first 15 minutes and increase the infusion rate every 15 to 30 minutes as follows: 20 mL/hour, 50 mL/hour, 100 mL/hour and finally 200 mL/hour.

- In addition, (pre) medication such as hydrocortisone, ranitidine, cimetidine, antiemetics, and diphenhydramine in line with existing local institutional guidelines all were allowed.

Patients who received 2X-111 in combination with trastuzumab participated in an intensified cardiac program including ECG, LVEF, cTnT and NT-proBNP measurements before start of every treatment cycle.

The following table summarizes the demographic characteristics of patients enrolled in each of the DEP and EPP stages:

Characteristic	Statistic	DEP	EPP
Age (years)	Mean (s.d.)	52.2 (10.6)	51.6 (11.5)
	Median (min, max)	52 (31, 73)	53 (25, 81)
Weight (kg)	Mean (s.d.)	75.1 (13.6)	81.7 (18.2)
	Median (min, max)	71 (41, 103)	82.0 (51, 126)
Height (cm)	Mean (s.d.)	172.1 (11.1)	172.4 (9.4)
	Median (min, max)	172 (153, 197)	170 (147, 191)
Body Surface Area (kg/m^2)	Mean (s.d.)	1.889 (0.211)	2.001 (0.242)
	Median (min, max)	1.873 (1.34, 2.29)	2.038 (1.60, 2.59)
Gender (N)	Female (%)	25 (67.6)	31 (66)
	Male (%)	12 (32.4)	16 (34)
Ethnicity (N)	Black (%)	1 (2.7)	1 (2.1)
	Caucasian/white (%)	34 (91.9)	44 (93.6)
	Oriental (%)	0 (0.0)	2 (4.3)
	Other (%)	2 (5.4)	0 (0)
Tumour Type (N)	BC (%)	13 (35.1)	15 (31.9)
	Mal. Glioma (%)	13 (35.1)	20 (42.6)
	Melanoma (%)	1 (2.7)	5 (10.6)
	Other (%)	7 (18.9)	0 (0)
	SCLC (%)	3 (8.1)	7 (14.9)
Her2/Neu on BC (N)	Negative (%)	1 (2.7)	7 (14.9)
	Positive (%)	12 (32.4)	8 (17.0)
Progesterone receptor on BC (N)	Negative (%)	9 (24.3)	11 (23.4)
	Positive (%)	4 (10.8)	4 (8.5)
Estrogen receptor on BC (N)	Negative (%)	6 (16.2)	7 (14.9)
	Positive (%)	7 (18.9)	8 (17.0)

Preliminary anti-cancer activity for solid tumors was assessed according to RECIST 1.1 criteria. The preliminary anti-cancer activity for recurrent malignant gliomas was assessed according to the RANO criteria. In order to evaluate the anti-cancer activity of the treatment, appropriate imaging procedures were performed to accurately assess the tumor size at baseline, at the last day (day 21 or in case of patients with recurrent malignant glioma enrolled in the dose expansion phase day 28) of every even cycle (e.g. cycle 2, 4, 6 etc.), and at withdrawal from study treatment. Unless not done within 14 days before start of treatment the MRI of the brain was performed to assess brain lesion sizes. Unless not done within 28 days before baseline, a CT/MRI-scan of chest/abdomen/pelvis was performed to assess solid tumor sizes. If corticosteroid treatment (e.g. dexamethasone or methylprednisolone) or increase in corticosteroid treatment was required between screening and the first cycle of 2X-111, the baseline MRI was re-performed after a minimum of 7 days of stable or decreasing doses of the corticosteroids. The first cycle of drug was not initiated until baseline MRI has been performed.

CT/MRI-scans of the chest/abdomen/pelvis were only obtained from patients with solid tumors and brain metastases. These assessments were not required for patients with recurrent malignant glioma. Identified lesions were consistently followed using the unique lesion number assigned at baseline. All tumor measurements were obtained using the same diagnostic procedure used at baseline. For each course in which a tumor assessment was made, standard tumor response criteria were applied and the response for that course documented in the patient file. All identified lesions at screening/baseline were followed using the same imaging procedure. A bone scan was only obtained if clinically indicated during the study if the patient developed symptoms or signs of bone metastases. If bone metastases were known to be present at screening, bone scintigraphy was performed in addition to and at the same time as the CT/MRI-scans throughout the study. All lesions were followed during treatment (i.e. target lesions as well as non-target lesions). All CT/MRI Images from patients enrolled in the dose expansion arms of the study were sent electronically to a central repository system.

Safety was assessed by means of physical examination, neurological examination (and a brain MRI if a neurological deficit was leading to WHO> 2), weight, vital signs, ECOG performance status, MMSE, HDS, laboratory evaluations (hematology, biochemistry and urinalysis and N-terminal Pro-Brain Natriuretic Peptide (NT-ProBNP) and cardiac Troponin T (cTnT)), electrocardiograms (ECG), LVEF (MUGA/ECHO)), and recording of concurrent illness/therapy and adverse events.

Clinical anti-cancer activity was assessed by best overall response (OR) by both, investigator, and computer-based methods. Overall, both methodologies reported similar results with the majority of best overall survival (OS) reported being stable diseases (SDs) while some partial responses (PRs) also being observed.

In the Dose Escalation Phase (DEP) group and in the glioma only patients, SD was the best OR recorded for 26.5% and 23.5% of the patients, as reported by the computer and investigator, respectively. At the same time, in the DEP group and for other solid tumors and across all single and combination arms, one PR (2.9%) was reported by the computer in the 2X-111 50 mg/m^2 + trastuzumab group. However, this response was deemed as SD by the investigator. The rate of SDs reported for this other (non-glioma) solid tumor group, was 23.3% and 20.6% for the computer and investigator, respectively.

In the Expansion Phase (EPP) group and for the glioma patients, both the computer and the investigator methods recorded the best OR as an SD rate of 17.8%. In the solid tumors group, the same SD rate of 26.7% was reported by both methods of assessment also. In addition, PR was also reported, 2.2% by the investigator and 4.4% by the computer.

The following tables summarize best overall responses by dose group and by cohort:

	Dose groups in mg/m^2										
	5	**10**	**20**	**30**	**40**	**50**	**60**	**70**	**40+T**	**50+T**	**Total**
						N (%)					
RANO: Malignant Glioma											
PD											
Computer				1 (33.3)		1 (33.3)					**2 (5.9)**
Investigator				2 (66.7)		1 (33.3)					**3 (8.8)**
SD											
Computer				1 (33.3)	2 (66.7)	1 (33.3)	3 (42.9)	2 (100)			**9 (26.5)**
Investigator					2 (66.7)	1 (33.3)	3 (42.9)	2 (100)			**8 (23.5)**
RECIST: Solid tumour											
PD											
Computer	3 (100)	2 (66.7)	2 (100)	1 (33.3)	1 (33.3)		4 (57.1)	1 (50)	1 (33.3)	1 (20)	**16 (47.1)**
Investigator	3 (100)	2 (66.7)	2 (100)	1 (33.3)	1 (33.3)		4 (57.1)	1 (50)	1 (33.3)	1 (20)	**16 (47.1)**
PR											
Computer										1 (20)	**1 (2.9)**
SD											
Computer		1 (33.3)				1 (33.3)			2 (66.7)	3 (60)	**7 (20.6)**
Investigator		1 (33.3)				1 (33.3)			2 (66.7)	4 (80)	**8 (23.5)**
Total [N; %]	**3 (100)**	**3 (100)**	**2 (100)**	**3 (100)**	**3 (100)**	**3 (100)**	**7 (100)**	**2 (100)**	**3 (100)**	**5 (100)**	**34 (100)**

	Dose groups in mg/m²						
	60 prog. Glioma	60 Glioma	50 Breast new	50 Breast rec.	50 SCLC	50 Melanoma	Total
	N (%)						
RANO: Malignant Glioma							
PD							
Computer	5 (62.5)	5 (50)					**10 (22.2)**
Investigator	5 (62.5)	5 (50)					**10 (22.2)**
SD							
Computer	3 (37.5)	5 (50)					**8 (17.8)**
Investigator	3 (37.5)	5 (50)					**8 (17.8)**
RECIST: Solid tumour							
PD							
Computer			4 (50)	3 (42.9)	3 (42.9)	3 (60)	**13 (28.9)**
Investigator			4 (50)	1 (14.3)	5 (71.4)	4 (80)	**14 (31.1)**
PR							
Computer				1 (14.3)		1 (20)	**2 (4.4)**
Investigator				1 (14.3)			**1 (2.2)**
SD							
Computer			4 (50)	3 (42.9)	4 (57.1)	1 (20)	**12 (26.7)**
Investigator			4 (50)	5 (71.4)	2 (28.6)	1 (20)	**12 (26.7)**
Total [N; %]	**8 (100)**	**10 (100)**	**8 (100)**	**7 (100)**	**7 (100)**	**5 (100)**	**45 (100)**

Finally, analysis of the three exploratory populations revealed that SDs are the predominant best OR. In the glioma patient group receiving 2X-111 greater or equal to 40 mg/m^2, 16 out of the 27 patients experienced PD. In the breast-patient-group receiving 2X-111 greater or equal to 40 mg/m^2, 2 out of 24 patients experienced PR according to the computer or investigator method of assessment, respectively and at the same time, 12 or 15 out of 24 experienced an SD. In the Her2+ breast patient group receiving 2X-111 greater or equal to 40 mg/m^2 in combination with trastuzumab, 2 or 1 out of 16 patients experienced PR according to the computer or investigator method of assessment, respectively and at the same time, 10 or 12 out of 24 experienced an SD. The following table summarizes those results:

	Dose groups in mg/m² > = 40 mg		
	Glioma	Breast	Her2+
		N (%)	
RANO: Malignant Glioma			
PD			
Computer	11 (40.7)		
Investigator	11 (40.7)		
SD			
Computer	16 (59.3)		
Investigator	16 (59.3)		
RECIST: Solid tumour			
PD			
Computer	1 (3.7)[38]	10 (41.7)	4 (25)
Investigator	1 (3.7)[38]	8 (33.3)	3 (18.8)
PR			
Computer		2 (8.3)	2 (12.5)
Investigator		1 (4.2)	1 (6.3)
SD			
Computer		12 (50)	10 (62.5)
Investigator		15 (62.5)	12 (75)
Total	**27 (100)**	**24 (100)**	**16 (100)**

All patients have reported at least one treatment emergent adverse event (grade I to IV) but all of them were manageable and none of them have been considered unexpected based on the previous experience from treatment with liposomal doxorubicin (Doxil/Caelyx) and/or non-clinical safety information with Allarity.

The number of infusions administered as single agent or in combination with trastuzumab to the individual patients ranged from 1 to 10. Long-term toxicity data (> 2 infusions of 2X-111) were available from 34 patients, all but one of these patients were treated with doses more or equal to 40 mg/m^2. One patient has received 10 infusions. The maximum total dose of 2X-111 delivered to date is 240 mg/m^2. Following treatment with 2X-111 infusion related reactions were reported in 27% of the patients in the Dose Escalation and 34% in the EPP. All infusion related reactions (dyspnea, chest pain, back pain, fatigue, headache, flushing, chills, tachycardia) that were observed in this study with 2X-111 were in between grade 1 to 3, but no grade 4 reactions. After modification of the initial infusion rate (5% given over the first 30 min and the remaining 95% over 60 min) at a dose of 30 mg/m^2, infusion reaction grade 1-2 has been reduced and reported in 16 out of 68 treated patients (23%), the majority still without any premedication. In all patients experiencing an infusion reaction the infusions were continued after a shorter treatment interruption. Only one case was reported as SAE (grade 2 bronchospasm). With respect to hematological toxicity, neutropenia was observed in 40.5%, leukocytopenia in 24.3% and thrombocytopenia in 18.9% of patients in the DEP. In EPP neutropenia occurred in 31.9%, leukocytopenia in 8.5% and thrombocytopenia in 4.3% of patients. In all patients with hematologic side effects the subsequent dose has been withheld for 1-2 weeks, per protocol and in 1 case also a dose reduction by 10 mg/m^2.

Palmar plantar erythrodysthesia (PPE) was reported in 45.9% of patients in DEP and 55.3% in EPP. However, no hand-foot syndrome grade 4 or 5 was reported. Grade 3 hand-foot syndrome was present in approximately 21.6% in DEP and 23.4% in EPP. While hand-foot syndrome caused by 2X-111 was reversible within one or two weeks, it caused dose delays and dose reductions in several patients. However, a favorable safety profile was observed and 2X-111 was relatively well tolerated in both patients with BCBM from solid tumors and patients with recurrent malignant gliomas.

Overview of Glioblastoma Multiforme (GBM)

Malignant brain tumors account for approximately 190,000 new cases and 40,000 deaths per year globally. In the U.S., gliomas account for 81% of all malignant brain tumors where glioblastoma (GBM) (WHO grade IV) is the most aggressive form and represents the most prevalent (54%) form of all gliomas and 46% of all primary malignant brain tumors. The majority of GBM (95%) has histologically been classified as primary GBM mostly in elderly without any clinical history of lower grade gliomas. Secondary GBM develops from lower grade gliomas in younger patients (age <45 years) in the course of many months to years of disease. Today the distinction is based on isocitrate dehydrogenase (IDH) mutations.

The prognosis of newly diagnosed GBM is poor with overall survival (OS) rates in the U.S. at 1-year, 2-year, and 5-year survival of 37.2%, 8.8%, and 5.1%, respectively. The current standard of care is tumor resection followed by radiotherapy combined with chemotherapy with TMZ and then continuing with TMZ maintenance, and results in median OS of 14.6 months, which does not seem to have been relevantly improved over the past several decades. Thus, the therapeutic results are still not satisfactory, and new and more efficacious therapies are needed. Only a subgroup of GBM patients (approximately 32%), who have a methylated MGMT (O6-methylguanine-DNA methyltransferase) promotor, may benefit from TMZ treatment. The MGMT gene is involved in DNA repair, and epigenetic silencing by promotor methylation has previously been shown to be associated with longer survival in patients receiving alkylating agents. It has been shown that TMZ treatment improves OS from 15.3 to 21.7 months in patients with MGMT silencing, while patients with unmethylated MGMT promotors had no significant benefit from TMZ.

In most GBM patients the disease will progress sooner or later, however there is no clear recommendations for second line treatment. Depending on the clinical picture of each individual patient the treatment of recurrent GBM includes a second surgical procedure with or without implantation of carmustine wafers, nitrosoureas, TMZ treatment, the VEGF-blocking antibody bevacizumab (Avastin®) alone or in combination with the topoisomerase 1 inhibitor irinotecan, and, in some countries, systemic chemotherapy (e.g. carmustine plus irinotecan). In a Danish study of bevacizumab in combination with irinotecan an overall response rate (ORR) of 30%, median PFS of 5 months, and median OS of 7.5 months was observed. However, the treatment options for recurrent GBM are limited and the prognosis is poor. Patients should therefore be encouraged to participate in clinical trials.

Rationale for Liposomal Doxorubicin in GBM

Several studies on established glioma cell lines have shown promising levels of therapeutic activity of doxorubicin. In the last decade, treatment of GBM with pegylated liposomal doxorubicin (Doxil®/Caelyx®) has been assessed in three small studies. The treatment has been shown to result in a modest positive effect (1.5 months) on survival. However, this effect has not been considered sufficient to justify the use of Doxil®/Caelyx® as a standard treatment option in patients with brain tumors according to treating clinicians and regulatory agencies.

Existing PEG-liposomal formulations of doxorubicin, such as Doxil®/Caelyx®, do not readily pass the BBB and therefore do not deliver sufficient levels of the drug to brain tumors in order to provide meaningful therapeutic benefit. Likewise, doxorubicin itself does not pass the BBB.

The FDA granted orphan drug designation for 2X-111 for the treatment of glioma on August 16, 2010 (FDA/103119). Additionally, on September 21, 2010, the orphan drug designation of 2X-111 for the treatment of glioma was approved by the EMA (EMA/OD/031/10).

2X-111 is a novel PEG-liposomal formulation of doxorubicin, which, by virtue of the glutathione modification on the liposomal surface, can pass the BBB and deliver therapeutically sufficient levels of doxorubicin to brain tumors. Accordingly, 2X-111 has the potential to be a new and beneficial therapeutic option for the treatment of GBM.

Rationale for Liposomal Doxorubicin in Breast Cancer (Brain Metastases)

Brain metastases are diagnosed in approximately 15% of unselected patients with advanced breast cancer. Over time, it has become increasingly clear that the biology of the primary tumor influences the pattern of metastatic spread, including the likelihood of relapse in the central nervous system (CNS). As many as half of patients with HER2-positive advanced breast cancer will develop brain metastases at some point in the course of their disease.

Within the HER2-positive subset, hormone receptor status appears to further define the risk of CNS relapse, with patients having hormone receptor-negative/HER2-positive tumors experiencing increased risk developing metastases in the CNS as the first site of relapses, compared with patients with hormone receptor-positive/HER2-positive tumors. Furthermore, patients with metastatic, triple-negative (ER, PR and HER2 negative) breast cancer are equally at high risk, with 25 – 46% of patients developing brain metastases at some point in the course of their disease. The timing of the CNS relapse also appears to vary by tumor subtype. Patients with non-luminal tumors (e.g. triple-negative cancers) appear to experience a shorter time to relapses in the CNS compared to patients with luminal tumors.

In a historical series of unselected patients with breast cancer brain metastases treated with whole-brain radiotherapy (WBRT), the median survival has been reported to be approximately five to six months. More recent analyses have identified performance status of the patient and the biologic tumor subtype as major drivers of prognosis. For example, in a multi-institutional retrospective database of over 400 patients with breast cancer brain metastases, a prognostic model (the Diagnosis-Specific Graded Prognostic Assessment, DSGPA) using these factors (plus age) was able to distinguish between patients experiencing a two-year median survival versus those with 3.4 months median survival.

Across multiple retrospective studies, the most striking differences consistently noted have been between patients with HER2-positive breast cancer (who carry the most favorable prognosis) and patients with triple-negative breast cancer. Based on several lines of evidence, it is likely that improved systemic tumor control is a major contributing factor to this difference. First, although one must interpret retrospective data cautiously because of issues with patient selection, it has been observed by multiple investigators that patients with HER2-positive tumors who continue anti-HER2 therapy following the diagnosis of brain metastases do far better than those who receive either no therapy, or chemotherapy without HER2-directed therapy. Second, as many as half of the patients with HER2-positive brain metastases die primarily from CNS progression of their disease (as opposed to systemic progression). Accordingly, the need for a brain-targeted therapy for the treatment of brain metastases is warranted in this patient population. This is distinguished from patients with triple-negative brain metastases, where patients most commonly die of uncontrolled systemic disease.

Existing PEG-liposomal formulations of doxorubicin, such as Doxil®/Caelyx®, do not readily pass the BBB and therefore do not deliver sufficient levels of the drug to brain tumors in order to provide meaningful therapeutic benefit. Likewise, doxorubicin itself does not pass the BBB.

2X-111 is a novel PEG-liposomal formulation of doxorubicin, which, by virtue of the glutathione modification on the liposomal surface, can pass the BBB and deliver therapeutically sufficient levels of doxorubicin to brain tumors. Accordingly, 2X-111 has the potential to a new and beneficial therapeutic option for the treatment of brain metastases of breast cancer.

Future Opportunities & Development Plans for 2X-111

In June of 2020, we out-licensed our 2X-111 program to Smerud Medical Research International, our long-time CRO partner in Europe, which was subsequently terminated on March 28, 2022. Allarity, SMERUD, and original drug owner 2BBB Medicines, B.V. are currently negotiating a revised agreement under which SMERUD will secure grant funding to advance this program, with DRP® companion diagnostic support from Allarity.

DRP® Companion Diagnostic for 2X-111

We anticipate that 2X-111 will be developed together with our retrospectively validated DRP® companion diagnostic for doxorubicin, which enables us to select the patients most likely to respond to the drug in our clinical trials. The FDA has previously approved our IDE applications for use of our DRP® companion diagnostics in clinical trials of two of our priority programs: Stenoparib and LiPlaCis®. Accordingly, we are confident the FDA will approve an eventual IDE for our Doxorubicin-DRP® companion diagnostic for U.S. clinical trials of 2X-111. The Doxorubicin-DRP®, which comprises 299 expressed genes, was initially developed using gene expression data from the National Cancer Institute NCI60 cancer cell lines panel.

The putative Doxorubicin-DRP®, developed through our DRP® platform using gene expression data from cancer cell line testing data, was retrospectively validated using biopsy materials from the screening of breast cancer patients for our LiPlaCis® trial (clinicaltrial.gov number NCT01861496). A total of 140 patients received epirubicin and were included in the analysis. The study population was diagnosed with primary BC between 1986 and 2015 and received epirubicin in the locally advanced or metastatic setting between May 1997 and November 2016. The hazard ratio for DRP scores differing by 50 percentage points was 0.55 (95% CI –0.93, one-sided). The results were published in Breast Cancer Res Treat. 2018 Aug 11.

In sum, our retrospectively validated Doxorubicin-DRP® companion diagnostic correctly identifies responder patients to 2X-111 and we expect this DRP® companion diagnostic will be used for all clinical programs to advance 2X-111.

Existing Liposomal Doxorubicin Drugs & Our Opportunity

There has not been a therapeutically meaningful new drug for the treatment of GBM since bevacizumab (Avastin®) was approved, by the FDA, in 2009 as a monotherapy for patients who have progressed on prior therapy. Prior to introduction of bevacizumab in the GBM treatment landscape, TMZ was approved, by the FDA in 2005, for the treatment of adult patients with newly diagnosed GBM concomitantly with radiotherapy and then as maintenance treatment. Nearly 20 years later, TMZ remains the only front-line therapy for GBM, and its effectiveness is limited. Similarly, the effectiveness of benefit of second-line therapeutic bevacizumab remains limited. Accordingly, there is pressing need for new and innovative therapies for the treatment of this aggressive and incurable cancer.

There is no currently approved, available therapy for the treatment of brain metastases of breast cancer, and these metastases remain fatal to breast cancer patients. Accordingly, there is pressing need for new and innovative therapies for the treatment of this aggressive and incurable metastatic cancer.

Worldwide annual sales TMZ exceeded $1 billion annually in 2009. The global GBM drugs market to projected to reach nearly $1.8 billion by 2027, expanding at a CAGR of 12.8% during the forecast period, driven by rising geriatric population, growing incidence cases and clinical pipeline of new products. The global breast cancer therapeutics market has been valued at over $19 billion in 2018 and is expected to reach over $40 billion by the year 2026, at a CAGR of 10.6%. Since an estimated 10-15% of breast cancer patients will develop brain metastases, which are fatal, the estimated annual market for new therapeutics to treat such brain metastases will exceed $4 billion by 2026.

While there are several approved PEG-liposomal doxorubicin formulations (e.g. Doxil®/Caelyx®) currently marketed for the treatment of numerous cancer, including breast cancer, these drugs do not pass the BBB. There are currently no approved, targeted liposomal formulations of doxorubicin on the market that are capable of passing the BBB and therefore treating both primary and secondary brain tumors. Accordingly, 2X-111 has the potential to be a novel, beneficial product with the potential, together with its DRP® companion diagnostic, to gain substantial market share not only in GBM and breast cancer (brain metastases) but as a new therapy for the numerous other primary and second brain tumors.

Overview of Our Prior Therapeutic Candidate Irofulven (DNA damaging agent) and Our Out-licensed Putative DRP® Companion Diagnostic (DELETE WHOLE SECTION?)

Mechanisms of Action

Irofulven (6-hydroxymethylacylfulvene) is a unique DNA damaging agent that is a semi-synthetic sesquiterpene derivative of illudin S, a natural toxin isolated from the Jack O'lantern mushroom (*Omphalotus illudens*). Irofulven has two primary anti-tumor mechanisms of action: first, it produces bulky single strand DNA adducts that are only repairable by the transcription coupled nucleotide excision repair (TC-NER) pathway; and second, it stalls RNA polymerase II leading to transcription and cell cycle arrest and apoptosis.

Irofulven is a prodrug. The active metabolite is created by the reduction of the unsaturated α−β ketone by the NADPH-dependent Prostaglandin Reductase 1 (PTGR1). This metabolite is unstable and highly reactive, binding to either protein or DNA. The DNA binding is primarily to the 3-N of deoxyadenosine (98%) with the remainder binding to 7-N deoxyguanine. The resulting bulky single strand adducts can cause single strand DNA breaks and S-phase double strand DNA breaks. The GG-NER, BER and MMR pathways do not detect or remove Irofulven-DNA adducts, which either persist into, or are created during, S-phase of cancer cell duplication and create double strand DNA breaks which may be repaired by Homologous Recombination.

Irofulven is more active *in vitro* against tumor cells of epithelial origin and is more resistant than other alkylating agents to deactivation by p53 loss and MDR15. Irofulven showed impressive anticancer results in xenograft models, shows synergy with topoisomerase I inhibitors, and has demonstrated activity against cell lines that are resistant to other therapies. Irofulven has significant scope for combination with other therapies, including PARP inhibitors, checkpoint inhibitors (e.g. PD-1 inhibitors) and standard chemotherapeutic regimes, and is synergistic with other therapies targeting the TC-NER pathway and other DNA damage pathways.

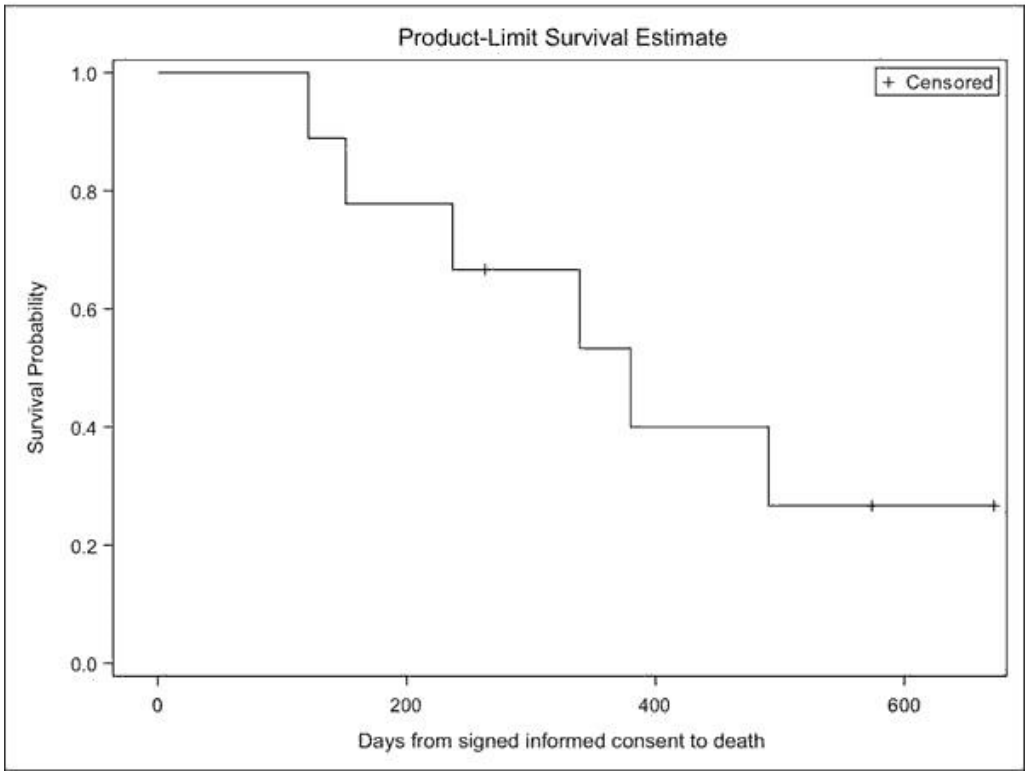
Irofulven causes apoptosis in sensitive tumor cell lines. Activation of caspases 3, 7, 8, and 9 has been well documented in Irofulven-treated tumor cell lines. Irofulven also causes upregulation of ATM/Chk2 and ATR-dependent FANCD2 mono-ubiquitination. In all cases, however, the functional linkage(s) between irofulven adducts (both DNA and protein) and subsequent pathway activation steps are, at present, not fully understood.

DRP®-Guided Phase 2 Clinical Trial

Prior to July 23, 2021, and our sale of Irofulven to Lantern Pharma, Inc., we commenced a DRP®-guided Phase 2 clinical trial of Irofulven in androgen receptor (AR)-targeted and Docetaxel-Pre-treated Metastatic Castration-Resistant Prostate Cancer (mCRPC) patients using our putative Irofulven-DRP® companion diagnostic to select and treat patients most likely to respond to the drug (study SMR-365). This trial was not completed and was an open-label, non-randomized, multi-center study in patients with docetaxel and AR-targeted therapy pre-treated mCRPC. Up to 27 mCRPC patients with predicted high probability of response to Irofulven (as determined by the Irofulven-DRP® companion diagnostic) were included. A high likelihood of Irofulven response was defined as a patient having an Irofulven-DRP® score of >80%. This study was suspended in 2019 when we internally deprioritized Irofulven. We had previously developed and patented a putative DRP® companion diagnostic specific for Irofulven, which we believe enables us to identify and treat the patients most likely to respond to this therapeutic candidate although we have not yet filed a PMA with the FDA for this companion diagnostic. To devote more of our development resources to our priority therapeutic candidates, on July 23, 2021, we terminated our drug development agreement for Irofulven and sold our inventory of Irofulven active pharmaceutical ingredients, ("API"), our clinical data and records ("Data"), and our know-how relating to Irofulven to Lantern Pharma, and granted a non-exclusive license to use our putative DRP® companion diagnostic specific for Irofulven. Although we may be entitled to future milestone payments and royalties if Lantern Pharma advances the development of Irofulven with or without our putative DRP® companion diagnostic specific for Irofulven, we will no longer devote any of our development resources to advance this therapeutic candidate.

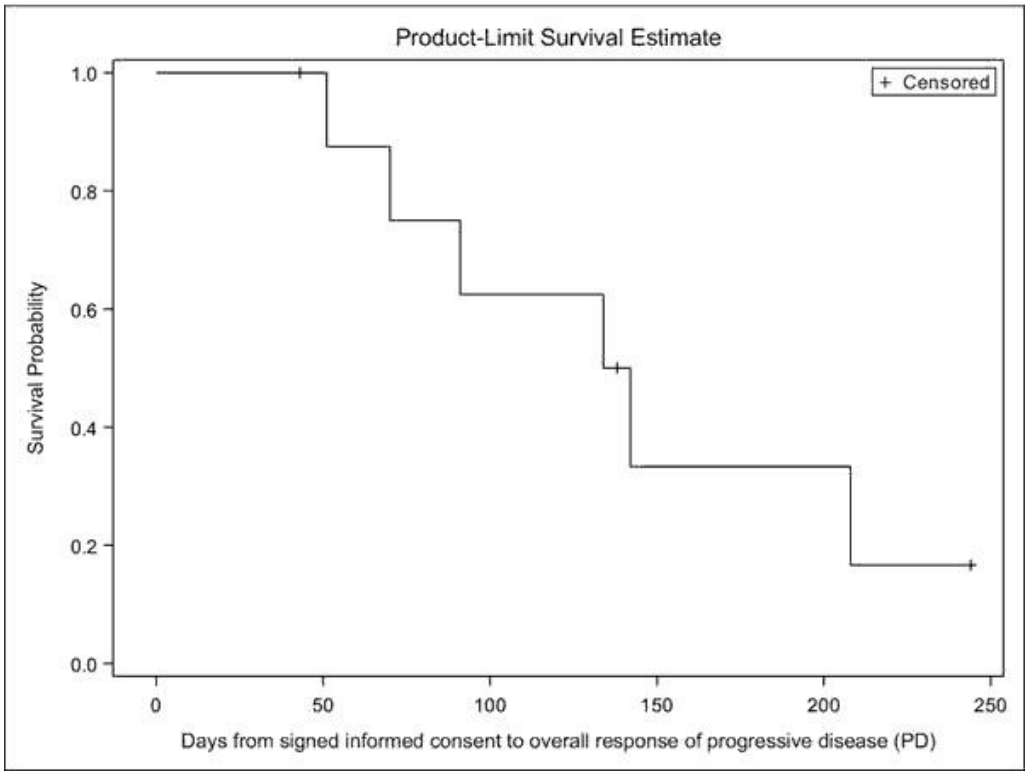
Study SMR-3165. Time (days) from enrolment to death of any cause.

The LIFETEST Procedure



Study SMR-3165. Time (days) from enrolment to overall response of progressive disease (PD).

The LIFETEST Procedure



Overview of Our PRP® (Patient Response Predictor)

Collections of drug specific putative DRP® companion diagnostics can be grouped together to form a panel of putative DRP® companion diagnostics that we believe can help guide therapeutic decision making for a given patient, in a true personalized medicine approach. For example, putative DRP® companion diagnostics for a number of cancer drugs with a similar mechanism-of-action, for example chemotherapeutics such as cisplatin, doxorubicin, and irofulven can be grouped together, by drug type (e.g. DNA damaging agents) in a panel to help identify which of these chemotherapeutics is most likely to benefit a particular patient. Similarly, putative DRP® companion diagnostics for a number of cancer drugs with differing mechanism-of-action, such as fulvestrant, cisplatin, and dovitinib, can be grouped together, by cancer type (e.g. drugs that treat metastatic breast cancer) in a panel to help identify which of these drugs is most likely to benefit a particular patient. We call such panels of putative DRP® companion diagnostics Patient Response Predictors (PRP®s).

We believe PRP®s, once approved, have the potential to achieve the true promise of personalized cancer care, specifically to pre-screen a given cancer patient for their likelihood of responding to a range of therapeutic options, then selecting the drug(s) most likely to benefit that patient, while avoiding the prescription of therapeutics that are not likely to benefit that patient. In practice, the treating oncologist and/or cancer center would provide us with a tumor biopsy from a given patient (or gene expression data from such biopsy) and we would then run a PRP® analysis, as requested by the oncologist, resulting in a PRP® report, provided to the oncologist and the patient, identifying the therapy options most likely to benefit the patient. This report would be somewhat analogous to currently marketed predictive diagnostic panels and reports, such as FoundationOne® (Foundation Medicine, Inc.), but with a different underlying technology base and therapeutic response predictive power.

An example of such a PRP® product for multiple myeloma was published in 2018 where the sensitivity of 67 patients to 14 drugs was predicted. A.J. Vangsted *et al.*, Gene 644 80-86)

We continue to explore the strategic and market potential of such PRP® panels. Market introduction and penetration of such personalized medicine diagnostic tests and reports is challenging and subject to close scrutiny of regulatory agencies such as the FDA, and also are very capital intensive to develop, bring to market, and expand sales. Accordingly, development of a potential PRP® product and business is not currently part of our priority strategy.

Intellectual Property

Our commercial success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other major oncology markets and countries for our investigational products and our DRP® companion diagnostics, to operate without being subject to the enforcement of third-party patents and proprietary rights, and to prevent others from infringing on our proprietary or intellectual property rights. We seek to protect our proprietary position by (1) filing, in the U.S. and certain other regions/countries (include the EU), patent applications intended to cover our DRP® companion diagnostics and their use with a particular therapeutic to guide patient therapy decision making, and maintaining any DRP® pending patent applications and issued patents in our major markets; (2) maintaining and advancing, and where possible expanding, existing patents and patent applications covering the composition-of-matter of our investigational products, their methods of use and related discoveries, their formulations and methods of manufacture, and related technologies, inventions and improvements that may be commercially important to our business; and (3) filing, in the U.S. and certain other regions/countries, new patent applications on novel therapeutic uses of our investigational products, alone or together with their DRP® companion diagnostics. We may also rely on trade secrets and know-how to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, and which are difficult to reverse engineer. We also intend to take advantage of regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available.

We have investigational products, and putative DRP® companion diagnostics, for a number of therapeutic targets, although none of our companion diagnostics have yet received FDA or other regulatory agency approval. As of the date of this report, our Company-owned patent portfolio consists of:

- 17 DRP® companion diagnostics patents granted covering 70 different cancer drugs, including 8 issued patents in the U.S. and 4 issued patents in the EU. Our issued patents cover, among others, DRP® companion diagnostics for Dovitinib, LiPlaCis®, 2X-111, and Irofulven. Our issued patent portfolio includes patents granted in the U.S., EU, China, Japan, Canada, and Australia.

- 27 DRP® companion diagnostics patent applications pending covering 2 additional drugs, including pending applications in the U.S., EU, China, Japan, Canada, India, Brazil and Australia. Our pending patent applications cover, among others, DRP® companion diagnostics for IXEMPRA® and for Stenoparib.

- Over 50 granted patents and pending patent applications, for composition-of-matter, methods of use, formulation, and methods of manufacturing, for many of our pipeline assets, including Dovitinib, Stenoparib, and 2X-111. These granted patents and applications generally cover the U.S. and EU, as well as numerous additional major world cancer therapeutics markets; although existing and remaining patent/application coverage varies from drug program to drug program. The dovitinib patent portfolio is being returned to Novartis. In some instances the original drug owner/licensor owns and controls such pre-existing patent/application portfolios (such as for Stenoparib).

- 1 U.S. patent application pending covering novel anti-viral uses of Stenoparib as a therapeutic for treatment of COVID-19 infection.

- The term of any patents that issue from our company-owned (or in-licensed) U.S. and foreign patent applications will vary in accordance with the laws of each jurisdiction and available patent term extension but is typically 20 years from the earliest priority application filing date. Expiration dates for certain patents covering our portfolio assets ranges between 2028 and 2032. Expiration dates for the DRP® companion diagnostic patents that cover our current pipeline programs will typically expire between 2030 and 2040. Any patents that may issue in the future from our company-owned (or in-licensed) pending patent applications are projected to expire between 2031 and 2041, unless extended or otherwise adjusted. Generally, the older and more developed the drug program the earlier the patent portfolio on the product will expire. For example, remaining patent portfolio term for dovitinib is less than remaining patent term for stenoparib. Such product patent portfolio expiration is independent from continuing patent coverage provided by DRP® companion diagnostics for each product.

- In countries or regions, such as the U.S. and EU, where regulatory approval of a companion diagnostic together with its drug, on the label, is available, approved DRP® companion diagnostics will substantially extend patent protection well after the core product patents (e.g. composition-of-matter) have expired.

We have obtained or are pursuing patent protection for our proprietary DRP® technology, a unique diagnostic platform, with a particular focus on the application of the DRP® technology to treat renal cell carcinoma, ovarian cancer, and metastatic breast cancer. Specifically, the DRP® technology is being applied to select patients to be treated with dovitinib, stenoparib, or ixabepilone. Our patent portfolio includes patents and applications in-licensed from Eisai Co., Ltd. ("Eisai") that protect stenoparib compositions and methods of its use for treatment.

DOVITINIB – Terminated program

Allarity's interest in Dovitinib has been terminated as has the agreement with Novartis. Therefore, there will be no more dovitinib development by Allarity.

STENOPARIB

Our stenoparib patent portfolio, which includes U.S. and foreign patents and patent applications, is positioned to protect aspects of our business in the United States and in key foreign jurisdictions. The following is a brief summary of the stenoparib patent portfolio, which includes patent families in-licensed from Eisai, as well as patent applications owned by Allarity.

In-licensed patents:

- Patents granted from national stage applications of Patent Cooperation Treaty Application No. PCT/US2008/078606 that are in-licensed from Eisai include composition of matter claims directed to genera and species encompassing stenoparib. Patents have issued in the United States (US 8,236,802 and US 8,894,989) and in key foreign jurisdictions including, e.g., Europe (EP 2209375), Canada (CA 2,700,903), China (CN 102083314B), Japan (JP 5439380), and South Korea (KR 10-1596526). The patents are scheduled to expire in 2028.

Owned patents:

- We are pursuing patent protection for the use of our DRP® technology in conjunction with stenoparib via national stage applications of Patent Cooperation Treaty Application No. PCT/EP2019/062508 filed in the United States, Australia, Canada, China, Europe, India, and Japan. This portfolio is scheduled to expire in 2039.

IXABEPILONE

Our ixabepilone patent portfolio, which is owned by us, is based on protecting our DRP® technology in the United States and in key foreign jurisdictions. We have filed national stage applications of Patent Cooperation Treaty Application No. PCT/EP2021/052132, which seeks to cover the use of the DRP® technology in conjunction with ixabepilone, in the United States and in key foreign jurisdictions, including Australia, Canada, China, Europe, India, and Japan starting in July 2022. This portfolio is scheduled to expire in 2041. We do not own or control any patents relating to ixabepilone itself in the EU market, where such patents have previously expired.

2X-111

We own exclusive, global rights to the use of our DRP® technology in conjunction with doxorubicin, which is the active therapeutic ingredient of 2X-111. A patent to this technology has issued in the United States (US 10,900,089) and Europe (EP18172585.4). Patent applications are also pending in Australia, Canada, China, Hong Kong, and India. This portfolio is scheduled to expire in 2038.

The patent positions for biotechnology and pharmaceutical companies like us are generally uncertain and can involve complex legal, scientific and factual issues. Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our investigational products and/or DRP® companion diagnostics and enforce the patent rights that we own or to which we have exclusive rights, and could affect the value of such intellectual property and the business. See section entitled "Risk Factors - Risks Related to Our Intellectual Property" for list of risks related to our intellectual property.

License Agreement with Novartis Pharma for Dovitinib

This agreement was terminated by Novartis effective January 26, 2024.

License Agreement with Eisai for Stenoparib

On July 6, 2017, we in-licensed the exclusive worldwide rights to all preventative, therapeutic and/or diagnostic uses related to cancer in humans and by amendment to the agreement on December 11, 2020, viral infections in humans (including, but not limited to, coronavirus vaccines and other treatments) for stenoparib from Eisai Inc. ("Eisai") pursuant to a license agreement. Upon the execution of the agreement in 2017, we paid Eisai a one-time, non-refundable, and non-creditable payment of $1 million. Pursuant to the license agreement, we are solely responsible for the development of stenoparib during the term of the agreement. The agreement also provides for a joint development committee consisting of six members, three appointed by us and three appointed by Eisai. One of our members of the joint development committee is designated chair of the committee and has the power to break any deadlock in decisions by the committee that must be made by a majority vote with each representative having one vote. The purpose of the committee is to implement and oversee development activities for stenoparib pursuant to the clinical development plan and serve as a forum for exchanging data, information, and development strategy.

Development Milestone Payments

Pursuant to the agreement, we have agreed to make milestone payments to Eisai in connection with the development of stenoparib by us or our affiliates, or by a third-party (a "Program Acquirer") that assumes control of the stenoparib development program from us corresponding to: (i) successful completion of a Phase 2 clinical trial; (ii) dosing of the first patient in the first Phase 3 clinical trial; (iii) submission of the first NDA with the FDA; (iv) submission of an MAA to the EMA; (v) submission of an NDA to the Ministry of Health Labor and Welfare of Japan, or the Pharmaceuticals and Medical Devices Agency of Japan, or any successor thereto (the "MHLW"); (vi) receipt of authorization by the FDA to market and sell a licensed product; (vii) receipt of approval of an MAA by the EMA for a licensed product; and (viii) receipt of approval by the MHLW in Japan for a licensed product. If all milestones have been achieved, we may be obligated to pay Eisai up to a maximum of $94 million. In addition, we have agreed to pay Eisai a one-time sales milestone payment in the amount of $50 million the first time our annual sales of licensed product are $1 billion or more.

Royalty Payments

In addition to the milestone payments described above, we have agreed to pay Eisai royalties based on annual incremental sales of product derived from stenoparib in an amount between 5% and 10% of annual sales of between $0 and $100 million, between 6% and 10% of annual sales between $100 million and $250 million, between 7% and 11% of annual sales between $250 million and $500 million, and between 11% and 15% of annual sales in excess of $500 million.

We are obligated to pay royalties under the agreement on a country-by-country and product-by-product basis for a period that commences with the first commercial sale of a product until the later of (i) the expiration of the last to expire valid claim of any licensed patent covering such licensed product in such country; or, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country or (iii) the 15 year anniversary of the date of first commercial sale of such licensed product in such country. However, the agreement may be sooner terminated without cause by us upon 120 days prior written notice, or upon written notice of a material breach of the agreement by Eisai that is not cured within 90 days (30 days for a payment default). Eisai also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 90 days (30 days for a payment default) or if we file for bankruptcy. By an amendment effective as of August 3, 2021, and executed by Eisai on August 23, 2021, Eisai also had the right to terminate the agreement if we did not complete a Phase 2 clinical trial before December 31, 2022, unless we elected to pay a $1 million extension payment ("Extension Payment"). Notwithstanding the foregoing, in the event we failed to enroll and dose at least 30 patients with the first dose of cancer drug in the ongoing Phase 2 Ovarian Cancer Clinical Trial by July 1, 2022, then the Extension Payment would have become due and payable in full on July 30, 2022. By a further amendment effective July 12, 2022, and executed by Eisai on August 17, 2022, in exchange for a payment of $100,000 on or before August 27, 2022, and a further $900,000 payment on or before April 1, 2023, which will constitute the payment of the Extension Payment, we will have until April 1, 2024, to complete a Phase 1b or Phase 2 Clinical Trial.

On May 26, 2023, the Company and Eisai entered into a fourth amendment to the Exclusive License Agreement with an effective date of May 16, 2023, to postpone the extension payment, restructure the payment schedule and extend the deadline to complete enrollment in a further Phase 1b or Phase 2 Clinical Trial for the Stenoparib (the "Product"). The Company agreed to pay Eisai in periodic payments as follows: (i) $100 which has been paid; (ii) $50 within 10 days of execution of the fourth amendment which has been paid; (iii) $100 upon completion of a capital raise (paid on July 18, 2023); and (iv) $850 on or before March 1, 2024. As of the date of this filing, the Company is currently negotiating a fifth amendment to the extend the timeframe of periodic payments due.

Option to Reacquire Rights to Stenoparib

For the period of time commencing with enrollment of the first five patients in a Phase 2 clinical trial pursuant to the clinical development plan and ending 90 days following completion of a successful Phase 2 trial (greater than or equal to 20% ORR by RECIST criteria), , Eisai has the option to reacquire our licensed rights to develop stenoparib for a purchase price equal to the fair market value of our rights, giving effect to the stage of development of stenoparib that we have completed under the agreement. We commenced a Phase 2 clinical trial in April 2019 and as of the date of this report, Eisai has not indicated an intention to exercise its repurchase option.

Sub-License Agreements with OncoHeroes Biosciences for Dovitinib & Stenoparib

All agreements with Oncoheroes are currently being re-evaluated by new leadership at Allarity. The sections below are retained for reference.

On January 2, 2022, we sub-licensed the exclusive worldwide rights to any and all pediatric cancer development and commercialization of dovitinib and stenoparib to OncoHeroes Biosciences, Inc. Upon the execution of the agreements, OncoHeroes paid us a one-time, non-refundable, and non-creditable payment of $350,000. Pursuant to the license agreements, OncoHeroes is solely responsible for the pediatric cancer development of stenoparib and dovitinib, together with their respective DRP® companion diagnostics, during the term of the agreements. The agreements also provide for a joint development committee consisting of five members, three appointed by OncoHeroes and two appointed by us. The purpose of the committee is to implement and oversee pediatric cancer development activities for stenoparib and dovitinib pursuant to the clinical development plan and serve as a forum for exchanging data, information, and development strategy. Under the agreements, Allarity will provide, at its own cost, DRP® companion diagnostic support for any pediatric clinical trials that OncoHeroes conducts in Europe; for any U.S. pediatric clinical trials, Allarity will facilitate DRP® companion diagnostic support through its U.S. CLIA lab partner, Almac, at OncoHeroes' cost. Further, under the Agreements, Allarity shall supply finished stenoparib and dovitinib to OncoHeroes at our cost of goods (to manufacture or have manufactured the drugs). In certain events where Allarity is unwilling or unable to supply sufficient amounts of the drugs, OncoHeroes can obtain manufacturing rights from Allarity. Allarity has notified OncoHeroes that its license to dovitinib has been terminated by Novartis.

Development Milestone Payments

Pursuant to the agreements, OncoHeroes will make milestone payments to us in connection with its development of stenoparib and dovitinib, or by a third-party (a "Program Acquirer") that assumes control of the development programs from OncoHeroes, corresponding to, for each drug: (i) upon receipt of authorization by the FDA to market and sell a licensed product; and (ii) upon receipt of approval of an MAA by the EMA for a licensed product. As noted above, because our agreement with Novartis has been terminated, our agreement with OncoHeroes may be subject to revision in the near future.

Royalty Payments

In addition to the milestone payments described above, OncoHeroes has agreed to pay us royalties based on annual incremental sales of any product derived from stenoparib in an amount between 5% and 8% of annual sales of between $0 and $100 million, between 9% and 11% of annual sales between $100 million and $200 million, and between 11% and 14% of annual sales above $200 million.

OncoHeroes is obligated to pay us royalties under the agreements on a country-by-country and product-by-product basis for a period that commences with the first commercial sale of a product until the later of (i) the expiration of the last to expire valid claim of any licensed patent covering such licensed product in such country; or, (ii) the 15 year anniversary of the date of first commercial sale of stenoparib in such country. However, the agreements may be sooner terminated upon written notice of Allarity of a material breach of the agreements by OncoHeroes that is not cured within 60 days. After the first anniversary of each agreement, OncoHeroes also has the right to terminate the agreements, at will, upon written notice to Allarity (i) 90 days in advance if prior to first commercial sale of license product or (ii) 180 days in advance if after first commercial sale of licensed product.

Option to Reacquire Rights

Under the terms of the agreements, Allarity has a first buy back option for licensed pediatric cancer field rights for each of stenoparib triggered by the first to occur of (i) written notice from Allarity to OncoHeroes that it has received an offer from a pharmaceutical company with at least $250 million of net sales (based upon its most recently-completed calendar year financial performance) that wishes to acquire global commercialization rights to the product in the licensed field (pediatric cancers) and retained field (all other cancers); or (ii) completion of the receipt of the first MAA (including an NDA) approval for a product in any country in the licensed territory (worldwide) in the licensed field; and (b) ending 120 days after the occurrence of the matters set forth in clause (i) and (ii) above, as applicable. Allarity may exercise its buy back option by submitting a written offer prior to the expiration of the option period outlined above. Upon the timely exercise by Allarity of its option: (i) any development milestone payments due from OncoHeroes to Allarity shall be cancelled, and (ii) the parties shall enter into exclusive good faith negotiations regarding a fair market value ("FMV") payment to OncoHeroes which will take into account the value generated by OncoHeroes to the product, and may include a one-off payment to OncoHeroes and royalties on future net sales for the product, or a one-time upfront payment, or such other FMV as the parties shall negotiate in good faith.

Development Option and License Agreement with R-Pharm for IXEMPRA®

All Ixempra work has been deprioritized by Allarity. The newly installed leadership has not yet made a final decision on the Ixempra program. Accordingly, these following sections remain for reference.

On March 1, 2019, we entered into an option to in-license the rights to any and all therapeutic and/or diagnostic uses in humans for IXEMPRA® in the European Union (including Great Britain but excluding Switzerland and Lichtenstein) (the "Territory") from R-Pharm U.S. Operating, LLC ("R-Pharm"), pursuant to a Development, Option and License Agreement (the "Option"). Upon the execution of the agreement, we paid R-Pharm a non-refundable, non-creditable option payment of $100,000 and agreed to an anniversary payment of $250,000 on or before March 1, 2020, which we have paid. Upon exercise of the option by us, we have agreed to pay R-Pharm an exercise payment of $250,000. By an amendment to the agreement effective August 4, 2022, the term of the option will expire on September 1, 2023, if not exercised by us before then. As of the date of this filing, we have not extended the option with R-Pharm.

Drug License and Development Agreement for Irofulven

From May 2015 until July 23, 2021, we in-licensed various rights to Irofulven from Lantern Pharma, Inc. pursuant to a drug license and development agreement.

Pursuant to the agreement, we were responsible for the development of Irofulven pursuant to a defined clinical development plan. The agreement also provides for a joint development committee, including representatives from Lantern Pharma and us, to regularly discuss, plan and inform the development of products under the agreement. In 2018, we commenced a DRP®-guided Phase 2 clinical trial of Irofulven in androgen receptor (AR)-targeted and Docetaxel-Pre-treated Metastatic Castration-Resistant Prostate Cancer (mCRPC) patients using our putative Irofulven-DRP® companion diagnostic to select and treat patients most likely to respond to the drug (study SMR-365). This trial was not completed and was an open-label, non-randomized, multi-center study in patients with docetaxel and AR-targeted therapy pre-treated mCRPC. Up to 27 mCRPC patients with predicted high probability of response to Irofulven (as determined by the Irofulven-DRP® companion diagnostic) were included. A high likelihood of Irofulven response was defined as a patient having an Irofulven-DRP® score of >80%. This study was suspended in 2019, when we deprioritized Irofulven as a therapeutic candidate in order to devote more of our development resources to our priority therapeutic candidates, and on July 23, 2021, we terminated our drug development agreement for Irofulven and sold our inventory of API, our clinical data and records, and our manufacturing know-how relating to Irofulven to Lantern Pharma, and granted a non-exclusive license to Lantern Pharma to use our putative DRP® companion diagnostic specific for Irofulven. Although we may be entitled to future milestone payments and royalties if Lantern Pharma advances the development of Irofulven with or without our putative DRP® companion diagnostic specific for Irofulven, we will no longer devote any of our development resources to advance this therapeutic candidate.

Asset Purchase Agreement between Allarity Therapeutics A/S and Lantern Pharma, Inc. for Irofulven

All work on Irofulven has been deprioritized. The newly installed leadership at Allarity has not made final decisions on the Irofulven program. Accordingly, these sections have been retained for reference.

On July 23, 2021, we entered into an Asset Purchase Agreement with Lantern Pharma, Inc. relating to our inventory of Irofulven active pharmaceutical ingredients ("API"), our clinical research data relating to Irofulven developed by us during the drug development program under the May 2015 Drug License and Development Agreement for Irofulven (the "Data") and terminated our obligation to further advance the development of Irofulven under the May 2015 agreement. Under the Asset Purchase Agreement, Lantern Pharma agreed to pay us $1 million on closing of the transaction, and additional amounts (i) when the inventory of Irofulven API is recertified with a longer shelf life; (ii) upon the initiation of treatment of the first patient in an investigator-led "compassionate use" ERCC2/3 mutation subgroup study using Irofulven in certain agreed upon investigators; (iii) upon the first to occur of (x) initiation of treatment of the first patient within an agreed upon time period after the closing of the transaction in any human clinical trial of Irofulven initiated by Lantern Pharma for regulatory purposes, and (y) initiation of treatment of the 26th patient in any human clinical trial of Irofulven after the closing of the transaction initiated by Lantern Pharma or under the investigator-led study; and (iv) upon the initiation of treatment of the second patient within an agreed upon time period after the closing of the transaction in any human clinical trial of Irofulven initiated by Lantern Pharma. In addition to the sale of our inventory of Irofulven API and Data to Lantern Pharma, we also granted Lantern Pharma a non-exclusive, worldwide license to use our putative Irofulven DRP® companion diagnostic to advance the development and commercialization of Irofulven and other Illudins (sesquiterpenes with anti-tumor properties produced by some mushrooms). We have also agreed not to engage in any drug development program for Illudins or any of its analogues or any use thereof for a period of five years.

Milestone Payments

Under the Asset Purchase Agreement, we would also be entitled to receive certain milestone payments relating to our out-licensed putative Irofulven DRP® companion diagnostic upon the occurrence of the following events: (i) upon the first use of our putative Irofulven DRP® companion diagnostic in a clinical trial for Irofulven; and (ii) upon the first regulatory approval of our putative Irofulven DRP® companion diagnostic as a companion diagnostic for use with an approved drug. In addition to the milestone payments relating to our putative Irofulven DRP® companion diagnostic, we would also be entitled to receive certain milestone payments relating to the development and commercialization of Irofulven upon the occurrence of the following events: (i) upon the first filing for regulatory approval for commercialization of Irofulven in the United Kingdom, Germany, France and Italy, or upon the first and second filings for regulatory approval for commercialization of Irofulven in countries located in the European Union that are not Germany, France or Italy; (ii) upon the first filing for regulatory approval for commercialization of Irofulven in the United States; (iii) upon receiving the first regulatory approval for commercialization of Irofulven in the United Kingdom, Germany, France and Italy, or upon the first and second receipts for regulatory approval for commercialization of Irofulven in countries located in the European Union that are not Germany, France or Italy, (iv) upon receiving the first regulatory approval for commercialization of Irofulven in the United States. If all milestones have been achieved, then we would be entitled to receive up to $16 million in milestone payments under the Asset Purchase Agreement.

Royalty Payments

In addition to the milestone payments described above, Lantern Pharma has agreed to pay us royalties based on annual incremental net sales of product derived from Irofulven, on a country by country basis, in an amount between 2% and 7% of annual sales of between $0 and $50 million, between 3% and 8% of annual sales between $50 million and $150 million, between 4% and 9% of annual sales between $150 million and $300 million, and between 5% and 10% of annual sales in excess of $300 million.

The royalty amounts we are entitled to receive may be subject to reduction in the event of generic competition, patent expiry, or if products are (i) sold in the form of a combination product containing one or more active pharmaceutical ingredients which are not Irofulven or (ii) sold under a bundled or capitated arrangement with one or more products which are not Irofulven or (iii) sold under an arrangement whereby the sale of the product is only available with or conditioned upon the purchase of other products.

License Agreement with 2-BBB Medicines B.V. for 2X-111

All work on 2X-111 within Allarity has been de-prioritized. New leadership has not yet made final decisions on the program. The following sections are retained for reference.

On March 27, 2017, we in-licensed the exclusive worldwide rights to the central nervous system ("CNS") and/or cerebrocardiovascular drug application, including the (preventive) treatment of peripheral effects of agents causing CNS disease or symptoms, including cancer, for 2X-111 from 2-BBB Medicines B.V. ("2-BBB") pursuant to a license agreement. Upon execution of the agreement, we paid 2-BBB a one-time, non-refundable, non-creditable payment of $500,000. Pursuant to the agreement, we are solely responsible for the development of 2X-111 during the term of the agreement.

Development and Sales Milestone Payments

Pursuant to the agreement, we have agreed to make milestone payments to 2-BBB in connection with the development of 2X-111 by us or our affiliates, or by a third-party (a "Program Acquirer") that assumes control of the 2X-111 development program from us corresponding to: (i) enrollment of the first ten patients required in a Phase 2 clinical trial; (ii) the successful completion of a Phase 2 clinical trial; (iii) dosing of the first patient in the first Phase 3 clinical trial; (iv) submission of the first NDA with the FDA; (v) submission of an MAA to the EMA in the European Union; (vi) submission of an NDA in the first of either China or India; (vii) receipt of the first authorization by the FDA to market and sell a licensed product; (viii) receipt of a MAA for a licensed product in the European Union; and (ix) receipt of regulatory approval in the first of either China or India. If all development milestones have been achieved, we may be obligated to pay 2-BBB up to a maximum of $27.75 million which could increase to $55.5 million if 2-BBB successfully expands the field of our license agreement to include all preventative, therapeutic and/or diagnostic uses related to cancer in humans. In addition to the development milestones described above, we have agreed to make a mid-level seven figure one-time payment upon our sales of a licensed product reaching $500 million annually and a low eight figure payment upon the first and second time our sales of a licensed product reaches $1 billion annually. If all sales milestones have been achieved, we would be obligated to pay 2-BBB up to a maximum of $22.5 million which could increase to $45 million if 2-BBB successfully expands the field of our license agreement to include all preventative, therapeutic and/or diagnostic uses related to cancer in humans.

Royalty Payments

In addition to the milestone payments described above, we have agreed to pay 2-BBB royalties based on annual incremental sales of product derived from 2X-111 in an amount between 5% and 10% of annual sales of between $0 and $100 million, between 6% and 13% of annual sales between $100 million and $250 million, and between 7% and 13% of annual sales in excess of $250 million. We are obligated to pay royalties under the agreement on a product-by-product and country-by-country basis, from the period of time commencing on the first commercial sale of any product in such country and expiring upon the latest of (a) the expiration of the last valid claim of a patent within (i) the 2-BBB intellectual property and/or (ii) the joint intellectual property in such country (if, but only if, such joint intellectual property arose from activities under the clinical development plan), or (b) the 10th anniversary of the date of first commercial sale of such product in such country. However, the agreement may be sooner terminated without cause by us upon 120 days prior written notice, or upon written notice of a material breach of the agreement by 2-BBB that is not cured within 90 days. 2-BBB also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 90 days (30 days for a payment default) or if we file for bankruptcy. 2-BBB also has the right to terminate the agreement in the event we challenge a 2-BBB patent and we have the right to terminate the agreement upon 30 days' notice for specified safety reason.

Out-License Agreement with SMERUD

In June of 2020, we out-licensed our secondary LiPlaCis® and 2X-111 programs to Smerud Medical Research International, our long-time CRO partner in Europe, for further Phase 2 clinical development of each program together with its DRP® companion diagnostic. On March 28, 2022, we restructured our LiPlaCis® license agreements with Smerud and original drug owner LiPlasome Pharma ApS, in a way that will enable Smerud to step into the shoes of Allarity and assume full control of this program for further development in a Smerud affiliated subsidiary, Chosa ApS, and to secure additional investment funding and collaborative development of the program through the affiliate. Pursuant to the terms of the Support Agreement (as described below in the section titled "LiPlaCis Support Agreement with Smerud, Chosa and LiPlasome") and in connection with the termination of our exclusive licensee rights to LiPlaCis® under the Amended License Agreement (as described below in the section titled "Amended and Restated License Agreement with LiPlasome Pharma ApS for LiPlaCis®"), we agreed to terminate our out-license agreement with SMERUD. However, notwithstanding the termination of the out-license agreement, we are currently engaged in discussions with Smerud in connection with the further development of 2X-111.

Amended and Restated License Agreement with LiPlasome Pharma ApS for LiPlaCis®

In January 2021, we entered into an Amended and Restated License Agreement with LiPlasome Pharma ApS ("LiPlasome") for the perpetual, exclusive, world-wide rights to develop, use and market LiPlaCis® for any indication which superseded all prior license and development agreements between us and LiPlasome (the "Original License Agreement"). On March 28, 2022, we entered into an amended and restated license agreement which assigned, amended and restated the Original License Agreement, pursuant to which the parties agreed to replace Allarity Europe with Chosa, an affiliate of Smerud, as exclusive licensee to further advance clinical development and commercialization of LiPlaCis® (the "Amended License Agreement"). Under the Amended License Agreement, Chosa replaced Allarity Europe as the exclusive licensee to the LiPlaCis® technology. In addition, Allarity Europe also granted Chosa an exclusive, royalty-free, transferable and sublicensable license for (i) its DRP® Companion Diagnostics that are specific for Cisplatin or LiPlaCis® for the research and development of LiPlaCis® products, and (ii) the use of any and all know-how and intellectual property rights owned by Allarity Europe for Chosa's use of our DRP® Companion Diagnostics that are specific for Cisplatin or LiPlaCis® for the development and commercialization of LiPlaCis® products, as contemplated in the Amended License Agreement.

Development Milestone Payments

Pursuant to the Amended License Agreement, Allarity Europe is entitled to receive certain milestone payments from Chosa relating to the development and commercialization of LiPlaCis® upon the occurrence of the following events, which milestone payments are to be shared with LiPlasome: (i) receipt of first regulatory approval of a product in the United States, (ii) receipt of first regulatory approval of a product in any country in Europe, including on a centralized filing basis by the EMA, (iii) the first achievement on a cumulative basis of net sales of a product in the United States, and (iv) the first achievement on a cumulative basis of net sales of a product in any country in Europe. Each milestone payment is payable one time only, regardless of the number of times the corresponding milestone event is achieved by a product and regardless of the number of products to achieve such milestone event. If all milestones are achieved, then we would be entitled to receive up to $3.5 million in milestone payments under the Amended License Agreement.

As a result of the Amended License Agreement, we no longer have any rights to use or commercialize LiPlaCis® and are only entitled to receive the milestone payments upon the achievement of the respective milestones.

LiPlaCis Support Agreement with Smerud, Chosa and LiPlasome

On March 28, 2022, and concurrent with the entry into the Amended License Agreement, we entered into the LiPlaCis Support Agreement with Allarity Europe, Smerud, Chosa and LiPlasome (the "Support Agreement"). Pursuant to the terms of the Support Agreement, we agreed (i) to pay to LiPlasome a certain percentage of the Commercialization Proceeds (as defined under the Original License Agreement) we received from Smerud by way of debt cancellation relating to prior work on LiPlaCis® by Smerud, which obligation was to be satisfied by the payment of 2,273,020 Danish Kroner to LiPlasome upon execution of the Support Agreement, (ii) to equally share the milestone payments under the terms of the Amended License Agreement, pursuant to which it was contemplated that upon the achievement of all the milestones, our pro rata share of the milestone payments would be up to $3.5 million, (iii) to amend and restate the Original License Agreement, and (iv) to terminate the Out-License Agreement with SMERUD as contemplated by the parties pursuant to the terms of the Support Agreement.

Manufacturing and Supply

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our investigational products for preclinical and clinical testing, as well as for commercial manufacture if any of our investigational products obtain marketing approval. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our investigational products, as well as for our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our investigational products.

To date, we have obtained APIs and drug product for our investigational products from either the original drug owner/licensee or from single-source third-party clinical manufacturing organizations (CMOs). We are in the process of developing our supply chain for each of our investigational products and intend to put in place framework agreements under which CMOs will generally provide us with necessary quantities of API and drug product on a project-by-project basis based on our development needs, and which agreements will provide us with intellectual property rights necessary to conduct the business. We may use a different CMO for each investigational product and will consider further diversification of drug product and supply organizations as circumstances warrant. Overall, as we advance our investigational products through development, we will start by seeking multiple sources for raw materials and address other potential points in concern over time.

Commercialization

We intend to retain significant development and commercial rights to our investigational products and, if marketing approval is obtained, to commercialize our investigational products on our own, or potentially with a partner, in the U.S. and other regions, either globally or on a region-by-region basis. We do not intend to build the necessary infrastructure and sales, marketing and commercial product distribution capabilities for the U.S., and potentially other regions, following further advancement of our investigational products. We instead prefer to build appropriate partnerships with marketing, sales, and distribution partners to effect launch and market penetration for each of our therapeutic programs. However, as we near approval and commercial launch of each program, we will assess the suitability of marketing and sales partners and reserve the right to potentially develop and implement our own infrastructure to support the commercial success of our programs. Clinical data, the size of the addressable patient population and the size of the commercial infrastructure and manufacturing needs and economics related to the foregoing may all influence or alter our commercialization plans.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including large pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for the research, development, manufacturing and commercialization of cancer therapies. Any investigational products that we successfully develop and commercialize will compete with new therapies that may become available in the future. Similarly, our core DRP® platform technology, and any drug-specific DRP® companion diagnostics that we develop and commercialize, will compete with new companion diagnostic technologies that may become available in the future.

We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop small molecules and drug conjugates, together with companion diagnostics, as treatments for cancer patients. There are many other companies that have commercialized and/or are developing such treatments for cancer including large pharmaceutical and biotechnology companies, such as AstraZeneca plc, Bristol-Myers Squibb Company ("BMS"), Merck, Pfizer in partnership with Merck KGaA, Regeneron Pharmaceuticals, Inc. in partnership with Sanofi Genzyme ("Sanofi") and Roche. There are also many other companies that are developing, have developed, and/or have commercialized patient-selective, companion diagnostic technologies/approaches for cancer patients, such as Foundation Medicine, Inc., Kura Oncology, Inc., and Lantern Pharma, Inc.

For our Stenoparib program, we are aware of a number of companies that are currently marketing approved PARP inhibitors and/or developing PARP inhibitors that are or may be competitive to our drug, such as Big Pharma companies AstraZeneca, BMS, Novartis, and GlaxoSmithKline (GSK), and smaller pharmaceutical players BeiGene and Clovis Oncology. To our knowledge, there is currently no approved or in development PARP inhibitor, for the treatment of ovarian cancer or other indications, that has an identical therapeutic profile to stenoparib, with or without its Stenoparib-DRP® companion diagnostic.

For our IXEMPRA® program, we are aware of a number of companies that are currently marketing approved microtubule inhibitors and/or developing microtubule inhibitors that are or may be competitive to our drug, such as Big Pharma companies Eisai and Sanofi, and smaller pharmaceutical players like Celgene and Veru Pharma. To our knowledge, there is currently no approved or in development microtubule inhibitor, for the treatment of metastatic breast cancer (mBC) or other indications, that has an identical therapeutic profile to IXEMPRA®, with or without its IXEMPRA®-DRP® companion diagnostic.

For our LiPlaCis® program, we are aware of a number of companies that are currently or have been developing liposomal formulations of cisplatin that are or may be competitive to our drug, such as Regulon, Inc. To our knowledge, there is currently no approved liposomal formulation of cisplatin. Furthermore, to our knowledge, there is no in development liposomal formulation of cisplatin, for the treatment of mBC or other indications, that has an identical therapeutic profile to LiPlaCis®, with or without its Cisplatin-DRP® companion diagnostic.

For our 2X-111 program, we are aware of a number of companies that are currently marketing approved liposomal formulations of doxorubicin and/or developing liposomal formulations of doxorubicin that are or may be competitive to our drug, such as Janssen Pharmaceuticals, Baxter, and Teva, and Zydus Cadilla. To our knowledge, there is currently no approved or in development Glutathione-modified liposomal formulation of doxorubicin, for the treatment of GBM or other indications, that has an identical therapeutic profile to 2X-111, with or without its Doxorubicin-DRP® companion diagnostic.

For our Irofulven-DRP® companion diagnostic that we have out-licensed to Lantern Pharma, we are aware of a number of companies that are currently marketing approved DNA damaging chemotherapeutics and/or developing DNA damaging chemotherapeutics that are or may be competitive to Irofulven. Many approved chemotherapeutics are now generic and sold by companies such as Teva Pharmaceuticals and Baxter. Some smaller pharmaceutical companies, such as Alkido Pharma and Lantern Pharma, are attempting to develop novel chemotherapeutics. Lantern Pharma, for example, is pre-clinically attempting to develop novel analogues of Irofulven. To our knowledge, there is currently no approved or in development DNA damaging agent, for the treatment of mCRPC or other indications, that has an identical therapeutic profile to Irofulven, with or without its Irofulven-DRP® companion diagnostic.

For our core DRP® platform technology (and its resulting drug specific DRP® companion diagnostics), we are aware of a number of companies that are currently marketing approved companion diagnostic platforms, or are attempting to develop such platforms, that are or may be competitive to (although distinct from) our DRP® platform, such as Foundation Medicine and Lantern Pharma. To our knowledge, there is currently no approved or developmental diagnostic technology or platform — for the development of drug-specific companion diagnostics to guide selection and treatment of cancer patients most likely to respond to a given drug — that is as broadly applicable, robust, and highly validated as our DRP® platform.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved drugs 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. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and enrolling subjects for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize therapeutic products that are safer or more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we or our collaborators may develop. Similarly, it is possible that our commercial opportunity may be reduced by the development and commercialization of competing companion diagnostic products that are superior to our DRP® companion diagnostics. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all our investigational products, if approved, are likely to be their degree of anti-cancer activity, tolerability profile, convenience and price, the effectiveness of companion diagnostics (if required), the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors. All these factors will be impacted by the value and superiority of our DRP® companion diagnostics over any competing companion diagnostic approaches that currently exist or evolve in the oncology market.

Government Regulation

Government authorities in the U.S. at the federal, state, and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority. Similar regulations and approvals exist in the EU and other major oncology therapeutic markets.

U.S. Drug Development

In the U.S., the FDA regulates drugs under the Food, Drug, and Cosmetic Act ("FDCA"). Similarly, in the European Union (EU), the European Medicines Agency (EMA) regulates the clinical trial, approval, and marketing of drugs. Drugs also are subject to other federal, state, and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. or EU requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's or EMA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our therapeutic candidates are considered small molecule drugs and must be approved by the FDA through the new drug application ("NDA"), and similarly by the EMA under an equivalent process, before they may be legally marketed in the U.S. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP;
- submission to the FDA of an Investigational New Drug (IND) application, which must become approved and effective before human clinical trials may begin;
- submission to the FDA of an Investigational Device Exemption (IDE) application, which must become approved and effective before a drug-specific DRP® companion diagnostic can be used in human clinical trials;
- approval by an independent Institutional Review Board (IRB) or ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well controlled human clinical trials in accordance with applicable IND regulations, GCP requirements and other clinical trial-related protocols and regulations to establish substantial evidence of the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of a NDA after completion of all pivotal trials;
- submission to the FDA of a Pre-Market Approval (PMA) application to allow use of a DRP® companion diagnostic on the market together with its approved drug;
- determination by the FDA within 60 days of its receipt of an NDA to accept the filing for substantive review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;

- potential FDA audit of the pre-clinical study and/or clinical trial sites that generated the data in support of the NDA filing;

- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the U.S.; and

- compliance with any post-approval requirements, including the potential requirement to implement a REMS and the potential requirement to conduct post-approval studies.

The data required to support an NDA are generated in two distinct developmental stages: pre-clinical and clinical. The pre-clinical and clinical testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approvals for any current and future therapeutic candidates will be granted on a timely basis, or at all, whether in the U.S, EU, or other region/country.

Pre-Clinical Studies and IND/IDE

The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation, and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The sponsor must submit the results of the preclinical studies, together with manufacturing information, retrospective data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Similarly, and IDE is a request for authorization from the FDA to use a diagnostic — in our case a DRP® companion diagnostic — to screen, select, and treat specific patients in a human clinical trial.

Pre-clinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of pre-clinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the pre-clinical tests, together with manufacturing information, retrospective data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. Similarly, an IDE sponsor must submit information about the prior development and validation of the diagnostic, including results of the pre-clinical tests, together with manufacturing information, retrospective data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IDE. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. Similarly, submission of an IDE for a DRP® companion diagnostic may not result in the FDA allowing use of such DRP® in an approved clinical trial.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB must also approve the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Clinical development in other major oncology markets, such as the EU, is subject to similar requirements and regulations.

A sponsor who wishes to conduct a clinical trial outside of the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA. The FDA will generally accept a well-designed and well conducted foreign clinical trial not conducted under an IND if the clinical trial is conducted in compliance with GCP and. the FDA is able to validate the data through an onsite inspection, if deemed necessary. An NDA based solely on foreign clinical data meeting U.S. criteria for marketing approval may be approved if (1) the foreign data are applicable to the U.S. population and U.S. medical practice, (2) the studies have been performed by clinical investigators of recognized competence and (3) the FDA is able to validate the data through an onsite inspection or other appropriate means, if deemed necessary.

Clinical trials in the U.S. generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the therapeutic candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, tolerability, and safety of the drug.

- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose and dosing schedule required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.

- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, are conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Sponsor is also responsible for submitting written IND safety reports, including reports of serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or *in vitro* testing that suggest a significant risk for human subjects, and any clinically significant increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Clinical development in other major oncology markets, such as the EU, is subject to similar requirements and regulations.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Concurrent with clinical trials, companies may complete additional animal safety studies and must develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process, as performed by the manufacturing facility, must be capable of consistently producing quality batches of our therapeutic candidates. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that our therapeutic candidates do not undergo unacceptable deterioration over their labeled shelf life.

NDA Review Process

Following completion of the clinical trials, data is analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of pre-clinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labeling, chemistry, and manufacturing information to ensure product quality and other relevant data. In short, the NDA is a request for approval to market the drug in the U.S. for one or more specified indications and must contain proof of safety and efficacy for a drug. Concomitantly, a PMA is submitted to the FDA as part of NDA approval that is conditioned on use of a companion diagnostic. In short, the PMA is a request for approval to market the companion diagnostic in the U.S., together with and required for prescription of the drug, for one or more specified indications and must contain clinical evidence of safety and efficacy and sufficient validation of the companion diagnostic used to select patients for treatment with the drug.

The NDA application must include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA. FDA approval of an NDA must be obtained before a drug may be legally marketed in the U.S. Similarly, FDA approval of a PMA must be obtained before a DRP® companion diagnostic may be legally marketed in the U.S.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each NDA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for each marketed human drug. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted NDAs before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must decide on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months, from the filing date, in which to complete its initial review of a new molecular-entity NDA and respond to the applicant, and six months from the filing date of a new molecular-entity NDA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often extended by FDA requests for additional information or clarification. Similarly, the FDA must decide on accepting a PMA for review within 45 days of receipt. After acceptance, the FDA will begin substantive review of the PMA. During the review process, FDA will notify the PMA applicant via major/minor deficiency letters of any information needed by FDA to complete the review of the application. FDA may refer the PMA to an outside panel of experts (advisory committee). In general, all PMAs for the first-of-a-kind device are taken before the appropriate advisory panel for review and recommendation.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an 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 and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies and/or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Similarly, an IDE application is considered approved 30 days after it has been received by the FDA, unless the FDA otherwise informs the sponsor via email prior to 30 calendar days from the date of receipt, that the IDE is approved, approved with conditions, or disapproved. In cases of disapproval, a sponsor can respond to the deficiencies.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product available in the U.S. for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. However, competitors may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our therapeutic candidates for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if a therapeutic candidate is determined to be contained within the scope of the competitor’s product for the same indication. If one of our therapeutic candidates designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union (EU) has similar, but not identical, requirements and benefits.

Expedited Development and Review Programs

The FDA has a fast-track program that is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for fast-track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for fast-track status any time before receiving NDA approval, but ideally no later than the pre-NDA meeting with the FDA.

Any product submitted to the FDA for marketing, including under a fast-track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies.

A product may also be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM"), which is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. FDA may withdraw drug approval or require changes to the labeled indication of the drug if confirmatory post-market trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions as it deems necessary to assure safe use of the product.

Additionally, a drug may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast-track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-Approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping requirements, requirements to report adverse events and comply with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations, known as "off-label promotion," and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for REMS, to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications;
- suspension or revocation of product approvals;
- product seizure or detention;
- refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Marketing and promotion of approved drugs in other major oncology markets, such as the EU, are subject to similar requirements and regulations.

Other U.S. Regulatory Matters

Pharmaceutical manufacturers are subject to various healthcare laws, regulation, and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Our conduct, including those of our employees, as well as our business operations and relationships with third parties, including current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market, and distribute any products for which we obtain marketing approval. The applicable federal, state, and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.
- The federal false claims, including the civil False Claims Act that can be enforced by private citizens through civil whistleblower or *qui tam* actions, and civil monetary penalties law prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.
- HIPAA prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters.

- HIPAA, as amended by HITECH, and their implementing regulations also impose obligations on covered entities such as health insurance plans, healthcare clearinghouses, and certain healthcare providers and their respective business associates and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information.

- The federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding certain payments and other transfers of value to physicians, as defined by such law, and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members; additionally, the Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act, under the provision titled "Fighting the Opioid Epidemic with Sunshine," in part, extends the reporting and transparency requirements for physicians under the Physician Payments Sunshine Act to physician assistants, nurse practitioners, and other mid-level practitioners, with reporting requirements going into effect in 2022 for payments made, or ownership and investment interests held, in 2021.

- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and require the registration of their sales representatives, state laws that require biotechnology companies to report information on the pricing of certain drug products, and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the PPACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion, and other activities also are potentially subject to federal and state consumer protection and unfair competition laws. In addition, the distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage, and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act as well as other applicable consumer safety requirements.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts.

Marketing, promotion, and sale of approved drugs in other major oncology markets, such as the EU, are subject to similar requirements and regulations. For example, in the EU, safeguarding the privacy, security and transmission of individually identifiable health information is subject to the General Data Protection Regulation (GDPR) and laws, which are widely considered to be the most stringent in the world.

U.S. Patent-Term Restoration and Marketing Exclusivity

Depending upon the timing, duration, and specifics of FDA approval of any future therapeutic candidates, some of our U.S. patents, if issued, may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits restoration of the patent term of up to five years as compensation for the lost opportunity to market the drug during the patent term while the drug was under the FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from regulatory approval. The patent-term restoration period is generally one-half the time between the effective date of an IND or the issue date of the patent, whichever is later, and the submission date of an NDA plus the time between the submission date of an NDA or the issue date of the patent, whichever is later, and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The US Patent Office (USPTO), in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA"), or a 505(b)(2) NDA submitted by another company for a generic version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness or generate such data themselves.

European Union Drug Development

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated, it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority ("NCA"), and one or more Ethics Committees ("ECs"). Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the EU will be identical. In the meantime, Clinical Trials Directive 2001/20/EC continues to govern all clinical trials performed in the EU.

European Union Drug Review and Approval

In the European Economic Area ("EEA"), which comprises the 28 Member States of the European Union and three European Free Trade Association States (Norway, Iceland, and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization ("MA"). There are two types of MAs.

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, of the EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions, and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific, or technical innovation or which are in the interest of public health in the EU.

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State ("RMS"). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics ("SOPC"), and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SOPC, labeling or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above-described procedures, before granting the MA, EMA or the competent authorities of the Member States of the EEA assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. Like the U.S. patent term-restoration, Supplementary Protection Certificates ("SPCs") serve as an extension to a patent right in Europe for up to five years. SPCs apply to specific pharmaceutical products to offset the loss of the ability to market a drug during the patent term due to the lengthy testing and clinical trials these products require prior to obtaining regulatory marketing approval.

Coverage and Reimbursement

Sales of our therapeutic products and DRP® companion diagnostics, if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the U.S., for example, principal decisions about reimbursement for new products are typically made by CMS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical therapeutic candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific therapeutic candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost effectiveness of our products. 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 obtained. Additionally, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private third-party payors often follow Medicare coverage policy and payment limitations in setting their own payment rates.

In addition, where a drug product requires a companion diagnostic (in our case, a DRP® companion diagnostic), then companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. In general, insurance payors will cover and reimburse a companion diagnostic where sufficient clinical proof is provided to support that use of the companion diagnostic improves healthcare outcomes and/or reduces healthcare expenses associated with a given drug.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Healthcare Reform

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the PPACA substantially changed the way healthcare is financed by both the government and private insurers and continues to significantly impact the U.S. pharmaceutical industry. The PPACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the HHS Secretary as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The PPACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price ("AMP"), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The PPACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Additionally, for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer.

There remain judicial and Congressional challenges to certain aspects of the PPACA, as well as efforts by the previous administration to repeal or replace certain aspects of the PPACA. Since January 2017, there have been several executive orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the PPACA have passed. In 2017, the Tax Act repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA's mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, among other things, amended the PPACA, effective January 1, 2019, to close the coverage gap in most Medicare Part D drug plans. In December 2018, CMS published a new final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In April 2020, the U.S. Supreme Court reversed a federal circuit decision that previously upheld Congress' denial of $12.0 billion in "risk corridor" funding. In December 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, in December 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. On June 17, 2021, the U.S. Supreme Court reversed the decision of the Fifth Circuit holding that the state plaintiffs lacked standing to challenge the individual mandate under Article III, Section 2 of the U.S. Constitution. It is unclear how future litigation and other efforts to repeal and replace the PPACA will impact the PPACA and our business. We will continue to evaluate the effect that the PPACA and its possible repeal and replacement has on our business. Complying with any new legislation, resulting in a material adverse effect on our business.

Other legislative changes have been proposed and adopted in the U.S. since the PPACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030 unless additional congressional action is taken. The CARES Act, which was signed into law in March 2020, and designed to provide financial support and resources to individuals and businesses affected by COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020, through December 31, 2020, and extended the sequester by one year, through 2030, to offset the added expense of the 2020 suspension. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny recently over the way drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. For example, at the federal level, the administration's budget proposals for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. Although a number of these and other measures may require additional authorization to become effective, Congress and the administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on July 24, 2020, the administration announced four executive orders to lower drug prices, including allowing importation of certain drugs, changing how drug rebates are negotiated by middlemen, like pharmacy benefit managers, and directing such rebates to be passed to patients as point-of-sale discounts, and requiring Medicare to pay certain Part B drugs at the lowest price available in economically comparable countries (the details of which were released on September 13, 2020 and also expanded the policy to cover certain Part D drugs). The president has delayed the effective date of the international drug pricing order, pending discussion with major drug companies. How these executive orders will be implemented and their impact on the industry remain uncertain. Additionally, the FDA recently released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. It is possible that additional governmental action is taken in response to the ongoing COVID-19 pandemic, which may impact our business. We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition, and results of operations.

Facilities

Our principal executive office is in Boston, MA USA, where we lease at-will, month-to-month share space where we are not bound by any lease. This office is sufficient to support our U.S.-based executive team members, most of whom are based on the East Coast of the U.S., including our CEO, CMO, and SVP of Corporate Development. Our principal laboratory and R&D facility is in Hoersholm, Denmark (just north of Copenhagen), where we have a modest space in a technology park, with an open-ended facility lease, which terminates upon 12-month notice. We believe that these existing facilities will be adequate for our current needs and that suitable additional or alternative space will be available in the future on commercially reasonable terms, if required.

Human Capital

As of March 1, 2024, we had 6 employees, 5 of whom were full-time and 1 half-time; and most of which were engaged in research and development activities. Of our employees, the majority are in Hoersholm, Denmark. Among our executive management team members, one is located near New York City, NY, and one is in Vancouver, British Columbia, Canada. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

We recognize that attracting, motivating, and retaining talent at all levels is vital to our continued success. Our employees are a significant asset, and we aim to create an environment that is equitable, inclusive, and representative in which our employees can grow and advance their careers, with the overall goal of developing, expanding, and retaining our workforce to support our current pipeline and future business goals. By focusing on employee retention and engagement, we also improve our ability to support our clinical-stage platform, business, and operations, and also protect the long-term interests of our securityholders. Our success also depends on our ability to attract, engage, and retain a diverse group of employees. Our efforts to recruit and retain a diverse and passionate workforce include providing competitive compensation and benefits packages and ensuring we listen to our employees.

We value agility, passion, and teamwork, and are building a diverse environment where our employees can thrive and one that inspires exceptional contributions and professional and personal development to achieve our mission to significantly change the practice of oncology. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives. We are committed to providing a competitive and comprehensive benefits package to our employees. Our benefits package provides a balance of protection along with the flexibility to meet the individual health and wellness needs of our employees.

We plan to continue to develop our efforts related to attracting, retaining, and motivating our workforce as we grow and develop and hire more employees.

Item 1A. Risk Factors.

An investment in our common stock involves a high degree of risk. Before making an investment decision, you should give careful consideration to the following risk factors, in addition to the other information included in this Annual Report, including our financial statements and related notes, before deciding whether to invest in shares of our common stock. The occurrence of any of the adverse developments described in the following risk factors could materially and adversely harm our business, financial condition, results of operations or prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Financial Position and Need for Capital

We have a limited operating history and have never generated any revenues other than from research grants and a limited number of DRP® biomarker development agreements, which may make it difficult to evaluate the success of our business to date and to assess our future viability.

We were incorporated as a Delaware corporation in April 2021 for the purposes of undertaking our Recapitalization Share Exchange. In December 2021, Allarity Therapeutics A/S, became our predecessor upon consummation of the Recapitalization Share Exchange, and was deemed to be the accounting acquirer in the Recapitalization Share Exchange. Our predecessor, Allarity Therapeutics A/S, was organized under the laws of Denmark on September 9, 2004, and was largely focused on organizing and staffing our company, raising capital, developing our proprietary DRP® companion diagnostics platform and acquiring the rights to, advancing the development of, our therapeutic candidates, including conducting clinical trials on our therapeutic candidates, and completing our Recapitalization Share Exchange. As such, we have a limited operating history and have not generated any revenues.

In addition, we have not yet demonstrated an ability to successfully obtain marketing approvals, manufacture drugs on a commercial scale, or conduct sales and marketing activities necessary for successful commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drugs.

We are dependent on a short-term bridge loan to finance our current operations. Our continued operations are dependent on us raising capital.

On January 18, 2024, we entered into a Securities Purchase Agreement with 3i, pursuant to which we issued and sold 3i a senior convertible promissory notes in an aggregate principal amount of $440,000 due on January 18, 2025 (the "First Note", and together with the Purchase Agreement, the "Transaction Documents") for an aggregate purchase price of $400,000, representing an approximate 10% original issue discount (the "Transaction"). We agreed to use the net proceeds from the sale of the Note for accounts payable and working capital purposes. Unless the Transaction Documents state otherwise, we may not prepay any portion of the principal amount of the Note without the Purchaser's prior written consent.

On February 13, 2024 (the "Second Closing"), the Parties entered into a Limited Waiver Agreement (the "Waiver Agreement") and agreed that the Second Closing can be consummated prior to the 30th calendar day following January 18, 2024. The Parties further waive any rights or remedies that they may have under Section 2.3 of the Purchase Agreement, solely in connection with the Second Closing, including any rights of termination, defaults, amendment, acceleration or cancellation that be triggered under the Purchase Agreement solely as a result of accelerating the Second Closing. As of the Second Closing, we issued and sold to the Purchaser a senior convertible promissory note in an aggregate principal amount of $440,000 (the "Principal Amount") due on February 13, 2025 (the "Second Note," and together with the First Note dated January 18, 2024, and Purchase Agreement, the "Second Transaction Documents") for an aggregate purchase price of $400,000, representing an approximately 10% original issue discount (the "Second Transaction"). We agreed to use the net proceeds from the sale of the Second Note for accounts payable and working capital purposes. Unless the Transaction Documents state otherwise, we may not prepay any portion of the principal amount of the Second Note without the Purchaser's prior written consent.

We will need to raise additional capital to support our operations and execute on our business plan. We may be required to pursue sources of additional capital through various means, including debt or equity financings. Any new securities that we may issue in the future may be sold on terms more favorable for our new investors than the terms of this offering. Newly issued securities may include preferences, superior voting rights, and the issuance of warrants or other convertible securities that will have additional dilutive effects. We cannot assure that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us. Further, we may incur substantial costs in pursuing future capital and/or financing, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as convertible notes and warrants, which will adversely impact our financial condition and results of operations. Our ability to obtain needed financing may be impaired by such factors as the weakness of capital markets, and the fact that we have not been profitable, which could impact the availability and cost of future financings. If the amount of capital we are able to raise from financing activities is not sufficient to satisfy our capital needs, we may have to reduce our operations accordingly.

In the event of default of the Secured Promissory Notes to 3i, LP, such default could adversely affect our business, financial condition, results of operations or liquidity.

The indebtedness evidenced by the secured promissory notes issued and to be issued to 3i, LP in connection with the bridge loan and obligation to pay an Alternative Conversion Floor Amount ("3i Promissory Notes") is secured by all of our assets pursuant to certain security agreement between the Company and 3i, LP ("Security Agreement"). Each of the secured 3i Promissory Notes matures on January 1, 2024 and carries an interest rate of at 5% per annum. 3i, LP may exchange 3i Promissory Notes for the Company's common stock, or other equity security, at an exchange price equal to the lowest price per share of the equity security sold to other purchasers, rounded down to the nearest whole share, if the Company concludes a future equity financing prior to the maturity date or other repayment of such promissory note. In addition, each 3i Promissory Note and interest earned thereon may be redeemed by the Company at its option or the holder may demand redemption if the Company obtains gross proceeds of at least $5 million in a financing in an amount of up to 35% of the gross proceeds of the financing. As a secured party, upon an event of default, 3i, LP will have a right to the collateral granted to them under the Security Agreement, and we may lose our ownership interest in the assets. A loss of our collateral will have a material adverse effect on our operations, our business and financial condition.

We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability. We need to raise additional capital to continue our operations, initiate clinical trials and to implement our business plan.

Since our inception of our predecessor, Allarity Therapeutics A/S, we have incurred losses and have an accumulated deficit of $94.5 million as of December 31, 2023. Our net losses were $11.8 million and $16.1 million for the years ended December 31, 2023, and 2022, respectively. As of December 31, 2023, our cash deposits of $166 thousand were determined to be insufficient to fund our current operating plan and planned capital expenditures for the next twelve months. These conditions give rise to a substantial doubt over our ability to continue as a going concern. We expect to incur substantial operating losses for the foreseeable future and may never achieve profitability. None of our current therapeutic candidates have been approved for marketing in the United States, or in any other jurisdiction, and may never receive such approval. It could be several years, if ever, before we have a commercialized drug that generates significant revenues. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain profitability. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue the development of our therapeutic candidates, including, but not limited to, advancing our DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer and our DRP®-guided Phase 2 clinical trial of IXEMPRA® as a treatment for metastatic breast cancer, being conducted at trial sites in Europe;

- initiate preclinical studies and clinical trials for any additional indications for our current therapeutic candidates and any future therapeutic candidates that we may pursue;

- continue to build our portfolio of therapeutic candidates through the acquisition or in-license of additional therapeutic candidates or technologies;
- continue to develop, maintain, expand and protect our intellectual property portfolio;
- continue to develop, maintain, and expand our proprietary DRP® companion diagnostics platform;
- pursue regulatory approvals for our current and future therapeutic candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing, distribution and other commercial infrastructure to commercialize any therapeutic candidate for which we may obtain marketing approval, or partner with third parties to affect the same;
- hire additional clinical, regulatory, scientific and accounting personnel; and
- incur additional legal, accounting and other expenses in operating as a U.S. listed public company.

To become and remain profitable, we must develop and eventually commercialize one or more therapeutic candidates with significant market potential or license one or more of our therapeutic candidates to an industry partner. This will require us to be successful in a range of challenging activities, including completing clinical trials of our therapeutic candidates, publishing our data and findings on our therapeutic candidates with peer reviewed publications, developing commercial scale manufacturing processes, obtaining marketing approval, manufacturing, marketing and selling any current and future therapeutic candidates for which we may obtain marketing approval, and satisfying any post-marketing requirements. We submitted an NDA to the U.S. FDA on our therapeutic candidate Dovitinib in December 2021 and on February 15, 2022, we received RTF letters for both our dovitinib NDA and our DRP®-Dovitinib companion diagnostic PMA. The FDA determined that our NDA was not sufficiently complete to permit a substantive review and therefore our NDA was not accepted for filing. The primary grounds of rejection asserted by the FDA relates to our use of prior Phase 3 clinical trial data, generated by Novartis in a "superiority" endpoint study against sorafenib (Bayer), to support a "non-inferiority" endpoint in connection with the DRP® Dovitinib companion diagnostic. We anticipate that the FDA will require a prospective Phase 3 clinical trial as well as additional dosage studies before regulatory approval of Dovitinib as a monotherapy and its companion diagnostic Dovitinib-DRP can be obtained. We have decided that the costs, risks and potential benefits of conducting these studies for dovitinib as a monotherapy for mRCC are no longer the best path toward commercial success.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will obtain marketing approval to commercialize any of our therapeutic candidates. If we are required by the FDA, or other regulatory authorities such as the European Medicines Agency, or EMA, to perform studies and trials in addition to those currently expected, or if there are any delays in the development, or in the completion of any planned or future preclinical studies or clinical trials of our current or future therapeutic candidates, our expenses could increase, and profitability could be further delayed.

A decline in the value of our company also could cause you to lose all or part of your investment.

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 this report. Our audited financial statements at December 31, 2023, and for the year then ended, were prepared assuming that we will continue as a going concern.

The report from our independent registered public accounting firm for the year ended December 31, 2023, includes an explanatory paragraph stating that our recurring losses from operations since inception and our accumulated deficit raise substantial doubt about our ability to continue as a going concern. Such an opinion 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 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 common stock or obtaining alternate financing. We cannot provide any assurance that we will be able to raise additional capital.

We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our drug development programs or commercialization efforts.

We anticipate that our expenses will increase as we advance our DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer. We have already begun paring down resource expenditures on any program other than stenoparib so that all internal resources can be devoted to accelerating stenoparib development in Ovarian Cancer. Even with a single program on stenoparib, there will be significant additional development costs. These may include any or all of the following: additional trials designed to seek regulatory approval; the expenses associated with regulatory and marketing approvals as well as sales, marketing, distribution and other commercial infrastructure spend; Commercial scale drug and Companion Diagnostic manufacture; Maintenance of our intellectual property portfolio; hiring and retaining additional personnel, such as clinical, quality control and scientific personnel; adding operational, financial and management information systems and personnel, including personnel to support our drug development and help us comply with our obligations as a public company; and adding equipment and physical infrastructure to support our research and development programs.

In addition, while we may seek one or more collaborators for future development of our current therapeutic candidates or any future therapeutic candidates that we may develop for one or more indications, we may not be able to enter into a partnership or out-license for any of our therapeutic candidates for such indications on suitable terms, on a timely basis or at all. In any event, our existing cash and cash equivalents will not be sufficient to fund all the efforts that we plan to undertake or to fund the completion of development of our therapeutic candidates or our other preclinical studies. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Further financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

We will need to seek additional funding, which future funding requirements, both short-term and long-term, will depend on many factors, including:

- the scope, progress, timing, costs and results of our DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer,;
- the costs associated with maintaining, expanding and updating our proprietary DRP® companion diagnostics platform;
- the costs, timing and outcome of seeking regulatory approvals;
- the costs of our licensing or commercialization activities for any of our therapeutic candidates that receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing drug sales, marketing, distribution and manufacturing capabilities;
- our headcount growth and associated costs as we expand our research and development activities as well as potentially establish a commercial infrastructure;

- our ability to enter into and the terms and timing of any collaborations, licensing agreements or other arrangements;
- revenue received from commercial sales, if any, of our current and future therapeutic candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending against intellectual property related claims;
- the number of future therapeutic candidates that we pursue and their development requirements;
- changes in regulatory policies or laws that may affect our operations;
- changes in physician acceptance or medical society recommendations that may affect commercial efforts;
- the costs of acquiring potential new therapeutic candidates or technology;
- the costs associated with maintaining and expanding our cybersecurity systems; and
- the costs of operating as a public company.

Internal Controls Over Financial Reporting

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, as of the end of the period covered by this report, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Act of 1934. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be included in our SEC reports is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, relating to the Company, including our consolidated subsidiaries, and was made known to them by others within those entities, particularly during the period when this report was being prepared. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2023.

We received a request for documents from the SEC in the investigation known as "In the Matter of Allarity Therapeutics, Inc.," the consequences of which are unknown.

In January 2023, we received a request to produce documents from the SEC that stated that the staff of the SEC is conducting an investigation known as "In the Matter of Allarity Therapeutics, Inc." to determine if violations of the federal securities laws have occurred. The documents requested appear to focus on submissions, communications and meetings with the FDA regarding our NDA for Dovitinib or Dovitinib-DRP. The SEC letter also stated that investigation is a fact-finding inquiry and does not mean that that the SEC has concluded that the Company or anyone else has violated the laws.

We do not know when the SEC's investigation will be concluded or what action, if any, might be taken in the future by the SEC or its staff as a result of the matters that are the subject to its investigation or what impact, if any, the cost of continuing to respond to inquiries might have on our financial position or results of operations. We have not established any provision for losses in respect of this matter. In addition, complying with any such future requests by the SEC for documents or testimony would distract the time and attention of our officers and directors or divert our resources away from ongoing business matters. This investigation may result in significant legal expenses, the diversion of management's attention from our business, could cause damage to our business and reputation, and could subject us to a wide range of remedies, including enforcement actions by the SEC. There can be no assurance that any final resolution of this or any similar matters will not have a material adverse effect on our financial condition or results of operations.

Risks Related to the Discovery and Development of Our Therapeutic Candidates

Clinical trials are very expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

The risk of failure for most of our therapeutic candidates is substantial. It is impossible to predict when or if any of our therapeutic candidates will prove effective or safe or effective in humans or will receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our therapeutic candidates, we must demonstrate through extensive preclinical studies and clinical trials that our therapeutic candidates are safe and effective in humans for use in each target indication. Preclinical investigation and clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the preclinical investigation or clinical trial process, or during the regulatory approval process.

In addition, the results of preclinical studies and earlier clinical trials may not be predictive of the results of later-stage preclinical studies or clinical trials. The results generated to date in preclinical studies and clinical trials for our therapeutic candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results.

Therapeutic candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and earlier stage clinical trials. In later-stage clinical trials, we will likely be subject to more rigorous statistical analyses than in completed earlier stage clinical trials. Several companies in the pharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their therapeutic candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same therapeutic candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our therapeutic candidates, the development timeline and regulatory approval and commercialization prospects for our therapeutic candidates, and, correspondingly, our business and financial prospects, would be materially and adversely affected.

We may encounter substantial delays in our preclinical studies or clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our therapeutic candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the therapeutic candidate for its intended indications. Preclinical studies and clinical trials are expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any preclinical studies or clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more preclinical studies or clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of preclinical or clinical development include:

- delays in conducting experiments or preclinical studies or unsatisfactory results from such experiments or studies;
- delays in reaching a consensus with regulatory authorities on trial design;
- delays in reaching agreement or failing to agree on acceptable terms with prospective CROs and clinical trial sites;
- delays in opening sites and recruiting suitable patients to participate in our clinical trials;
- delays in enrollment due to travel or quarantine policies, or other factors, related to COVID-19, other pandemics or other events outside our control;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a class of therapeutic candidates or after an inspection of our clinical trial operations or trial sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- occurrence of serious adverse events associated with the therapeutic candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

For instance, committee and staff shortages causing delays at processing the trials at the investigator sites resulting in delayed and slow patient enrollment, which may delay, limit or prevent our employees and CROs from continuing research and development activities, impede the ability of patients to enroll or continue in clinical trials, or impede testing, monitoring, data collection and analysis or other related activities, any of which could delay our clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. In addition, current inflation levels could lead to further increases in the costs for clinical supply both in the U.S. and Europe, which could lead to further increases in our development costs and materially affect our results of operations.

Any inability to timely and successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to achieve regulatory and commercialization milestones. In addition, if we make manufacturing or formulation changes to our therapeutic candidates, we may need to conduct additional testing to bridge our modified therapeutic candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our therapeutic candidates, if approved, or allow our competitors to bring comparable drugs to market before we do, which could impair our ability to successfully commercialize our therapeutic candidates and may harm our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our therapeutic candidates, we may:

- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Our drug development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all.

Further, we, the FDA or an institutional review board ("IRB") may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice, ("GCP"), regulations, that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our Investigational New Drug ("IND") Applications, or INDs, or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our therapeutic candidates could be negatively impacted, and our ability to generate revenues from our therapeutic candidates may be delayed or eliminated entirely.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including committee and staff shortages causing delays at processing the trials at the investigator sites resulting in delayed and slow patient enrollment. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll enough patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size and health of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the therapeutic candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- sufficient number of patients willing to consent to a recent biopsy; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for therapeutic candidates that are in the same therapeutic areas as our therapeutic candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial site. Moreover, because our therapeutic candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies rather than enroll patients in any future clinical trial.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our current or planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our therapeutic candidates.

If we fail to comply with our obligations in the agreements under which we have licensed the intellectual property rights from third parties for our therapeutic candidate stenoparib or otherwise experience disruptions to our business relationships with our licensors, we could lose rights to advance the development of dovitinib and stenoparib which would have a material adverse effect on our business.

We have entered into intellectual property license agreements with third party licensors for our primary therapeutic candidate, stenoparib that are important to our business. These license agreements impose various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with any obligations under any of these agreements with our licensors, we may be subject to termination of the license agreements in whole or in part; increased financial obligations to our licensors or loss of exclusivity in a particular field or territory, in which case our ability to develop or commercialize the therapeutic candidate covered by the license agreement will be impaired.

In addition, disputes may arise regarding intellectual property rights subject to the license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- if a third-party expresses interest in an area under a license that we are not pursuing, under the terms of certain of our license agreements, we may be required to sublicense rights in that area to a third party, and that sublicense could harm our business; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the therapeutic candidate covered by the license agreement which would have a material adverse effect on our business.

We may expend our limited resources to pursue a particular therapeutic candidate or indication and fail to capitalize on therapeutic candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs that we identify for specific indications using our proprietary DRP® companion diagnostics platform. As a result, we may forego or delay pursuit of opportunities with other therapeutic candidates or for other indications, even those that we have begun investigating and that may have shown promise, that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial therapies or profitable market opportunities. Our spending on current and future research and development programs and therapeutic candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular therapeutic candidate, we may relinquish valuable rights to that therapeutic candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such therapeutic candidate.

We have limited experience in drug discovery and drug development and may not receive regulatory approval to market our therapeutic candidates.

Prior to the acquisition of our therapeutic candidates, we were not involved in and had no control over their preclinical and clinical development. In addition, we rely upon the parties from whom we have acquired our therapeutic candidates from to have conducted such research and development in accordance with the applicable protocol, legal, regulatory, and scientific standards, having accurately reported the results of all clinical trials conducted prior to our acquisition of the applicable therapeutic candidate, and having correctly collected the data from these studies and trials. To the extent any of these has not occurred, our expected development time and costs may be increased, which could adversely affect our prospects for marketing approval of, and receiving any future revenue from, these therapeutic candidates.

We are dependent on our ability to advance the development of our therapeutic candidates. If we are unable to complete the clinical development of, obtain marketing approval for or successfully commercialize our therapeutic candidate, either alone or with a collaborator, or if we experience significant delays in doing so, our business could be substantially harmed.

Although we submitted an NDA to the FDA for our therapeutic candidate dovitinib in December 2021, we currently do not have any drugs that have received regulatory approval and may never be able to develop marketable therapeutic candidates. In addition, if we do not obtain the regulatory approval for and successfully commercialize our therapeutic candidates or experience significant delays in doing so, we may never generate any revenue or become profitable. We are investing a significant portion of our efforts and financial resources in the advancement of dovitinib, stenoparib. Our prospects are substantially dependent on our ability, or those of any future collaborator, to develop, obtain marketing approval for and successfully commercialize therapeutic candidates in one or more disease indications.

The success of stenoparib**,** and our other therapeutic candidates will depend on several factors, including the following:

- our ability to successfully complete clinical trials to obtain regulatory approval for our therapeutics candidates without significant delay. On February 15, 2022, we receive RTF letters for both our dovitinib NDA and our DRP®-Dovitinib companion diagnostic PMA. The FDA determined that our NDA was not sufficiently complete to permit a substantive review and therefore or NDA was not accepted for filing. The primary grounds of rejection asserted by the FDA relates to our use of prior Phase 3 clinical trial data, generated by Novartis in a "superiority" endpoint study against sorafenib (Bayer), to support a "non-inferiority" endpoint in connection with the DRP® Dovitinib companion diagnostic. We anticipate that the FDA will require a prospective Phase 3 clinical trial as well as additional dosage studies before regulatory approval of Dovitinib as a monotherapy and its companion diagnostic Dovitinib-DRP can be obtained. We have decided that the costs, risks and potential benefits of conducting these studies for dovitinib as a monotherapy for mRCC are no longer the best path toward commercial success.

- advancing our DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer,
- initiation, progress, timing, costs and results of clinical trials of other potential therapeutic candidates;
- establishment of a safety, tolerability and efficacy profile that is satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and relevant global markets;
- the performance of our future collaborators, if any;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishment of supply arrangements with third-party raw materials suppliers and manufacturers;
- establishment of arrangements with third-party manufacturers to obtain finished drug product that is appropriately packaged for sale;
- protection of our rights in our intellectual property portfolio;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

Many of these factors are beyond our control, including the results of clinical trials, the time required for the FDA or any comparable foreign regulatory authorities to review any regulatory submissions we may make, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we are unable to develop, receive marketing approval for and successfully commercialize dovitinib and our other therapeutic candidates, on our own or with any future collaborator or experience delays as a result of any of these factors or otherwise, our business could be substantially harmed. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, expensive and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our therapeutic candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but can take many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. The results of preclinical studies and early clinical trials of our therapeutic candidates may not be predictive of the results of later-stage clinical trials. Therapeutic candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. It is not uncommon for companies in the biotechnology and pharmaceutical industries to suffer significant setbacks in advanced clinical trials due to nonclinical findings made while clinical studies were underway and safety or efficacy observations made in clinical studies, including previously unreported adverse events. Our future clinical trial results may not be successful, and notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. The historical failure rate for therapeutic candidates in our industry is high. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a therapeutic candidate's clinical development and may vary among jurisdictions. We have not obtained final regulatory approval for any therapeutic candidate and it is possible that none of our existing therapeutic candidates or any therapeutic candidates we may seek to develop in the future will ever obtain regulatory approval.

Our therapeutic candidates could fail to receive regulatory clearance or marketing approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, including, but not limited to, the use of genomic or biomarker signatures to identify patients that may respond to drug efficacy;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a therapeutic candidate is safe and effective for its proposed indication;
- we may be unable to identify and recruit a sufficient number of patients with relevant genomic or biomarker signatures in order to conduct clinical trials on our therapeutic candidates or the FDA or comparable foreign regulatory authorities may not approve a DRP® companion diagnostic that is required to select patients responsive to one of our therapeutic candidates;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our therapeutic candidates may not be sufficient to support the submission of an NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We have not previously completed all clinical trials for any of our therapeutic candidates and we have relied on the clinical trial results of others to advance dovitinib to the submission of an unsuccessful NDA filing with the FDA. Consequently, we may not have the necessary capabilities, including adequate staffing, to successfully manage the execution and completion of any clinical trials we initiate in a way that leads to our obtaining marketing approval for our therapeutic candidates in a timely manner, or at all. This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our therapeutic candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our therapeutic candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our drugs, may grant approval contingent on the performance of costly post-marketing clinical trials, may approve a therapeutic candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that therapeutic candidate or may restrict its distribution. Any of the foregoing restrictions or requirements could materially harm the commercial prospects for our therapeutic candidates.

We have not successfully filed an NDA to the FDA or similar drug approval filings to comparable foreign authorities, for any therapeutic candidate, and we cannot be certain that any of our therapeutic candidates will be successful in clinical trials or receive regulatory approval. Further, our therapeutic candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our therapeutic candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our therapeutic candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patients that we are targeting for our therapeutic candidates are not as significant as we estimate, or if the price we charge for our therapeutic candidate is too high, we may not generate significant revenues from sales of such drugs, if approved.

We plan to seek regulatory approval to commercialize our therapeutic candidates both in the United States and the European Union and in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and possible limitations placed upon commercial sales, pricing and distribution of our therapeutic candidates, and we cannot predict success in these jurisdictions.

Our business strategy of using our proprietary DRP® companion diagnostics platform to advance therapeutic candidates that have previously failed therapeutic clinical trial endpoints in Phase 2 or later clinical trials conducted by others and that we believe may be successfully developed with a DRP® companion diagnostic may not be successful, and important issues relating to safety and efficacy remain to be resolved for most of our therapeutic candidates. Our strategy also involves risks and uncertainties that differ from other biotechnology companies that focus solely on new therapeutic candidates that do not have a history of failed clinical trials.

Our therapeutic candidate portfolio includes small molecules that others have tried, but failed, to develop into an approved commercialized drug. Our strategy to use our proprietary DRP® companion diagnostics platform to identify and subsequently clinically advance therapeutic candidates that have previously failed clinical trial endpoints but that we believe have potential to succeed with a DRP® companion diagnostic may not be successful.

Our business strategy includes a focus on leveraging our proprietary DRP® companion diagnostics platform to streamline the drug development process and to identify patients that will benefit from therapeutic candidates that other biotechnology or pharmaceutical companies have abandoned or shelved after initiating clinical trials under an IND application filed with the FDA, including candidates that have failed to achieve statistical significance on the original endpoints established in the clinical trials. We use our proprietary DRP® companion diagnostics platform to advance therapeutic candidates by targeting and evaluating patient sub-populations having gene signatures, determined by our DRP® companion diagnostics platform, that will potentially correlate with drug efficacy and patient response to treatment. While we have not yet successfully received regulatory or marketing approval for any of our therapeutic candidates or companion diagnostics, and while we believe that our approach has the potential to reduce the cost and time of drug development through the identification and selection of patient populations more likely to respond to therapy, our strategy involves risks and uncertainties that differ from other biotechnology companies that focus solely on new therapeutic candidates that do not have a history of failed clinical development. These risks and uncertainties include, but are not limited to, the following:

- The remaining term of the initial patents filed with respect to a therapeutic candidate may be significantly less than the patent term for a newly discovered therapeutic candidate;

- Potential out-licensees, alliance partners and collaborators may view a therapeutic candidate identified with our proprietary DRP® companion diagnostics platform with more skepticism because of its history of failed clinical trials, thereby requiring a higher level of additional data and further explanations of mechanisms of action in order to overcome this skepticism and obtain commercially reasonable terms for future development or collaboration;

- Key personnel and institutional knowledge relating to a therapeutic candidate that we couple with a DRP® companion diagnostic may no longer be available for us;

- The current standard of care in the targeted therapeutic indication for the DRP® companion diagnostic-selected patient population may be different than the standard of care that existed during the candidate's last clinical trial, which will require more time and resources from us to reassess and redesign the regulatory development path for the DRP® -coupled therapeutic candidate; and

- The DRP®-coupled therapeutic candidate may be perceived to be in an "older" therapeutic drug type or focus area of oncology, thereby generating less enthusiasm and support compared to therapeutic focus areas of oncology that may be perceived as more recent.

We rely on Smerud Medical Research International and Chosa ApS for the development of our LiPlaCis® DRP® companion diagnostic.

We have out-licensed our LiPlaCis® DRP® companion diagnostic to Chosa ApS, an affiliate of our long-time CRO partner Smerud Medical Research International, in our efforts to advance the clinical development of this asset. Chosa ApS intends to conduct expanded enrollment of a DRP®-guided Phase 2 clinical trial in Europe for LiPlaCis®, with the intent of establishing sufficient clinical results to garner the interest of a larger pharmaceutical acquirer or partner to advance the program through Phase 3 clinical trials and, if approved, to market. Although Chosa ApS and SMERUD will be solely responsible for the development of LiPlaCis®, we intend to support these clinical trials with our proprietary DRP® companion diagnostics and our clinical trial and regulatory expertise, as requested. Under the agreements, we are entitled to receive certain specified milestone payments from Chosa ApS and SMERUD. As a result of these agreements, we rely on Chosa ApS and SMERUD for the further development of LiPlaCis®.

We may depend on enrollment of patients with specific genomic or biomarker signatures, identified through DRP® companion diagnostics, in our clinical trials in order for us to continue development of our therapeutic candidates. If we are unable to enroll patients with specific genomic or biomarker signatures in our clinical trials, our research, development and commercialization efforts could be adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients with genomic or biomarker signatures we have identified by our DRP® companion diagnostics platform, and who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. Patient enrollment is affected by many factors including the size and nature of the patient population with the specific genomic or biomarker signature we have identified, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, the size of the patient population required for analysis of the trial's primary endpoints, the proximity of patients to study sites, our ability to recruit clinical trial investigators with the appropriate competencies and experience, our ability to obtain and maintain patient consents, the risk that patients enrolled in clinical trials will drop out of the trials before completion, and competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. We will compete with other pharmaceutical companies for clinical sites, physicians and the limited number of patients who fulfill the stringent requirements for participation in oncology clinical trials. Also, due to the confidential nature of clinical trials, we do not know how many of the eligible patients may be enrolled in competing studies and who are consequently not available to us for our clinical trials. Our clinical trials may be delayed or terminated due to the inability to enroll enough patients. The delay or inability to meet planned patient enrollment may result in increased costs and delay or termination of our trials, which could have a harmful effect on our ability to develop drugs.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

Although we intend to advance our ongoing DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer, being conducted at trial sites in Europe, we are exploring certain clinical trials for other indications, there can be no assurance that the FDA will accept our proposed trial designs. We may experience delays in our clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory clearance to commence a trial or obtaining regulatory approval to utilize a DRP® companion diagnostic in a trial to select and treat patients;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in our CRO's schedules relating to testing patients involved in our clinical trials;
- obtaining institutional review board, or IRB, approval at each site;
- recruiting suitable patients to participate in a trial;

- identifying clinical sites with adequate infrastructure (including data collection) to conduct the trial;
- clinical sites deviating from trial protocol or dropping out of a trial;
- addressing patient safety concerns that arise during the course of a trial;
- having patients complete a trial or return for post-treatment follow-up;
- adding a sufficient number of clinical trial sites; or
- manufacturing sufficient quantities and quality of a therapeutic candidate for use in clinical trials.

We may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our therapeutic candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- we may not have the ability to test patients for our clinical trials that require a specific genomic or biomarker signature in order to qualify for enrollment;
- clinical trials of our therapeutic candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our therapeutic candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the cost of clinical trials of our therapeutic candidates may be greater than we anticipate;
- the supply or quality of our therapeutic candidates or other materials necessary to conduct clinical trials of our therapeutic candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our therapeutic candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues and may conduct clinical trials in ways they view as advantageous to themselves but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our therapeutic candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our therapeutic candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our therapeutic candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;

- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;

- be subject to additional post-marketing testing requirements; or

- have the drug removed from the market after obtaining marketing approval.

Furthermore, we intend to rely on CROs, cancer research centers and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we intend to have agreements governing their committed activities. They may not perform as required or we may face competition from other clinical trials being conducted by other pharmaceutical companies.

We could encounter delays if a clinical trial is suspended or terminated by us, by the Institutional Review Board or IRB of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our current and future therapeutic candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

If we experience delays in the completion of, or termination of, any clinical trial of our therapeutic candidates, the commercial prospects of our therapeutic candidates will be harmed, and our ability to generate revenues from any of these therapeutic candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our therapeutic candidate development and approval process and jeopardize our ability to commence drug sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our therapeutic candidates.

Our therapeutic candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our therapeutic candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. The clinical evaluation of some of our therapeutic candidates in patients is still in the early stages and it is possible that there may be side effects associated with their use. In such an event, we, the FDA, the IRBs at the institutions in which our studies are conducted, or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our therapeutic candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our therapeutic candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our therapeutic candidates. Inadequate training in recognizing or managing the potential side effects of our therapeutic candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our therapeutic candidates receives marketing approval, and we or others later identify undesirable side effects caused by such drugs, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such drugs;
- we may be required to recall a drug or change the way such a drug is administered to patients;
- additional restrictions may be imposed on the marketing or distribution of the particular drug or the manufacturing processes for the drug or any component thereof;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or contraindication;
- we may be required to implement Risk Evaluation and Mitigation Strategies (REMS) or create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- our drug may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular therapeutic candidate or for particular indications of a therapeutic candidate, if approved, and could significantly harm our business, results of operations and prospects.

diagnostics platform in an attempt to create a pipeline of therapeutic candidates using biomarker identification and patient stratification for the development of oncology drugs in a personalized medicine approach. While we believe that applying our proprietary DRP® companion diagnostics platform to drugs that have failed, been abandoned or otherwise failed to meet clinical endpoints and then developing a precision oncology approach that identifies the mechanism of action, potential combination drug usage and potentially responsive patient population is a strategy, our approach has not been approved by the FDA or any equivalent foreign regulatory authority. While we have retrospectively validated our proprietary DRP® companion diagnostics platform in 35 clinical trials conducted by other companies, we have not yet received approval from the FDA or other regulatory agency to market a companion diagnostic. Because our approach is both innovative and in the early stages of development, the cost and time needed to develop our therapeutic candidates is difficult to predict, and our efforts may not result in the successful discovery and development of commercially viable medicines. We may also be incorrect about the effects of our therapeutic candidates on the diseases of our defined patient populations, which may limit the utility of our approach or the perception of the utility of our approach. Furthermore, our estimates of our defined patient populations available for study and treatment may be lower than expected, which could adversely affect our ability to conduct clinical trials and may also adversely affect the size of any market for medicines we may successfully commercialize. Our approach may not result in time savings, higher success rates or reduced costs as we expect it to, and if not, we may not attract collaborators or develop new drugs as quickly or cost effectively as expected and therefore we may not be able to commercialize our approach as originally expected.

Our proprietary DRP® companion diagnostics platform may fail to help us select and treat likely responder patients for our therapeutic candidates or help us identify additional potential therapeutic candidates.

Any drug development that we are conducting using our proprietary DRP® companion diagnostics platform may not be successful or have commercial value or therapeutic utility. Our proprietary DRP® companion diagnostics platform may initially show promise in identifying potential therapeutic candidates, yet fail to yield viable therapeutic candidates for clinical development or commercialization for a number of reasons, including:

- research programs to identify new therapeutic candidates will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify new therapeutic candidates. If we are unable to identify suitable additional compounds for preclinical and clinical development, our ability to develop therapeutic candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price;

- compounds identified through our proprietary DRP® companion diagnostics platform may not demonstrate efficacy, safety or tolerability at levels acceptable to regulatory authorities;

- our DRP® companion diagnostics platform may fail to successfully identify likely responder patients and therefore not yield greater therapeutic benefit than observed in un-selected patients.

- potential therapeutic candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance;

- competitors may develop alternative therapies that render our potential therapeutic candidates non-competitive or less attractive; or

- a potential therapeutic candidate may not be capable of being produced at an acceptable cost.

Any failure by us to comply with existing regulations could harm our reputation and operating results.

We will be subject to extensive regulation by U.S. federal and state and foreign governments in each of the markets where we intend to sell our therapeutic candidates if and after they are approved. For example, we will have to adhere to all regulatory requirements including the FDA's current GCPs, Good Laboratory Practice, or GLP, and GMP requirements. If we fail to comply with applicable regulations, including FDA pre-or post- approval cGMP requirements, then the FDA or other foreign regulatory authorities could sanction us. Even if a drug is FDA-approved, regulatory authorities may impose significant restrictions on a drug's indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing studies.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation. We will need to expend significant resources on compliance efforts and such expenses are unpredictable and might adversely affect our results.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our therapeutic candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

In addition, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

We may be subject to extensive regulations outside the United States and may not obtain marketing approvals for drugs in Europe and other jurisdictions.

In addition to regulations in the United States, should we or our collaborators pursue marketing approvals for our therapeutic candidates internationally, we and our collaborators will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our drugs. Whether or not we, or our collaborators, obtain applicable FDA regulatory clearance and marketing approval for a drug, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the drug in those countries. The requirements and process governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country.

We expect to pursue marketing approvals for IXEMPRA® and our other therapeutic candidates in Europe and other jurisdictions outside the United States with collaborative partners. The time and process required to obtain regulatory approvals and reimbursement in Europe and other jurisdictions may be different from those in the United States regulatory and approval in one jurisdiction does not ensure approvals in any other jurisdiction; however, negative regulatory decisions in any jurisdiction may have a negative impact on the regulatory process in other jurisdictions.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, health information privacy and security laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Although we do not currently have any therapeutic products on the market, our current and future operations may be, directly or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers, physicians and other parties through which we may market, sell and distribute our therapeutic products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal false claims, including the False Claims Act, which can be enforced through whistleblower actions, and civil monetary penalties laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, commonly referred to as the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the Final HIPAA Omnibus Rule, i.e. health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

- the U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the PPACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Our inability to obtain or retain sufficient clinical trial liability insurance at an acceptable cost to protect against potential liability claims could prevent or inhibit our ability to conduct clinical trials for therapeutic candidates we develop.

Although we currently have clinical trial liability insurance, in the future we may need to secure additional coverage before commencing patient enrollment for our clinical trials in the United States or other jurisdictions. Any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our existing insurance or that is more than the limits of our insurance coverage. We expect we will supplement our clinical trial coverage with product liability coverage in connection with the commercial launch of other therapeutic candidates we develop in the future; however, we may be unable to obtain such increased coverage on acceptable terms or at all. If we are found liable in a clinical trial lawsuit or a product liability lawsuit in the future, we will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Risks Related to the Approval and Commercialization of Our Therapeutic Candidates

Even if we are successful in completing all preclinical studies and clinical trials, we may not be successful in commercializing one or more of our therapeutic candidates.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our therapeutic candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our therapeutic candidates, and our ability to generate revenue will be materially impaired.

Our therapeutic candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, export and import are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the European Medicines Agency (the "EMA") and similar regulatory authorities outside of the United States. Failure to obtain marketing approval for a therapeutic candidate will prevent us from commercializing the therapeutic candidate. We have not submitted an application for or received marketing approval for any of our therapeutic candidates in the United States or in any other jurisdiction.

We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party clinical research organizations or other third-party consultants or vendors to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the therapeutic candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our therapeutic candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If any of our therapeutic candidates receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the drug.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the therapeutic candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted drug application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical studies and clinical trials could delay, limit or prevent marketing approval of a therapeutic candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved drug not commercially viable.

If our drugs do not gain market acceptance, our business will suffer because we might not be able to fund future operations.

A number of factors may affect the market acceptance of our drugs or any other products we develop or acquire, including, among others:

- the price of our drugs relative to other products for the same or similar treatments;
- the perception by patients, physicians and other members of the health care community of the effectiveness and safety of our drugs for their indicated applications and treatments, or the value of our DRP® companion diagnostics in improving patient benefit;
- our ability to fund our sales and marketing efforts; and
- the effectiveness of our sales and marketing efforts.

If our drugs do not gain market acceptance, we may not be able to fund future operations, including developing, testing and obtaining regulatory approval for new therapeutic candidates and expanding our sales and marketing efforts for our approved drugs, which would cause our business to suffer.

We may in the future develop therapeutic candidates in combination with other therapies and that may expose us to additional risks.

We may develop future therapeutic candidates for use in combination with one or more currently approved cancer therapies. Even if any therapeutic candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our therapeutic candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our therapeutic candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our therapeutic candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or similar foreign regulatory authorities. We will not be able to market and sell our therapeutic candidates we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or similar foreign regulatory authorities do not approve or revoke the approval of these other drugs, or if safety, efficacy, manufacturing or supply issues arise with the drugs we choose to evaluate in combination with our therapeutic candidates, we may be unable to obtain approval of or market our therapeutic candidates.

We may rely on orphan drug status to commercialize some of our therapeutic candidates, and even if orphan drug status is approved, such approval may not confer marketing exclusivity or other commercial advantages or expected commercial benefits.

We may rely on orphan drug exclusivity for our therapeutic candidates. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a drug that has orphan drug designation subsequently receives the first FDA marketing approval for the disease for which it has such designation, the drug is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, and except in limited circumstances the applicable exclusivity period is ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we, or any future collaborators, obtain orphan drug designation for a therapeutic candidate, we, or they, may not be able to obtain or maintain orphan drug exclusivity for that therapeutic candidate. We may not be the first to obtain marketing approval of any therapeutic candidate for which we have obtained orphan drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products, and it is possible that another company also holding orphan drug designation for the same therapeutic candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure enough of the drug to meet the needs of patients with the rare disease or condition. Further, even if we, or any future collaborators, obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the drug from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the drug with orphan exclusivity is unable to maintain sufficient drug quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process, nor does it prevent competitors from obtaining approval of the same therapeutic candidate as ours for indications other than those in which we have been granted orphan drug designation.

On August 3, 2017, the U.S. Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's preexisting regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

A Breakthrough Therapy designation by the FDA for our therapeutic candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our therapeutic candidates will receive marketing approval.

We may seek a breakthrough therapy designation for some of our therapeutic candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our therapeutic candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive Breakthrough Therapy designation, the receipt of such designation for a therapeutic candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our therapeutic candidates qualify as breakthrough therapies, the FDA may later decide that the drugs no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

A Fast Track designation by the FDA may not lead to a faster development or regulatory review or approval process.

We may seek Fast Track designation for some of our therapeutic candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular therapeutic candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

Failure to obtain marketing approval in foreign jurisdictions would prevent our therapeutic candidates from being marketed abroad.

To market and sell our drugs in the European Union and many other foreign jurisdictions, we or our potential third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA marketing approval. The regulatory approval process outside of the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside of the United States, it is required that the drug be approved for reimbursement before the drug can be approved for sale in that country. We or our potential third-party collaborators may not obtain approvals from regulatory authorities outside of the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our drugs in any market.

If we are required by the FDA to obtain approval of a DRP® companion diagnostic in connection with approval of a therapeutic candidate, and we do not obtain or face delays in obtaining FDA approval of a DRP® diagnostic device, we will not be able to commercialize the therapeutic candidate and our ability to generate revenue will be materially impaired.

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic drug or indication, the FDA generally will not approve the therapeutic drug or new therapeutic drug indication if the companion diagnostic is not also approved or cleared for that indication. Under the Federal Food, Drug, and Cosmetic Act, or FDCA, companion diagnostics are regulated as medical devices, and the FDA has generally required companion diagnostics intended to select the patients who will respond to cancer treatment to obtain Premarket Approval, or a PMA, for the diagnostic. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. A PMA is not guaranteed and may take considerable time, and the FDA may ultimately respond to a PMA submission with a "not approvable" determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. As a result, if we are required by the FDA to obtain approval of a companion diagnostic for a therapeutic candidate, and we do not obtain or there are delays in obtaining FDA approval of a diagnostic device, we may not be able to commercialize the therapeutic candidate on a timely basis or at all and our ability to generate revenue will be materially impaired.

Our business strategy involving drug development includes the development of a companion diagnostic using our proprietary DRP® companion diagnostics platform for each of our therapeutic candidates. On April 2, 2021, we filed a PMA with the FDA for a companion diagnostic for dovitinib, which is currently under review by the FDA, and we intend to file a PMA for each of our therapeutic candidates if, and when, we decide to pursue the submission of an NDA for each therapeutic candidate.

Any therapeutic candidate for which we obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market and we may be subject to substantial penalties if we fail to comply with regulatory requirements, improperly promoted off-market label uses of our drugs or therapeutic candidates or if we experience unanticipated problems with our drugs, when and if any of them are approved.

Any therapeutic candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such drug, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a therapeutic candidate is granted, the approval may be subject to limitations on the indicated uses for which the drug may be marketed or to the conditions of approval, including the requirement to implement a REMS. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If any of our therapeutic candidates receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the drug.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the drug, including the adoption and implementation of REMS. The FDA and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the post-approval marketing and promotion of drugs to ensure they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our drugs for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our drugs, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have various consequences, including:

- restrictions on such drugs, manufacturers or manufacturing processes;
- restrictions and warnings on the labeling or marketing of a drug;
- restrictions on drug distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the drugs from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of drugs;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our drugs;
- drug seizure;
- injunctions or the imposition of civil or criminal penalties; or
- litigation involving patients using our drugs.

We operate in a highly competitive and rapidly changing industry.

Biotechnological and pharmaceutical drug development is highly competitive and subject to rapid and significant technological advancements. Our success is highly dependent upon our ability to in-license, acquire, develop, and obtain regulatory approval for new and innovative drugs on a cost-effective basis and to market them successfully, as well as maintaining the competitive advantages of our DRP® companion diagnostics platform. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies who already possess a large share of the market, specialty pharmaceutical and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in the United States, the European Union, and other jurisdictions.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved drugs than we do. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. 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 further increase because 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, drugs that are more effective or less costly than any therapeutic candidate that we may develop.

Established pharmaceutical and biotechnology companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our therapeutic candidates less competitive. Similarly, such companies may invest heavily to accelerate discovery and development of novel companion diagnostic approaches that make our DRP® companion diagnostics platform less competitive. In addition, any new drug that competes with an approved drug must demonstrate compelling advantages in efficacy, convenience, tolerability and safety to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations.

The availability of our competitors' drugs, or competitive companion diagnostics, could limit the demand and the price we are able to charge for any therapeutic candidate we commercialize, if any. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition and results of operations.

If we are unable to develop satisfactory sales and marketing capabilities, we may not succeed in commercializing our therapeutic candidate.

We have no experience in marketing and selling drug products. We have not yet entered into arrangements for the sale and marketing of stenoparib, or any other therapeutic candidate, although we are exploring several such arrangements. Typically, pharmaceutical companies would employ groups of sales representatives and associated sales and marketing staff numbering in the hundreds to thousands of individuals to call on this large number of physicians and hospitals. We may seek to collaborate with a third-party to market our drugs or may seek to market and sell our drugs by ourselves. If we seek to collaborate with a third-party, we cannot be sure that a collaborative agreement can be reached on terms acceptable to us. If we seek to market and sell our drugs directly, we will need to hire additional personnel skilled in marketing and sales. We cannot be sure that we will be able to acquire, or establish third-party relationships to provide, any or all these marketing and sales capabilities. The establishment of a direct sales force or a contract sales force or a combination direct and contract sales force to market our drugs will be expensive and time-consuming and could delay any drug launch. Further, we can give no assurances that we may be able to maintain a direct and/or contract sales force for any period or that our sales efforts will be sufficient to generate or to grow our revenues or that our sales efforts will ever lead to profits.

Even if we obtain regulatory approvals to commercialize stenoparib, or our other future therapeutic candidates, our therapeutic candidates may not be accepted by physicians or the medical community in general.

There can be no assurance that stenoparib and other future therapeutic candidates or any other therapeutic candidate successfully developed by us, independently or with partners, will be accepted by physicians, hospitals and other health care facilities. Stenoparib and any future therapeutic candidates we develop will compete with several drugs manufactured and marketed by major pharmaceutical and biotech companies. The degree of market acceptance of any drugs we develop depends on several factors, including:

- our demonstration of the clinical efficacy and safety of stenoparib and other future therapeutic candidates;
- timing of market approval and commercial launch of stenoparib and other future therapeutic candidates;
- the clinical indication(s) for which stenoparib and other future therapeutic candidates are approved;
- drug label and package insert requirements;

- advantages and disadvantages of our therapeutic candidates compared to existing therapies, particularly in combination with our DRP® companion diagnostics;
- continued interest in and growth of the market for anticancer tyrosine kinase inhibitory, PARP inhibitory, and microtubule inhibitory drugs;
- strength of sales, marketing, and distribution support;
- drug pricing in absolute terms and relative to alternative treatments;
- future changes in health care laws, regulations, and medical policies; and
- availability of reimbursement codes and coverage in select jurisdictions, and future changes to reimbursement policies of government and third-party payors.

Significant uncertainty exists as to the coverage and reimbursement status of any therapeutic candidate for which we obtain regulatory approval. In the United States and markets in other countries, sales of any drugs for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations.

Healthcare reform measures could hinder or prevent our therapeutic candidates' commercial success.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare drugs and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our drugs which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the United States and some foreign jurisdictions, there have been several legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our drugs profitably.

Congress periodically adopts legislation like the PPACA and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, that modifies Medicare reimbursement and coverage policies pertaining to prescription drugs. Implementation of these laws is subject to ongoing revision through regulatory and sub regulatory policies. Congress also may consider additional changes to Medicare policies, potentially including Medicare prescription drug policies, as part of ongoing budget negotiations. While the scope of any such legislation is uncertain at this time, there can be no assurances that future legislation or regulations will not decrease the coverage and price that we may receive for our proposed drugs. Other third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking coverage and reimbursement from Medicare and private payors. Our proposed drugs may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our proposed drugs on a profitable basis. Further federal and state proposals and health care reforms are likely which could limit the prices that can be charged for the therapeutic candidates that we develop and may further limit our commercial opportunities. Our results of operations could be materially adversely affected by proposed healthcare reforms, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during drug development, clinical trials and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved drugs.

Governmental efforts to pursue regulatory reform may limit the FDA's ability to engage in oversight and implementation activities in the normal course, and that could negatively impact our business.

Prior presidential administrations have taken several executive actions, including the issuance of several executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. On January 30, 2017, President Trump issued an executive order, applicable to all executive agencies, including the FDA, requiring that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This executive order included a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the executive order required agencies to identify regulations to offset any incremental cost of a new regulation. While the current Biden administration has revoked this executive order, no assurances can be given that a future presidential administration will not issue a similar executive order. If a future presidential administration were to issue a similar executive order, it would be difficult to predict how those requirements would be implemented, and the extent to which they would impact the FDA's ability to exercise its regulatory authority. If future executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our therapeutic candidates and affect the prices we may charge for such therapeutic candidates.

The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our therapeutic candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

The PPACA includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers. There remain judicial, executive and congressional challenges to certain aspects of the PPACA. Since 2017, there have been executive orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. In addition, while Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the PPACA such as removing penalties, effective January 1, 2019, for not complying with the PPACA's individual mandate to carry health insurance. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. In 2018, a U.S. District Court ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was effectively repealed by Congress as part of the Tax Act. Additionally, in 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. The U.S. Supreme Court heard oral argument on the case on November 10, 2020, and issued its decision on June 17, 2021, holding that the state plaintiff's in the case challenging the constitutionality of minimum essential health care coverage provisions of the PPACA lacked standing to bring an action under Article III, Section 2 of the U.S. Constitution. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the PPACA. Although the U.S. Supreme Court had not yet ruled on the constitutionality of the PPACA, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the PPACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA.

Notwithstanding the Supreme Court recent ruling on standing to challenge the constitutionality of the PPACA, it is unclear how additional litigation and the healthcare reform measures of the Biden administration will impact the PPACA and our business. We continue to evaluate the effect that the PPACA and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2030 unless Congress takes additional action. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020, through December 31, 2021. Recently, there has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. congressional inquiries and legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, at the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020, the administration announced several executive orders to lower drug prices that attempt to implement several of the administration's proposals. Additionally, the FDA recently released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. It is possible that additional governmental action is taken in response to the COVID-19 pandemic, which may impact our business. We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved therapeutic product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our therapeutic candidates.

Governments outside of the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the countries of the European Union and Canada, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our therapeutic candidate to other available therapies. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

If we or any third-party manufacturers or contractors we engage now or in the future fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could harm our business.

We and third-party manufacturers we engage now are, and any third-party manufacturers we may engage in the future will be, subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations, including work conducted through third-party manufacturers or contractors, involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Liability under certain environmental laws governing the release and cleanup of hazardous materials is joint and several and could be imposed without regard to fault. We also could incur significant costs associated with civil or criminal fines and penalties or become subject to injunctions limiting or prohibiting our activities for failure to comply with such laws and regulations.

Although we maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development, or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our current and any future third-party contract manufacturers or other contractors, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our drugs, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our therapeutic candidates or drugs. In addition, our supply chain may be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions because of their non-compliance with environmental, health and safety laws and regulations.

We may experience challenges with the acquisition, development, enhancement or deployment of technology necessary for our proprietary DRP® companion diagnostics platform.

Our proprietary DRP® companion diagnostics platform and other aspects of our business strategy requires sophisticated computer systems and software for data collection, data processing, cloud-based platforms, analytics, statistical projections and forecasting, and other applications and technologies. We seek to address our technology risks by increasing reliance on the use of innovations by cross-industry technology leaders and adapt these innovations for their biopharmaceutical and diagnostic use in our proprietary DRP® companion diagnostics platform. Some of the technologies supporting these industries are changing rapidly and we must continue to adapt to these changes in a timely and effective manner at an acceptable cost. There can be no guarantee that we will be able to develop, acquire or integrate new technologies, that these new technologies will meet our needs or achieve our expected goals, or that we will be able to do so as quickly or cost-effectively as our competitors. Significant technological change could render our proprietary DRP® companion diagnostics platform obsolete. Our continued success will depend on our ability to adapt to changing technologies, manage and process ever-increasing amounts of data and information and improve the performance, features and reliability of our services in response to changing client and industry demands. We may experience difficulties that could delay or prevent the successful design, development, testing, and introduction of advanced versions of our proprietary DRP® companion diagnostics platform, limiting our ability to identify new therapeutic candidates. New services, or enhancements to existing services, using our proprietary DRP® companion diagnostics platform may not adequately meet our requirements. Any of these failures could have a material adverse effect on our operating results and financial condition.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully perform their contractual legal and regulatory duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our therapeutic candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party medical institutions, clinical investigators, contract laboratories and other third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all our drugs in clinical development.

Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practices, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our therapeutic candidates. As a result, our results of operations and the commercial prospects for our therapeutic candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical trial protocols or to GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We are substantially dependent on third parties for the manufacture of our clinical supplies of our therapeutic candidates and Clinical Laboratory Improvements Act ("CLIA") diagnostic laboratories to test patient biopsies in support of our clinical trials, and we intend to rely on third parties to produce commercial supplies of any approved therapeutic candidate. Therefore, our development of our drugs could be stopped or delayed, and our commercialization of any future drug could be stopped or delayed or made less profitable if third-party diagnostic laboratories lose their CLIA credentials or manufacturers fail to obtain approval of the FDA or comparable regulatory authorities or fail to provide us timely test results or with drug products in sufficient quantities or at acceptable prices.

The manufacture of pharmaceutical products is complex and requires significant expertise, capital investment, process controls and know-how. Common difficulties in pharmaceutical manufacturing may include: sourcing and producing raw materials, transferring technology from chemistry and development activities to production activities, validating initial production designs, scaling manufacturing techniques, improving costs and yields, establishing and maintaining quality controls and stability requirements, eliminating contaminations and operator errors, and maintaining compliance with regulatory requirements. We do not currently have nor do we plan to acquire the infrastructure or capability internally in accordance with cGMP prescribed by the FDA or to produce an adequate supply of compounds to meet future requirements for clinical trials and commercialization of our drugs. Drug manufacturing facilities are subject to inspection before the FDA will issue an approval to market a new drug product, and all the manufacturers that we intend to use must adhere to the cGMP regulations prescribed by the FDA.

We expect therefore to rely on third-party manufacturers for clinical supplies of our therapeutic candidates that we may develop. These third-party manufacturers will be required to comply with current good manufacturing practices, or cGMPs, and other applicable laws and regulations. We will have no control over the ability of these third parties to comply with these requirements, or to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities do not approve the facilities of these third parties for the manufacture of our other therapeutic candidates or any drugs that we may successfully develop, or if it withdraws any such approval, or if our suppliers or contract manufacturers decide they no longer want to supply or manufacture for us, we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all. Any of these factors would significantly impact our ability to develop, obtain regulatory approval for or market our therapeutic candidates and adversely affect our business.

We and/or our third-party manufacturers may be adversely affected by developments outside of our control, and these developments may delay or prevent further manufacturing of our drugs. Adverse developments may include labor disputes, resource constraints, shipment delays, inventory shortages, lot failures, unexpected sources of contamination, lawsuits related to our manufacturing techniques, equipment used during manufacturing, or composition of matter, unstable political environments, pandemics, acts of terrorism, war, natural disasters, and other natural and man-made disasters. If we or our third-party manufacturers were to encounter any of the above difficulties, or otherwise fail to comply with contractual obligations, our ability to provide any drug for clinical trial or commercial purposes would be jeopardized. This may increase the costs associated with completing our clinical trials and commercial production. Further, production disruptions may cause us to terminate ongoing clinical trials and/or commence new clinical trials at additional expense. We may also have to take inventory write-offs and incur other charges and expenses for drugs that fail to meet specifications or pass safety inspections. If production difficulties cannot be solved with acceptable costs, expenses, and timeframes, we may be forced to abandon our clinical development and commercialization plans, which could have a material adverse effect on our business, prospects, financial condition, and the value of our securities.

We also rely on third-party diagnostic laboratories certified under CLIA for testing of patient biopsies in our clinical trials. Under the CLIA, diagnostic laboratories are subject to inspection and certification by the CMS and if a diagnostic laboratory we use to test patient biopsies fail their CMS inspection or lose their CMS certification for the type of tests we need, our clinical trials could be delayed or the results from our clinical trials may not be acceptable to the FDA or an equivalent foreign regulatory authority.

We, or third-party manufacturers on whom we rely, may be unable to successfully scale-up manufacturing of our therapeutic candidates in sufficient quality and quantity, which would delay or prevent us from developing our therapeutic candidates and commercializing approved drugs, if any.

In order to conduct clinical trials of our therapeutic candidates and commercialize any approved therapeutic candidates, we, or our manufacturers, will need to manufacture them in large quantities. We, or our manufacturers, may be unable to successfully increase the manufacturing capacity for any of our therapeutic candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or any of our manufacturers, are unable to successfully scale up the manufacture of our therapeutic candidates in sufficient quality and quantity, the development, testing, and clinical trials of that therapeutic candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting drug may be delayed or not obtained, which could significantly harm our business. If we are unable to obtain or maintain third-party manufacturing for commercial supply of our therapeutic candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our therapeutic candidates successfully.

Our failure to find third-party collaborators to assist or share in the costs of drug development could materially harm our business, financial condition and results of operations.

Our strategy for the development and commercialization of our proprietary therapeutic candidates may include the formation of collaborative arrangements with third parties. Existing and future collaborators have significant discretion in determining the efforts and resources they apply and may not perform their obligations as expected. Potential third-party collaborators include biopharmaceutical, pharmaceutical and biotechnology companies, academic institutions and other entities. Third-party collaborators may assist us in:

- funding research, preclinical development, clinical trials and manufacturing;
- seeking and obtaining regulatory approvals; and
- successfully commercializing any future therapeutic candidates.

If we are not able to establish further collaboration agreements, we may be required to undertake drug development and commercialization at our own expense. Such an undertaking may limit the number of therapeutic candidates that we will be able to develop, significantly increase our capital requirements and place additional strain on our internal resources. Our failure to enter into additional collaborations could materially harm our business, financial condition and results of operations.

In addition, our dependence on licensing, collaboration, and other agreements with third parties may subject us to a number of risks. These agreements may not be on terms that prove favorable to us and may require us to relinquish certain rights in our therapeutic candidates. To the extent we agree to work exclusively with one collaborator in each area, our opportunities to collaborate with other entities could be curtailed. Lengthy negotiations with potential new collaborators may lead to delays in the research, development or commercialization of therapeutic candidates. The decision by our collaborators to pursue alternative technologies or the failure of our collaborators to develop or successfully commercialize any therapeutic candidate to which they have obtained rights from us could materially harm our business, financial condition and results of operations.

Risks Related to Our Business and Industry

We have insufficient cash to continue our operations past December 2023, our continued operations are dependent on us raising capital and these conditions give rise to substantial doubt over the Company's ability to continue as a going concern

The Company has incurred significant losses and has an accumulated deficit of $94.5 million as of December 31, 2023. As of December 31, 2023, our cash deposits of $166 thousand is insufficient to fund our current operating plan and planned capital expenditures past December 2023. Further, we believe that our existing cash and cash equivalents as of March 7, 2024, and our anticipated expenditures and commitments for the next twelve months, will not enable us to fund our operating expenses and capital expenditure requirements for the twelve months from the date of this prospectus. These conditions give rise to substantial doubt over the Company's ability to continue as a going concern. We will need to raise additional capital after this offering to support our operations and execute our business plan. We will be required to pursue sources of additional capital through various means, including debt or equity financings. Newly issued securities may include preferences, superior voting rights, and the issuance of warrants or other convertible securities that will have additional dilutive effects. We cannot assure that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us and may cause existing shareholders both book value and ownership dilution. Further, we may incur substantial costs in pursuing future capital and/or financing, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as convertible notes and warrants, which will adversely impact our financial condition and results of operations. Our ability to obtain needed financing may be impaired by such factors as the weakness of capital markets, and the fact that we have not been profitable, which could impact the availability and cost of future financings. If the amount of capital we are able to raise from financing activities is not sufficient to satisfy our capital needs, we may have to reduce our operations accordingly.

We are delinquent in our payment to Eisai

In consideration for extension of certain deadlines and payment obligations, the Company entered in several amendments to an Exclusive License Agreement with Eisai. On May 26, 2023, the Company and Eisai entered into a fourth amendment to the Exclusive License Agreement with an effective date of May 16, 2023, under which the Company agreed to pay Eisai in periodic payments as follows: (i) $100,000; (ii) $50,000 within 10 days of execution of the fourth amendment; (iii) $100,000 upon completion of a capital raise (of which items (i) and (iii) have been paid): and (iv) $850,000 on or before March 1, 2024. Under the Exclusive License Agreement, the Company will have until April 1, 2024, to complete enrollment in a further Phase 1b or Phase 2 Clinical Trial of the Product. If the Company has not achieved successful completion of a further Phase 1b or Phase 2 Clinical Trial of the Product prior to April 1, 2024, Eisai may terminate the Agreement in its entirety, in its sole discretion on at least 120 days prior written notice. In light of our financial condition and dependence on financing for our operations, we may be unable to meet the payment requirements under the fourth amendment and we may lose our right to use stenoparib, which will adversely affect our ability to conduct our clinical trials and to achieve our business objectives and adversely affect our financial results.

A dispute with our former Chief Executive Officer could be costly and adversely affect our business.

On December 8, 2023, Mr. Cullem was terminated as our Chief Executive Officer for cause under his employment agreement. Mr. Cullem has indicated that his termination should be without cause. Any dispute with Mr. Cullem could be costly and become a distraction to our management and employees and adversely affect our business.

Unstable global market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have from time-to-time experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

If we fail to satisfy The Nasdaq Capital Market continued listing requirements and do not regain compliance, our Common Stock will be delisted.

If we fail to meet any other Nasdaq listing requirements and do not regain compliance, we may be subject to delisting by Nasdaq. In the event our Common Stock is no longer listed for trading on Nasdaq, our trading volume and share price may decrease and you may have a difficult time selling your shares of Common Stock. In addition, we may experience difficulties in raising capital which could materially adversely affect our operations and financial results. Further, delisting from Nasdaq markets could also have other negative effects, including potential loss of confidence by partners, lenders, suppliers, and employees. Finally, delisting could make it harder for you and the Company to sell the securities and hard for us to raise capital.

We will need to increase the size of our organization and the scope of our outside vendor relationships, and we may experience difficulties in managing growth.

As of March 1, 2024, we employed a total of 5 full-time employees and 1 part-time employee. Our current internal departments include research and development, finance, and administration. We intend to expand our management team to include an operation ramp up of additional scientific development and technical staff required to achieve our business objectives. We will need to expand our managerial, operational, technical, and scientific, financial, and other resources in order to manage our operations and clinical trials, establish independent manufacturing, continue our research and development activities, and commercialize our therapeutic candidates. Our management and scientific personnel, systems, and facilities currently in place may not be adequate to support our future growth.

Our need to effectively manage our operations, growth and various projects requires that we:

- manage our ongoing and future clinical trials effectively;
- manage our internal development efforts effectively while carrying out our contractual obligations to licensors, contractors and other third parties;
- continue to improve our operational, financial and management controls and reporting systems and procedures; and
- attract and retain sufficient numbers of talented employees.

We may utilize the services of vendors and research partners or collaborators to perform tasks including preclinical studies and clinical trial management, statistics and analysis, regulatory affairs, medical advisory, market research, formulation development, chemistry, manufacturing and control activities, other drug development functions, legal, auditing, financial advisory, and investor relations. Our growth strategy may also entail expanding our group of contractors or consultants to implement these and other tasks going forward. Because we rely on numerous consultants to outsource many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our therapeutic candidate or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may be unable to successfully implement the tasks necessary to further develop and commercialize our therapeutic candidate and, accordingly, may not achieve our research, development and commercialization goals.

We depend on our senior management team, and the loss of one or more of our executive officers or key employees or an inability to attract and retain highly skilled employees could adversely affect our business.

Our business depends largely upon the continued services of our founder and Chief Scientific Officer, Dr. Steen Knudsen, Ph.D., and Thomas Jensen, our Interim Chief Executive Officer. We do not maintain "key person" insurance for Messrs. Knudsen and Jensen or any of our other key employees. We also rely on employees in the areas of research and development, regulatory compliance and approvals, and general and administrative functions. From time to time, there may be additional changes in our executive management and employees resulting from the hiring or departure of executives or other key employees which could disrupt our business. The replacement of one or more of our executive officers or other key employees would likely involve significant time and costs and may significantly delay or prevent the achievement of our business objectives.

To continue to execute our growth strategy, we also must attract and retain highly skilled personnel. We might not be successful in maintaining our unique culture and continuing to attract and retain qualified personnel. We have from time to time in the past experienced, and we expect to continue to experience in the future, difficulty in hiring and retaining highly skilled personnel with appropriate qualifications. The pool of qualified personnel with experience in bioinformatics, genomics, or experience working with the biopharma market is limited overall. In addition, many of the companies with which we compete for experienced personnel have greater resources than we have.

In addition, in making employment decisions, particularly in the biotechnology and pharmaceutical industries, job candidates often consider the value of the stock options or other equity instruments they are to receive in connection with their employment. Volatility in the price of our stock might, therefore, adversely affect our ability to attract or retain highly skilled personnel. Furthermore, the requirement to expense stock options and other equity instruments might discourage us from granting the size or type of stock option or equity awards that job candidates require to join our company. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects could be severely harmed.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that violates (1) the laws and regulations of the FDA, the EMA, and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the U.S. and abroad and (4) laws that require the true, complete and accurate reporting of financial information or data. Sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including information obtained during clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of therapeutic candidates, which could result in regulatory sanctions and serious harm to our reputation.

Although we adopted a code of business conduct and ethics, it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to follow such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm and the delay, reduction, termination or restructuring of our operations.

International operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the U.S.

Our business will be subject to risks associated with conducting business internationally. Some of our suppliers, industry partners and clinical study centers are located outside of the U.S. Furthermore, our business strategy incorporates potential international expansion as we seek to obtain regulatory approval for, and commercialize, our therapeutic candidates in patient populations outside the U.S. If approved, we may hire sales representatives and conduct physician and patient association outreach activities outside of the U.S. Doing business internationally involves several risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- delays or interruptions of clinical trial due to backup at ethical committees and staff shortages causing delays in processing the trials at investigator sites resulting in delayed and slow patient enrollment. ;
- additional potentially relevant third-party patent and other intellectual property rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our therapeutic candidates and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our future international expansion and operations and, consequently, our results of operations.

Our failure to successfully acquire, develop and market additional therapeutic candidates could impair our ability to grow.

As part of our growth strategy, we may evaluate, acquire, license, develop and/or market additional therapeutic candidates and technologies. We anticipate these investments will constitute a material portion of our business. However, our internal research capabilities are limited, and we may be dependent upon pharmaceutical and biopharmaceutical companies, academic scientists and other researchers to sell or license therapeutic candidates or technologies to us. The success of this strategy depends partly upon our ability to identify, select, and acquire promising pharmaceutical therapeutic candidates for further development together with our proprietary DRP® companion diagnostics platform. The process of proposing, negotiating, and implementing a license or acquisition of a therapeutic candidate is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of therapeutic candidates and technologies. We have limited resources to identify and execute the acquisition or in-licensing of potential therapeutic candidates and technologies and to integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. Furthermore, we may not be able to acquire the rights to additional therapeutic candidates on terms that we find acceptable, or at all.

In addition, future acquisitions of intellectual property rights may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's and technical personnel's time and attention to develop acquired therapeutic candidates or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisition costs;
- higher than expected acquisition costs; and
- increased amortization expenses.

Any therapeutic candidate that we acquire may require additional development efforts prior to commercial sale or out-licensing, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All therapeutic candidates are prone to risks of failure typical of pharmaceutical drug development, including the possibility that a therapeutic candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any drugs that we may develop or approved drugs that we may acquire will be manufactured profitably or achieve market acceptance.

We have obtained statistical data, market data and other industry data and forecasts used throughout this report from market research, publicly available information and industry publications which we believe are reliable.

This report contains estimates, projections and other information concerning our industry, our business and the markets for our therapeutic candidates, including data regarding the estimated size of such markets and the incidence of certain medical conditions. We obtained the industry, market and similar data set forth in this report from our internal estimates and research and from academic and industry research, publications, surveys and studies conducted by third parties, including governmental agencies. In some cases, we do not expressly refer to the sources from which this data is derived. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information.

Risks Related to Our Intellectual Property

If we do not obtain patent term extension for any therapeutic candidates we may develop or obtain a patent on our DRP® companion diagnostic for a therapeutic candidate, our business may be materially harmed.

In the United States, depending upon the timing, duration, and specifics of any FDA marketing approval of a therapeutic candidate, the patent term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the lost opportunity to market the drug during the patent term while the drug was under the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the typical statutory expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of regulatory approval, and only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, when our therapeutic candidates receive FDA approval, we expect to apply for patent term extensions on patents directed to those therapeutic candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of the relevant patents, or otherwise failing to satisfy applicable requirements. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, or if we are not able to obtain a patent on our DRP® companion diagnostic for our therapeutic candidate, our competitors may obtain approval of competing drugs following the expiration of our patent rights, or use a similar companion diagnostic, and our business, financial condition, results of operations, and prospects could be materially harmed.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our drugs.

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes several significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, inter parties review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent.

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

We or our licensors may become involved in lawsuits to protect or enforce our patent or other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate, or otherwise violate our or our licensors' issued patents or other intellectual property. As a result, we or our licensors may need to file infringement, misappropriation or other intellectual property related claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us alleging that we infringe, misappropriate, or otherwise violate their intellectual property. In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we or our licensors have asserted are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter parties review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings).

An adverse result in any such proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly and could put any of our owned or in-licensed patent applications at risk of not yielding an issued patent. A court may also refuse to stop the third-party from using the technology at issue in a proceeding on the grounds that our owned or in-licensed patents do not cover such technology. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during this type of litigation. Any of the foregoing could allow such third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations, and prospects.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our therapeutic candidates and use our proprietary. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to pursuing these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as our therapeutic candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. We may not be aware of all such intellectual property rights potentially relating to our technology and therapeutic candidates and their uses. Thus, we do not know with certainty that our technology and therapeutic candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate, or otherwise violate any third-party's intellectual property.

Even if we believe that third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of misappropriation, infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any technology or therapeutic candidate covered by the asserted third-party patents. To successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

If we are found to infringe, misappropriate or otherwise violate a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing, manufacturing, and marketing our technology and therapeutic candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive; thereby giving our competitors and other third parties access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or drug. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right and could be forced to indemnify our collaborators or others. A finding of infringement could prevent us from commercializing our therapeutic candidates or force us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our therapeutic candidates, seek new regulatory approvals, and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the USPTO and foreign patent agencies in several stages or annually over the lifetime of our owned and in-licensed patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. With respect to our patents, we rely on an annuity service to remind us of the due dates and to make payment after we instruct them to do so. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical products or technology. If we or our licensors fail to maintain the patents and patent applications directed to our therapeutic candidates, it would have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

We are party to license and funding agreements that impose, and we may enter into additional licensing and funding arrangements with third parties that may impose, diligence, development and commercialization timelines, milestone payment, royalty, insurance, and other obligations on us. Under our existing licensing and funding agreements, we are obligated to pay certain specified milestone payments and royalties on net drug sales of therapeutic candidates or related technologies to the extent they are covered by the agreements. If we fail to comply with such obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements or require us to grant them certain rights. Such an occurrence could materially adversely affect the value of any therapeutic candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

Additionally, these and other license agreements may not provide exclusive rights to use the licensed intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and drugs in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products and technology in fields of use and territories not included in such agreements. In addition, we may not have the right to control or participate in the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications directed to the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drugs that are the subject of such licensed rights could be adversely affected.

We may need to obtain additional licenses from others to advance our research or allow commercialization of our therapeutic candidates. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all, or such licenses may be non-exclusive. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all.

If we are unable to obtain rights to necessary third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, therapeutic candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and therapeutic candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and

- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and therapeutic candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents and patent applications we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Despite our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize therapeutic candidates and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors will have the freedom to seek regulatory approval of, and to market, products and technologies identical to ours upon successful negotiation with the relevant licensor. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, and enforcing patents on therapeutic candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license exclusively.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

We may be subject to claims by third parties asserting that our employees, consultants, contractors or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting we have misappropriated their trade secret or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants, contractors and advisors were previously employed, or may currently be employed, at universities or other pharmaceutical or biotechnology companies, including our competitors or potential competitors. Although we try to ensure that our employees, contractors, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees, consultants, contractors and advisors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our intellectual property assignment agreements with them may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third-party, and we could be required to obtain a license from such third-party to commercialize our technology or products, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees.

In addition to seeking patents for some of our technology and therapeutic candidates, we also rely on trade secrets and confidentiality agreements relating to the development of our proprietary DRP® companion diagnostics platform to protect our unpatented know-how, technology, and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. Although we may not have done so in the past, we intend to enter into confidentiality and invention or patent assignment agreements with our employees and consultants in the future. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be materially and adversely harmed.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- depending on applicable law, we, or our license partners or current or future collaborators, might not have been the first to invent or file patent applications for or may have derived from a later-filed patent application the inventions covered by the issued patent or pending patent applications that we license or may own in the future;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that some or all of our owned and in-licensed pending patent applications or those we may own or in-license in the future will not result in issued patents or the claims that issue may be narrow in scope and not provide us with a competitive advantage, including as a result of actions by our competitors;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies or investigational products that are patentable or protectable as a trade secret;
- the patents of others may harm our business, including by preventing us from discovering, developing or commercializing our investigational products; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property or may independently develop such trade secret and be free to exploit it.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Owning our Securities

We currently do not satisfy The Nasdaq Global Market continued listing requirements and if we fail to regain compliance our Common Stock will be delisted.

The listing of our common stock on The Nasdaq Global Market is contingent on our compliance with The Nasdaq Global Market's conditions for continued listing. On April 20, 2022, we received notice from the Nasdaq Listing Qualifications stating that because we had not yet filed our Annual Report on Form 10-K for the year ended December 31, 2021 (the "Form 10-K") by its due date, we were no longer in compliance with the listing requirement which requires listed companies to timely file all required periodic financial reports with the SEC. On May 17, 2022, we filed our Form 10-K with the SEC. Subsequent to the filing of the Form 10-K, we were late in filing our Form 10-Q for the quarterly periods ended March 31 and June 30, 2022.

On August 23, 2022 we received a letter from Nasdaq Regulation advising that we were not in compliance with the Nasdaq Listing Rules (the "Rules") for failing to file our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022. We were given 60 days to submit a plan to regain compliance and, if our plan is accepted by Nasdaq, we may be granted an exception of up to 180 calendar days, or until February 20, 2023, to regain compliance. On October 7, 2022, we filed the delinquent Form 10-Q and regained compliance.

On October 12, 2022, we received a letter from Nasdaq Listing Qualifications notifying us that the Company's stockholders' equity as reported in its Quarterly Report on Form 10-Q for the period ended June 30, 2022 (the "Form 10-Q"), did not satisfy the continued listing requirement under Nasdaq Listing Rule 5450(b)(1)(A) for The Nasdaq Global Market, which requires that a listed company's stockholders' equity be at least $10.0 million. As reported on the Form 10-Q, the Company's stockholders' equity as of June 30, 2022, was approximately $8.0 million. Pursuant to the letter, we were required to submit a plan to regain compliance with Nasdaq Listing Rule 5450(b)(1)(A) by November 26, 2022. After discussions with the Nasdaq staff, on December 12, 2022, we filed a plan to regain and demonstrate long-term Nasdaq compliance including seeking to phase-down to The Nasdaq Capital Market. On December 21, 2022, the Company received notification from the Nasdaq staff that they have granted the Company an extension of time until April 10, 2023, to regain and evidence compliance with the Rule. If the Nasdaq staff determines to seek the delisting our common stock on the Nasdaq, we intend to appeal such determination before the Nasdaq Hearing Panel.

On November 21, 2022, the Company received another written notice from Nasdaq indicating that the Company is not in compliance with the minimum bid price requirement of $1.00 per share under the Nasdaq Listing Rules. Based on the closing bid price of the Company's listed securities for the last 30 consecutive business days from October 10, 2022 to November 18, 2022, the Company no longer met the minimum bid price requirement set forth in Listing Rule 5550(a)(2). Although the Company is currently evaluating various alternative courses of action to regain compliance, there is no guarantee or assurance that the Company will be able to regain compliance and meet the listing standards. In the event the Company does not regain compliance by the prescribed deadline, the Company may be eligible for additional time to regain compliance or may face delisting. If the Company is unable to regain compliance, the Company may transfer to the Nasdaq Capital Market, subject to the Company's satisfaction of the Nasdaq Capital Market's continued listing requirements, but there is no assurance that we will be able to satisfy the listing requirements for the Nasdaq Capital Market.

On December 20, 2022, the Company received a notification letter from Nasdaq Regulation of non-compliance with the Rules requiring listed securities to maintain a minimum market value of publicly held shares of $5,000,000 and if the Company does not regain compliance with the Rule prior to the expiration of the compliance period on June 19, 2023, it will receive written notification that its securities are subject to delisting.

On February 8, 2023, the Company received a notification letter from Nasdaq notifying the Company that due to the resignation of Soren G. Jensen from the Company's board and audit committee, effective on February 4, 2023, the Company no longer complies with Nasdaq's independent director and audit committee requirements as set forth in Nasdaq Listing Rules 5605(b)(1)(A) and 5605(c)(4) which requires a majority of the board of directors to be comprised of independent directors and an audit committee of at least three independent directors. In accordance with Nasdaq Listing Rules, the Company has a cure period to regain compliance as follows: (i) until the earlier of the Company's next annual shareholders' meeting or February 4, 2024; or (ii) if the next annual shareholders' meeting is held before August 3, 2023, then the Company must evidence compliance no later than August 3, 2023.

On June 6, 2023, we received a letter from the Nasdaq hearings panel that granted the Company's request for continued listing on the Nasdaq Stock Market LLC until July 1, 2023, and the Company's transfer to The Nasdaq Capital Market, subject to the following conditions: (1) on or before July 1, 2023, the Company demonstrates compliance with Nasdaq Listing Rule 5450(b)(1) dealing with primary equity securities listed on the Global Market, and on or before July 1, 2023, the Company demonstrates compliance with Nasdaq Listing Rule 5450(a)(1) dealing with a minimum bid of $1.00 per share. On June 14, 2023, we received a clarification letter from Nasdaq granting the Company's request for continued listing on The Nasdaq Capital Market and transfer to The Nasdaq Capital Market, subject to the following: (1) on or before July 10, 2023, the Company demonstrates compliance with Listing Rule 5550(a)(2); and (2) on or before July 14, 2023, the Company demonstrates compliance with Listing Rule 5550(b).

On July 14, 2023, the Company received a letter from Nasdaq confirming that the Company has regained compliance with the bid price and equity concerns, as required by the Nasdaq hearings panel decision dated June 6, 2023, as amended. The Company is subject to a panel monitor for a period of one year from the July 14, 2023, letter pursuant to Nasdaq Listing Rule 5815(d)(4)(B), which includes continued compliance with the stockholders' equity requirement and other continued listing requirements. Failure to meet the stockholders' equity requirement of $2,500,000 would result in immediate delisting, subject to the Company's right to appeal. As of June 30, 2023, the Company had a stockholders' deficit of $723,000. Subsequent to June 30, 2023, on July 10, 2023, the Company completed a public offering of common stock or pre-funded warrants and warrants to purchase common stock raising gross proceeds of approximately $11 million. After giving effect to the July 10, 2023, public offering, the Company's stockholders' equity as of June 30, 2023, on a pro forma basis, was $4.355 million. As of September 30, 2023, the Company had a stockholders' deficit and will need to raise capital in order to meet Nasdaq's stockholders' equity requirement.

On October 27, 2023, we received notification from Nasdaq that it has determined that the bid price of our Common Stock had closed at less than $1 per share over the previous 30 consecutive business days, and, as a result, did not comply with Listing Rule 5550(a)(2). Further, Nasdaq also noted that we effected a 1:35 reverse stock split on March 24, 2023, and a 1:40 reverse stock split on June 28, 2023. Because we effected one or more reverse stock splits over the prior two-year period with a cumulative ratio of 250 shares or more to one, we will not be afforded a 180-calendar day period to demonstrate compliance with the Listing Rule 5550(a)(2) pursuant to Listing Rule 5810(c)(3)(A)(iv).

In that regard, unless we requested an appeal from such determination, trading of our Common Stock would have been suspended at the opening of business on November 7, 2023, and a Form 25-NSE would have been filed with the SEC which would have removed our Common Stock from listing and registration on The Nasdaq Stock Market. We filed a notice of appeal and received a hearing date of February 1, 2024. During such appeal, our Common Stock will continue to be listed on The Nasdaq Capital Market. On November 16, 2023, we received an additional notification indicating that the Company's stockholders' equity as reported in its Quarterly Report on Form 10-Q for the period ended September 30, 2023, did not satisfy the continued listing requirement under Nasdaq Listing Rule 5810(c)(3) which serves as an additional basis for delisting. The Company intends to present its views with respect to this additional deficiency at the Panel Hearing on February 1, 2024.

In November 2023, we received correspondence from Nasdaq Regulatory Compliance seeking more information surrounding our determination that our April and July 2023 offerings were deemed "Public Offerings" within the meaning of Listing Rule IM5635-3 to avoid shareholder approval for such offerings. We provided our response to Nasdaq Regulatory Compliance's questions. In November 2023, we received additional correspondence from Nasdaq Regulatory Compliance seeking information in connection with the issuance of warrants in September 2023 pursuant to inducement letters sent to holders of public warrants issued in the April and July 2023 public offerings. We believe that our April and July 2023 offerings were public offerings within the meaning of Listing Rule IM 5635-3, and that the issuance of the warrants in September 2023 was structured in manner that such issuance did not require shareholder approval. In this regard, we sought advice from consultants in structuring these issuances to comply with Nasdaq Listing Rules. No assurance can be given that Nasdaq Regulatory Compliance will agree with our analysis and determine that the April and July 2023 public offerings and issuance of the September 2023 warrants required shareholder approval. If Nasdaq Listing Qualifications determines that we should have sought shareholder approval for the April and July 2023 public offerings and September 2023 warrant issuance, we may be subject to delisting.

On February 1, 2024 we attended a hearing with Nasdaq to present our case for extending the time we have to achieve minimum listing status. We are awaiting the outcome of that hearing.

In addition, if we fail to meet the Nasdaq listing requirements and do not regain compliance, we will be subject to delisting by Nasdaq. In the event our common stock is no longer listed for trading on The Nasdaq Global Market and we are unable to transfer to The Nasdaq Capital Market, our trading volume and share price may decrease and you may have a difficult time selling your shares of common stock. In addition, we may experience difficulties in raising capital which could materially adversely affect our operations and financial results. Further, delisting from Nasdaq markets could also have other negative effects, including potential loss of confidence by partners, lenders, suppliers and employees. Finally, delisting could make it harder for you and the Company to sell the securities and hard for us to raise capital.

If our business developments and achievements do not meet the expectations of investors or securities analysts or for other reasons the expected benefits do not occur, the market price of our common stock traded on Nasdaq may decline.

If our business developments and achievements do not meet the expectations of investors or securities analysts, the market price of common stock traded on Nasdaq may decline. The trading price of our common stock could be volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. Any of the factors listed below could have a negative impact on your investment in our securities and our securities may trade at prices significantly below the price you paid for them. In such circumstances, the trading price of our securities may not recover and may experience a further decline.

Factors affecting the trading price of our securities may include:

- adverse regulatory decisions;
- any delay in our regulatory filings for our therapeutic candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- the impacts of the ongoing COVID-19 pandemic and related restrictions as they may related to our clinical trials;
- the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of our therapeutic candidates;
- adverse results from, delays in or termination of clinical trials;
- unanticipated serious safety concerns related to the use of our therapeutic candidates;
- lower than expected market acceptance of our therapeutic candidates following approval for commercialization, if approved;
- changes in financial estimates by us or by any securities analysts who might cover our securities;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our business prospects or management;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;

- disputes or other developments relating to intellectual property rights, including patents, litigation matters and our ability to obtain, maintain, defend, protect and enforce patent and other intellectual property rights for our technologies;

- significant lawsuits, including patent or stockholder litigation;

- proposed changes to healthcare laws in the U.S. or foreign jurisdictions, or speculation regarding such changes;

- general political and economic conditions; and

- other events or factors, many of which are beyond our control.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

The price of our common stock has fluctuated substantially.

The price of our common stock has fluctuated substantially. Therefore, some investors who have purchased our common stock at high prices face the risk of losing a significant portion of their original investment if they have to sell at a time when the price of our common stock has declined. In addition, the volatility of our stock price could cause other consequences including causing a short squeeze due to the difference in investment decisions by short sellers of common stock and buy-and-hold decisions of longer investors.

You should consider an investment in our securities to be risky, and you should invest in our securities 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 report, are:

- sale 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 financings to conduct and complete research and development activities including, but not limited to, our proposed clinical trials, and other business activities;

- possible delays in the expected recognition of revenue due to lengthy and sometimes unpredictable sales timelines;

- the timing and success of introductions of new drugs by our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;

- network outages or security breaches;

- the lack of market acceptance and sales growth for our therapeutic candidates, if any, that receive marketing approval;

- our ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;

- commencement, enrollment or results of our clinical trials for our therapeutic candidates or any future clinical trials we may conduct;

- changes in the development status of our therapeutic candidates;

- any delays or adverse developments or perceived adverse developments with respect to the FDA's review of our planned NDA, PMA and clinical trials;
- any delay in our submission for studies or drug approvals or adverse regulatory decisions, including failure to receive regulatory approval for our therapeutic candidates;
- unanticipated safety concerns related to the use of our therapeutic candidates;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy and future issuances of securities;
- sales of large blocks of common stock by our stockholders, including, but not limited to, sales by 3i, LP as a result of the exercise of the warrant issued in our PIPE Financing ("PIPE Warrant") and conversion of Series A Preferred Stock into common stock and the liquidation of the PIPE Financing, and exchange of outstanding secured promissory notes for common stock;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new drugs;
- reputational issues;
- competition from existing technologies and drugs or new technologies and drugs that may emerge;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new drugs, 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 properties, 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 are subject to penalties if we fail to meet certain conditions of the Certificate of Designations of the Series A Preferred Stock and related registration rights agreement.

We are authorized to issue up to 500,000 shares of preferred stock, 20,000 shares of which have been designated as Series A Preferred Stock and sold in connection with the PIPE Financing, 200,000 shares of Series B Preferred Stock of which all of the 190,786 shares of Series B Preferred Stock issued have been redeemed, and 50,000 shares of which has been designated as Series C Preferred Stock and sold in a private placement. We could issue a series of preferred stock that could, depending on the terms of the series, impede or discourage an acquisition attempt or other transaction that some, or a majority, of the holders of our common stock might believe to be in their best interests or in which the holders of our common stock might receive a premium over the market price of the common stock. Additionally, the issuance of preferred stock may adversely affect the rights of holders of our common stock by restricting dividends on our common stock, diluting the voting power of our common stock or subordinating the liquidation rights of our common stock.

If certain defined "triggering events" defined in the Certificate of Designations occur, such as a breach of the Registration Rights Agreement, suspension of trading, or our failure to convert the Series A Preferred Stock into common stock when a conversion right is exercised, failure to issue our common stock when the PIPE Warrant is exercised, failure to declare and pay to any holder any dividend on any dividend date, certain defaults on our debts or contractual obligations, or upon a "bankruptcy triggering event" (as defined in the Certificate of Designations), then we may be required to pay a dividend that is added to the stated value on the Series A Preferred Stock in the amount of 18% per annum, but paid quarterly in cash, so long as the triggering event is continuing, or to redeem the Series A Preferred Stock for cash in an amount of 125% of the stated value of the Series A Preferred Stock and in the event that we experience a "Change of Control" (as defined in the Certificate of Designations) we may also be required to redeem the Shares at a premium of 125% of their stated value. In addition, if thirty days after our common stock commences trading on Nasdaq the average daily dollar volume for the 10 days previous to conversion divided by 10 is less than $2,500,000, then the Series A Preferred Stock shall be entitled to a one-time dividend equal to an 8% increase in the stated value of the Preferred Share, or an $80 increase per share in stated value, resulting in a stated value of $1,080 per Preferred Share. This dividend was paid during the first quarter of 2022.

On May 4, 2022, the Company and the Investor entered into a Forbearance Agreement and Waiver, dated April 27, 2022, wherein the Investor confirmed that no Triggering Event as defined under the COD has occurred prior to April 27, 2022, that a Triggering Event under Section 5 (a)(ii) will and has occurred on April 29, 2022, and that in consideration for the Registration Delay Payments the Company is obligated to pay under the RRA, and additional amounts the Company is obligated to pay under the COD and the Investor's legal fees incurred in the preparation of the Forbearance Agreement and Waiver in the aggregate of $538,823 paid upon execution of the Forbearance Agreement and Waiver, and so long as the Company pays the Registration Delay Payments that become due and payable under the RRA after the execution of the Forbearance Agreement and Waiver, the Investor has agreed to forbear exercising any rights or remedies that it may have under the COD that arises as a result of a Triggering Event under Section 5(a)(ii) of the COD and Section 4(c)(ii) of the PIPE Warrant until the earlier to occur of (i) the date immediately prior to the date of occurrence of a Bankruptcy Triggering Event, (ii) the date of occurrence of any other Triggering Event under Section 5(a) of the COD (excluding any Triggering Event arising solely as a result of Section 5(a)(ii) of the COD and Section 4(c)(ii) of the PIPE Warrant), (iii) the time of any breach by the Company under the Forbearance Agreement and Waiver, (iv) the Resale Availability Date as defined therein and (v) June 4, 2022 (such period, the "Forbearance Period"). Provided that the Company is not in breach of its obligations under Forbearance Agreement and Waiver, effective as of the Trading Day immediately following the date the Company cures the Triggering Event under Section 5(a)(ii) of the COD, the Investor agrees to waive any rights or remedies that it may have under the COD that arises as a result of a Triggering Event under Section 5(a) of the COD and Section 4(c)(ii) of the PIPE Warrant that may have arisen prior to the date of the Forbearance Agreement and Waiver.

As a result of these or other factors, the issuance of preferred stock could diminish the rights of holders of our common stock, or delay or prevent a change of control of the Company and could have an adverse impact on the market price of our common stock.

Future sales, or the perception of future sales, by us or our stockholders in the public market could cause the market price for our common stock to decline.

The sale of shares of our common stock in the public market, or the perception that such sales could occur, could harm the prevailing market price of shares of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that it deems appropriate.

As of January 18, 2024, we had (i) 1,417 shares of Series A Preferred Stock outstanding that could be converted into 3,419,035 shares of Common Stock based upon a conversion price of $0.4476 and stated value of $1,080, subject to adjustment, (ii) 255,556 shares of Common Stock issuable upon exercise of warrants to purchase shares of Common Stock at an exercise price of $1.00 per share which were issued in a public offering that closed in April 2023 and July 2023; (iii) 9,846,339 shares of Common Stock issuable upon exercise of a warrant to purchase Common Stock at an exercise price of $0.4476 per share issued pursuant to a Modification and Exchange Agreement dated April 20, 2023, as amended, and (iv) 4,877,778 shares of Common Stock issuable upon exercise of warrants to purchase shares of Common Stock at an exercise price of $1.00 per share issued to the September Investors. The holder of the Series A Preferred Stock and holders of our warrants may convert, exercise or exchange their securities into shares of Common Stock, which sales thereof could adversely affect the market price of shares of our Common Stock, and dilute stockholders ownership of our Common Stock.

Because there are no current plans to pay cash dividends on shares of our Common Stock for the foreseeable future, you may not receive any return on investment unless you sell your shares of Common Stock for a price greater than that which you paid for it.

We intend to retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends as a public company in the future will be made at the discretion of our Board of Directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our Board of Directors may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur or from restrictions imposed by any preferred stock we may issue in the future. As a result, you may not receive any return on an investment in our Common Stock unless you sell your shares of Common Stock for a price greater than that which you paid for it.

We may incur substantial penalties if we fail to maintain the effectiveness of our registration statement covering the resale of our Common Stock issued to 3i, LP upon conversion of our Series A Preferred Stock, and the Common Stock issuable upon the exercise of the Inducement Warrants by the September Investors.

Under the terms of the First Amendment to Registration Right Agreement with 3i, L.P. dated April 20, 2023 ("Amended RRA") with 3i, LP, if we fail to maintain the effectiveness of the registration statement beyond defined allowable grace periods, we will incur certain registration delay payments equal to 2% of 3i, LP's investment that has not yet been converted to Common Stock and sold pursuant to the registration statement upon our failure to maintain the effectiveness of the registration statement and every 30 days thereafter. For example, as a result of the Company's delay in filing its periodic reports with the SEC in 2022, a Triggering Event under Section 5(a)(ii) of the Original Series A COD, occurred on or about April 29, 2022, and that in consideration for the Registration Delay Payments that the Company was obligated to pay under the Amended RRA, and additional amounts the Company was obligated to pay under the Original Series A COD, together with 3i, LP's legal fees incurred in the preparation of the Forbearance Agreement and Waiver dated April 27, 2022, the Company agreed to pay 3i, LP an aggregate amount of $538,823 which was paid pursuant to that certain Forbearance Agreement and Waiver with 3i, LP. In addition, if we fail to file a registration statement related to the Exchange Shares and Exchange Warrants by a specific date pursuant to the Modification and Exchange Agreement, we will incur registration delay payments equal to 2% of 3i, LP's investment on the date of the filing failure and each thirty-day period thereafter until the filing failure is cured.

In connection with the Inducement Warrants, we agreed to file a Resale Registration Statement on or before October 15, 2023, and to use commercially reasonable efforts to have such Resale Registration Statement declared effective by the SEC within 90 days following the date of the issuance of the Inducement Warrants and to keep the Resale Registration Statements effective at all times until no holder of the Inducement Warrants owns any Inducement Warrants or Inducement Warrant Shares. We also granted liquidated damages to the September Investors in the event of (i) a Public Information Failure or (ii) a Stockholder Approval Failure, and the September Investors are unable to sell their Inducement Warrant Shares. In either event, or both events, we will be required to pay the September Investors an amount in cash equal to 1.5% of the aggregate exercise price of the Inducement Warrants held by the Holder on the day of a Public Information Failure and/or Stockholder Approval Failure and on every 30th day (pro rated for periods totaling less than 30 days) thereafter until the Public Information Failure and Stockholder Approval Failure are cured.

There is no assurance that an active and liquid trading market in our common stock will develop.

Even though our shares of common stock are currently listed on Nasdaq, there can be no assurance that we will be able to comply with the listing requirements to maintain the listing despite our efforts. In addition, there can be no assurance that any broker will be interested in trading our common stock. Therefore, it may be difficult to sell any shares you acquire if you desire or need to sell them. We cannot provide any assurance that an active and liquid trading market in our common stock will develop or, if developed, that the market will continue.

Our Certificate of Incorporation and our by-laws, and Delaware law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our Certificate of Incorporation and our bylaws could make it more difficult for a third-party to acquire us, even if closing such a transaction would be beneficial to our stockholders. We are authorized to issue up to 500,000 shares of preferred stock, of which 20,000 shares have been designated as Series A Preferred Stock, of which 1,417 are outstanding as of January 8, 2024, 200,000 shares have been designated as Series B Preferred Stock, $0.0001 par value per share ("Series B Preferred Stock") of which none are issued and outstanding, and 50,000 shares have been designated as Series C Preferred Stock, none of which are issued and outstanding. The remaining preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our Board of Directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our Common Stock, and therefore, reduce the value of our Common Stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third-party and thereby preserve control by the present management.

Provisions of our Certificate of Incorporation, by-laws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, our Certificate of Incorporation and bylaws and Delaware law, as applicable, among other things:

- provide for a classified board of directors;
- provide the board of directors with the ability to alter the by-laws without stockholder approval;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

Our Certificate of Incorporation designates the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) as the exclusive forum for certain types of claims that the federal courts do not have exclusive jurisdiction, which may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable.

Article Fourteenth of our Certificate of Incorporation specifies that unless we consent in writing to the selection of an alternative forum, the court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (a) any derivative action or proceeding brought on our behalf; any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us or to our stockholders; (b) any action asserting a claim against us arising pursuant to the Delaware General Corporation Law ("DGCL") or Certificate of Incorporation or our by-laws; or (c) or any action asserting a claim against us that is governed by the internal affairs doctrine. There is uncertainty as to whether a court would enforce this provision with respect to claims under the Securities Act where the state courts have concurrent jurisdiction and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. The exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes against us and our directors, officers and other employees, which may discourage such lawsuits, or may require increased costs to bring a claim. The exclusive forum provision does not apply to actions brought to enforce a duty or liability created by the Exchange Act or any other claim for which federal courts have exclusive jurisdiction.

General Risk Factors

We are an "emerging growth company" and a "smaller reporting company" and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies, which could 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, or the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) 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. 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, 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 not electing to delay such adoption of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. 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. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our December 2021 offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including presenting only the two most recent fiscal years of audited financial statements and reduced disclosure obligations regarding executive compensation in this report and our periodic reports and proxy statements. We will 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. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and drug approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

Financial reporting obligations of being a public company in the United States require well defined disclosure and procedures and internal control over financial reporting that that are expensive and time-consuming requiring our management to devote substantial time to compliance matters.

The reporting obligations associated with being a public company in the United States require significant expenditures and will place significant demands on our management and other personnel, including costs resulting from our reporting obligations under the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act of 2002, as amended, (the "Sarbanes-Oxley Act"), the Dodd-Frank Wall Street Reform and Consumer Protection Act, as amended, (the "Dodd-Frank Act"), and the listing requirements of the stock exchange on which our securities are to be listed. These rules require the establishment and maintenance of effective disclosure controls and procedures and internal controls over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company." In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

If we fail to comply with the rules under the Sarbanes-Oxley Act related to our disclosure controls and procedures or internal controls over our financial reporting in the future, or, if we discover additional material weaknesses and other deficiencies in our internal controls over financial reporting, our stock price could decline significantly and raising capital could be more difficult.

Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal controls over financial reporting after a transition period ending with our second annual report on Form 10-K filed under Section 13(a) of the Exchange Act. If we fail to comply with the rules under the Sarbanes-Oxley Act related to disclosure controls and procedures in the future, or, if in the future we discover additional material weaknesses and other deficiencies in our internal controls over financial reporting, our stock price could decline significantly and raising capital could be more difficult.

We may acquire other companies or technologies, which could divert our management's attention, result in dilution to our stockholders and otherwise disrupt our operations and adversely affect our operating results.

We may in the future seek to acquire or invest in businesses, applications and services or technologies that we believe could complement or expand our services, enhance our technical capabilities, or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various expenses in identifying, investigating, and pursuing suitable acquisitions, whether or not they are consummated.

In addition, we have limited experience in acquiring other businesses. If we acquire additional businesses, we may not be able to integrate the acquired personnel, operations and technologies successfully or effectively manage the combined business following the acquisition. We also may not achieve the anticipated benefits from the acquired business due to several factors, including:

- inability to integrate or benefit from acquired technologies or services in a profitable manner;
- unanticipated costs or liabilities associated with the acquisition;
- difficulty integrating the accounting systems, operations and personnel of the acquired business;

- difficulties and additional expenses associated with supporting legacy drugs and hosting infrastructure of the acquired business;
- difficulty converting the customers, if any, of the acquired business onto our platform and contract terms, including disparities in the revenue, licensing, support or professional services model of the acquired company;
- diversion of management's attention from other business concerns;
- adverse effects to our existing business relationships with business partners and customers as a result of the acquisition;
- the potential loss of key employees;
- use of resources that are needed in other parts of our business; and
- use of substantial portions of our available cash to consummate the acquisition.

In addition, a significant portion of the purchase price of companies we acquire may be allocated to acquired goodwill and other intangible assets, which must be assessed for impairment at least annually. In the future, if our acquisitions do not yield expected returns, we may be required to take charges to our operating results based on this impairment assessment process, which could adversely affect our results of operations.

Acquisitions could also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business, and financial position may suffer.

Market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over inflation, energy costs, geopolitical issues, the U.S. mortgage market and a declining real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

Failure to comply with current or future federal, state and foreign laws and regulations and industry standards relating to privacy and data protection laws could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and our collaborators and third-party providers may be subject to federal, state and foreign data privacy and security laws and regulations. In the U.S., numerous federal and state laws, and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, such as Section 5 of the Federal Trade Commission Act, that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party providers.

In many jurisdictions, enforcement actions and consequences for noncompliance are rising. In the U.S., these include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies. In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us. If we fail to follow these security standards, even if no customer information is compromised, we may incur significant fines or experience a significant increase in costs. Many state legislatures have adopted legislation that regulates how businesses operate online, including measures relating to privacy, data security and data breaches. Laws in all 50 states require businesses to provide notice to customers whose personally identifiable information has been disclosed because of a data breach. The laws are not consistent, and compliance in the event of a widespread data breach is costly. States are also constantly amending existing laws, requiring attention to frequently changing regulatory requirements. Furthermore, California recently enacted the California Consumer Privacy Act (the "CCPA"), which became effective in January 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. At this time, we do not collect personal data on residents of California, but should we begin to do so, the CCPA will impose new and burdensome privacy compliance obligations on our business and will raise new risks for potential fines and class actions.

Foreign data protection laws, including EU General Data Protection Regulation (the "GDPR"), may also apply to health-related and other personal information obtained outside of the U.S. The GDPR, which came into effect in 2018, introduced new data protection requirements in the European Union, as well as potential fines for noncompliant companies of up to the greater of €20.0 million or 4% of annual global revenue. The regulation imposes numerous new requirements for the collection, use and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e.g., the right to access, correct and delete their data). Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the U.S., and the efficacy and longevity of current transfer mechanisms between the EU and the U.S. remains uncertain. For example, in 2016, the EU and U.S. agreed to a transfer framework for data transferred from the EU to the U.S., called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. Because we undertake clinical trials in Europe, we are subject to the GDPR and as a result will increase our responsibility and potential liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

Compliance with U.S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators and third-party providers to comply with U.S. and foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or experience security breaches or other unauthorized or improper access.

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to privacy and information security incidents, such as data breaches, damage from computer viruses and unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such material system failure or security breach to our knowledge to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our therapeutic candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

Unauthorized disclosure of sensitive or confidential data, including personally identifiable information, whether through a breach of computer systems, systems failure, employee negligence, fraud, or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. To the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our therapeutic candidates could be delayed.

As we become more dependent on information technologies to conduct our operations, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business. Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently and often are not recognized until launched against a target, we and our partners may be unable to anticipate these techniques or to implement adequate preventative measures. Further, we do not have any control over the operations of the facilities or technology of our cloud and service providers, including any third-party vendors that collect, process and store personal data on our behalf. Our systems, servers and platforms and those of our service providers may be vulnerable to computer viruses or physical or electronic break-ins that our or their security measures may not detect. Individuals able to circumvent such security measures may misappropriate our confidential or proprietary information, disrupt our operations, damage our computers or otherwise impair our reputation and business. We may need to expend significant resources and make significant capital investment to protect against security breaches or to mitigate the impact of any such breaches. There can be no assurance that we or our third-party providers will be successful in preventing cyber-attacks or successfully mitigating their effects. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our future therapeutic candidates could be delayed.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business, or our market, or if they change their recommendations regarding our securities adversely, the price and trading volume of common stock could decline.

The trading market for common stock will be influenced by the research and reports that industry or securities analysts may publish about us, our business, market, or competitors. Securities and industry analysts do not currently, and may never, publish research on us. If no securities or industry analysts commence coverage of us, our share price and trading volume would likely be negatively impacted. If any of the analysts who may cover us change their recommendation regarding our common stock adversely, or provide more favorable relative recommendations about our competitors, the price of our common stock would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline.

Comprehensive tax reform bills could adversely affect our business and financial condition.

The U.S. government recently enacted comprehensive federal income tax legislation that includes significant changes to the taxation of business entities. These changes include, among others, a permanent reduction to the corporate income tax rate. Notwithstanding the reduction in the corporate income tax rate, the overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected. This report does not discuss any such tax legislation or the way it might affect purchasers of our common stock. We urge our stockholders to consult with their legal and tax advisors with respect to any such legislation and the potential tax consequences of investing in our common stock.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity.

We continue to augment the capabilities of our people, processes, and technologies in order to address our cybersecurity risks. Our cybersecurity risks, and the controls designed to mitigate those risks, are integrated into our overall risk management governance and are reviewed yearly by our Board of Directors.

Risk Management and Strategy

As of December 31, 2023, we have implemented a set of cybersecurity and data protection policies and procedures. Risks from cybersecurity threats are regularly evaluated as a part of our broader risk management activities. Our employees have received cybersecurity awareness trainings, including specific topics related to social engineering and email frauds. Important security measures such as multifactor authentication, firewalls, Endpoint Detection and Response (EDR), encryption, etc. have been implemented. We continue to augment the capabilities of our people, processes, and technologies in order to address our cybersecurity risks. Currently we are in the process of expanding our risk management procedure to include a broader cybersecurity risk management process. The updated risk management process will include annual review by our Board of Directors

Governance

Our Board of Directors are currently implementing as oversight procedure for IT governance and cyber security risk management. It is expected that IT governance and cybersecurity will be included in the company's quarterly management review meetings under the supervision of our senior leadership, including our Chief Executive Officer and Chief Financial Officer, with regularly meets with and provides periodic briefings to our Board of Directors regarding our cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties, and the like.

Cybersecurity Threat Disclosure

To date, we are not aware of any cybersecurity threats that have materially affected or are reasonably likely to materially affect the Company. For further discussion of cybersecurity risks, please see Item 1A, "*Risk Factors*."

Item 2. Properties.

Our principal executive office is in Boston, MA USA, where we lease at-will, month-to-month virtual office space in a technology park, where we are not bound by any lease. Our current monthly rent for the office space is approximately $85 per month. We believe this office is sufficient to support our U.S.-based executive team members, all of whom are based on the East Coast of the U.S. In each of the fiscal years ended December 31, 2023 and 2022, we paid approximately $1,110 in lease payments. We believe that our current existing facilities will be adequate for our current needs.

Our principal laboratory and R&D facility is in Hoersholm, Denmark (just north of Copenhagen), where we lease a space in a technology park consisting of approximately 4,283 square feet, for $8,107 per month. As of January 31, 2023, the facility lease is continuing on a month-to-month basis. In each of the fiscal years ended December 31, 2023 and 2022, we paid approximately $97,284 in lease payments.

Item 3. Legal Proceedings.

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties and an adverse result in these or other matters may arise from time to time that may harm our business. To the best knowledge of management, there are no material legal proceedings pending against us.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market for Common Stock

Our common stock is listed on Nasdaq Global Market under the symbol "ALLR." Prior to the consummation of the Recapitalization Share Exchange on December 20, 2021, Allarity Therapeutics A/S ordinary shares were listed on the Nasdaq First North Growth Market: Stockholm under the symbol "ALLR:ST."

Holders of Record of Common Stock

As of the date of this report, we had 2 stockholders of record for our common stock. The foregoing number of stockholders of record does not include an unknown number of stockholders who hold their stock in "street name."

Dividend Policy

On November 22, 2022, our Board declared a dividend of Series B Preferred Stock to the stockholders of record of common stock and Series A Preferred Stock as of December 5, 2022 (the "Record Date"). On the Record Date, each share of common stock outstanding received 0.016 of a share of Series B Preferred Stock and each share of Series A Preferred Stock outstanding received 1.744 shares of Series B Preferred Stock. We issued an aggregate of 190,786 shares of Series B Preferred Stock, which were redeemed on February 3, 2023.

We do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our common stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our Board of Directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our Board of Directors may deem relevant.

Recent Sales of Unregistered Securities

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results Of Operations.

The following discussion and analysis provide information which our management believes is relevant to an assessment and understanding of Allarity consolidated results of operations and financial condition. You should read the following discussion and analysis of our financial condition and results of operations together with our audited consolidated financial statements and notes thereto included elsewhere in this report. In addition to historical financial information, this discussion contains forward-looking statements based upon our current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this report. Unless otherwise indicated or the context otherwise requires, references in this Management's Discussion and Analysis of Financial Condition and Results of Operations section to "Allarity," "we," "us," "our," and other similar terms refer to Allarity Therapeutics, Inc. and its consolidated subsidiaries.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a pharmaceutical company focused on discovering and developing highly targeted anti-cancer drug candidates. Using its Drug Response Predictor (DRP®) platform, the Company identifies the value in drug assets that have otherwise been discontinued by identifying patient populations where these drugs are active. The Company's t lead drug candidate is the poly-ADP-ribose polymerase (PARP) inhibitor stenoparib. The microtubule inhibitor agent IXEMPRA, and the tyrosine kinase inhibitor (TKI) dovitinib have been deprioritized and terminated, respectively.

Recent Corporate Developments

Bridge Loans

On November 22, 2022, the Company entered into a Secured Note Purchase Agreement with 3i, LP (the "Secured Note Purchase Agreement") for a bridge loan to extend the Company's cash runaway beyond December 31, 2022, in order to provide the Company with more time to complete the process of amending its Certificate of Incorporation to increase it authorized share capital and proposed reverse stock split to facilitate additional capital investments (the "Bridge Loan"). Under the Secured Note Purchase Agreement, the Company has authorized the sale and issuance of three 3i Promissory Notes, with the first note in an aggregate principal amount of $350,000 to be issued at closing (which loan was received in November 2022); the second note in the principal amount of $1,666,640 to be issued at closing and which represents the payment of $1,666,640 due to 3i, LP in Alternative Conversion Floor Amounts, as defined in the Certificate of Designations, that began to accrue on July 14, 2022; and the third note in an aggregate principal amount of $650,000 with respect to a new loan to be funded upon the Company filing a registration statement with SEC in connection with a registered offering. As of December 31, 2022, all of the notes have been issued and are outstanding. Each 3i Promissory Note matures on January 1, 2024, carries an interest rate of 5% per annum, and is secured by all of the Company's assets pursuant to the Security Agreement. In addition, 3i, LP may exchange the 3i Promissory Notes for the Company's common stock, or other equity security, at an exchange price equal to the lowest price per share of the equity security sold to other purchasers, rounded down to the nearest whole share, if the Company concludes a future equity financing prior to the maturity date or other repayment of the 3i Promissory Notes. In addition, each 3i Promissory Note and interest earned thereon may be redeemed by the Company at its option or the holder may demand redemption if the Company obtains gross proceeds of at least $5 million in a financing in an amount of up to 35% of the gross proceeds of the financing.

On January 18, 2024, we entered into a Securities Purchase Agreement with 3i, pursuant to which we issued and sold 3i a senior convertible promissory note in an aggregate principal amount of $440,000 due on January 18, 2025 (the "First Note," and together with the Purchase Agreement, the "Transaction Documents") for an aggregate purchase price of $400,000 representing an approximate 10% original issue discount. We agreed to use the net proceeds from the sale of the First Note for accounts payable and working capital purposes. Unless the Transaction Documents state otherwise, we may not prepay any portion of the principal amount of the First Note without the Purchaser's prior written consent.

On February 13, 2024 (the "Second Closing"), the parties to the Purchase Agreement entered into a Limited Waiver Agreement (the "Waiver Agreement") and agreed that the Second Closing can be consummated prior to the 30th calendar day following January 18, 2024. The parties to the Purchase Agreement further agreed to waive any rights or remedies that they may have under Section 2.3 of the Purchase Agreement, solely in connection with the Second Closing, including any rights of termination, defaults, amendment, acceleration or cancellation that be triggered under the Purchase Agreement solely as a result of accelerating the Second Closing. As of the Second Closing, we issued and sold to 3ia senior convertible promissory note in an aggregate principal amount of $440,000 due on February 13, 2025 (the "Second Note," and together with the First Note dated January 18, 2024, and Purchase Agreement, the "Transaction Documents") for an aggregate purchase price of $400,000, representing an approximately 10% original issue discount (the "Second Transaction"). We agreed to use the net proceeds from the sale of the Second Note for accounts payable and working capital purposes. Unless the Second Transaction Documents state otherwise, we may not prepay any portion of the principal amount of the Second Note without the Purchaser's prior written consent.

Termination of Chief Executive Officer

On December 8, 2023, James G. Cullem was terminated as our Chief Executive Officer for cause under his employment agreement. In addition, Mr. Cullem was also terminated from all other officer positions with the Company and all other positions with its subsidiaries. Mr. Cullem has indicated that his termination should be without cause. Under Mr. Cullem's employment agreement, disputes are subject to mediation. Effective January 27, 2024, Mr. Cullem resigned as a director of the Company.

On December 8, 2023, Thomas Jensen, age 45, was appointed by the Company's Board of Directors as Interim Chief Executive Officer to replace Mr. Cullem. Since July 2022, Mr. Jensen has served as Senior Vice President, Investor Relations and was previously the Company's Senior Vice President, Information Technology since July 2021. Mr. Jensen has also served as Senior Vice President, Information Technology of Allarity Therapeutics A/S, the Company's predecessor, since June 2020. Mr. Jensen previously served as the Chief Technology Officer of the Company's predecessor from 2004 to June 2020. Mr. Jensen co-founded Allarity Therapeutics A/S in 2004. Mr. Jensen also established and currently leads our laboratories in Denmark. Mr. Jensen is a current member of the Company's Board of Directors. There is no family relationship between Mr. Jensen and any director or executive officer of the Company. Prior to appointment as Chief Executive Officer, Mr. Jensen was paid consulting fees for his services to the Company. At this time, Mr. Jensen and the Company have not entered into any material plan, contract or arrangement related to his appointment as an officer.

Novartis Termination Notice

On January 26, 2024, we received written notice from Novartis indicating their decision to terminate our Agreement based on material breach for lack of financial payment. The termination took effect on January 26, 2024.

Consulting Agreement

On November 21, 2023, the Company's audit committee entered into a two month consulting agreement with Mr. Jeremy R. Graff, Ph.D. Dr. Graff has been in the Biotech/ Pharma industry for more than 25 years, garnering deep experience and expertise in the preclinical and clinical development of targeted, small and large molecule therapeutics as well as novel immunotherapeutics. His 16+ years of Big Pharma experience included numerous leadership roles of increasing responsibility. He also served as a key scientific advisor for Lilly Bioventures and the $6.5 billion acquisition of Imclone systems. He and his research groups have been responsible for delivering numerous novel therapeutics to, and through, the clinic- most notably Lilly's Verzenio (a CDK4/6 inhibitor for breast cancer).

Pursuant to his consulting agreement, Dr. Graff will provide consulting and advisory services on Company's research and development programs in the field of small molecule inhibitors and their use in the treatment of cancer.

Additional Issuances of Common Stock Upon Exercise of Certain Warrants

On December 5, 2023, we received exercise notices from holders of certain warrants pursuant to which we authorized (i) the issuance of 562,311 shares of Common Stock pursuant to exercise of common stock purchase warrants at $1.00 per share for $562,311 in cash, and (ii) the issuance of 500,000 shares of Common Stock pursuant to partial exercise of Exchange Warrant (as defined below) on a cashless exercise basis.

NASDAQ Delisting Notifications

On October 27, 2023, we received notification from Nasdaq Listing Qualifications staff that it has determined that the bid price of our Common Stock has closed at less than $1 per share over the previous 30 consecutive business days, and, as a result, does not comply with Listing Rule 5550(a)(2). Further, Nasdaq also noted that we effected a 1:35 reverse stock split on March 24, 2023, and a 1:40 reverse stock split on June 28, 2023. Because we effected one or more reverse stock splits over the prior two-year period with a cumulative ratio of 250 shares or more to one, we will not be afforded a 180-calendar day period to demonstrate compliance with Listing Rule 5550(a)(2) pursuant to Listing Rule 5810(c)(3)(A)(iv).In that regard, unless the Company requested an appeal from such determination, trading of the Company's Common Stock would have been suspended at the opening of business on November 7, 2023, and a Form 25-NSE would have been filed with the Securities and Exchange Commission which would have removed the Company's Common Stock from listing and registration on The Nasdaq Stock Market.

The Company requested an appeal for such determination and was given a hearing date of February 1, 2024 (the "Panel Hearing"). During the appeal period, the Company's Common Stock will continue to be listed on The Nasdaq Stock Market.

On November 16, 2023, we received an additional notification indicating that the Company's stockholders' equity as reported in its Quarterly Report on Form 10-Q for the period ended September 30, 2023, did not satisfy the continued listing requirement under Nasdaq Listing Rule 5810(c)(3) which serves as an additional basis for delisting. The Company intends to present its views with respect to this additional deficiency at the Panel Hearing.

In November 2023, we received correspondence from Nasdaq Regulatory Compliance seeking more information surrounding our determination that our April and July 2023 offerings were deemed "Public Offerings" within the meaning of Listing Rule IM5635-3 to avoid shareholder approval for such offerings. We provided our response to Nasdaq Regulatory Compliance's questions. In addition, in In November 2023, we received additional correspondence from Nasdaq Regulatory Compliance seeking information in connection with the issuance of warrants in September 2023 pursuant to inducement letters sent to holders of public warrants issued in the April and July 2023 public offerings. We believe that our April and July 2023 offerings were public offerings within the meaning of Listing Rule IM 5635-3, and that the issuance of the warrants in September 2023 was structured in manner that such issuance did not require shareholder approval. In this regard, we sought advice from consultants in structuring these issuances to comply with Nasdaq Listing Rules. No assurance can be given that Nasdaq Regulatory Compliance will agree with our analysis and determine that the April and July 2023 public offerings and issuance of the September 2023 warrants required shareholder approval. If Nasdaq Listing Qualifications determines that we should have sought shareholder approval for the April and July 2023 public offerings and September 2023 warrant issuance, we may be subject to delisting.

On February 1, 2024, we attended a de-listing appeal hearing with Nasdaq, the outcome of which is pending as of the date of this filing.

Amendments to the Certificate of Designation of Series A Preferred Stock

On January 14, 2024, pursuant to the terms of the January 14th, 2024, 3i LP Bridge Loan, the Company modified the conversion price of the 3i Exchange Warrants from $1.00 to $0.4476, thereby increasing the number of Exchange Warrants outstanding from 4,407,221 at December 31, 2023 to 9,846,339 outstanding at January 14, 2024. Also on January 14, 2024, the conversion price of the outstanding 1,417 shares of Series A Preferred Stock was revised from $1.00 to $0.4476. We filed the Fifth Certificate of Amendment to Amended and Restated Certificate of Designations of Series A Convertible Preferred Stock (the "Fifth Amendment") with the Secretary of State of the State of Delaware to reflect the new conversion price of the Series A Preferred Stock of $0.4476. At a stated value of $1,080 for each share of Series A Preferred Stock, the revised price of $0.4476 per share results in the 1,417 shares being convertible into 3,419,035 common shares as of January 14, 2024.

Modification to Conversion Price of Series A Preferred Stock

On February 13, 2024, pursuant to the terms of the February 13, 2024, Bridge Loan, the Company modified the conversion price of the 3i Exchange Warrants from $0.4476 to $0.4050 and thereby increased the number of Exchange Warrants outstanding from 9,846,339 on January 18, 2024, to 10,882,028 on February 13, 2024. The Company also agreed to amend the conversion price of the Series A Preferred Stock to equal $0.405 as soon as practicable. We filed the Sixth Certificate of Amendment to Amended and Restated Certificate of Designations of Series A Convertible Preferred Stock (the "Sixth Amendment") with the Secretary of State of the State of Delaware to reflect the new conversion price of the Series A Preferred Stock of $0.405. At a stated value of $1,080 for each share of Series A Preferred Stock, the revised price of $0.405 per share results in the 1,296 shares being convertible into 3,456,000 common shares.

Risks and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry, including but not limited to, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval for any drug product candidate that it may identify and develop, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel and collaboration partners, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations, and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval prior to commercialization. Even if the Company's research and development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Financial Operations Overview

Since our inception in September of 2004, we have focused substantially all our resources on conducting research and development activities, including drug discovery and preclinical studies, establishing, and maintaining our intellectual property portfolio, the manufacturing of clinical and research material, hiring personnel, raising capital and providing general and administrative support for these operations. In recent years, we have recorded very limited revenue from collaboration activities, or any other sources. We have funded our operations to date primarily from convertible notes and the issuance and sale of our securities.

Since our inception of our predecessor, Allarity Therapeutics A/S, we have incurred losses and have an accumulated deficit of $94.5 million as of December 31, 2023. Our net losses were $11.9 million and $16.1 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, our cash deposits of $166 thousand were determined to be insufficient to fund our current operating plan and planned capital expenditures for the next twelve months. Substantially all our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses over at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- advance drug candidates through clinical trials;
- pursue regulatory approval of drug candidates;
- operate as a public company;
- continue our preclinical programs and clinical development efforts;
- continue research activities for the discovery of new drug candidates; and
- manufacture supplies for our preclinical studies and clinical trials.

Components of Operating Expenses

Research and Development Expenses

Research and development expenses include:

- expenses incurred under agreements with third-party contract organizations, and consultants;
- costs related to production of drug substance, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical trials; and
- employee-related expenses, which include salaries, benefits and stock-based compensation.

We expense all research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks and estimates of services performed using information and data provided to us by our vendors and third-party service providers. Non-refundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and accounted for as prepaid expenses. The prepayments are then expensed as the related goods are delivered and as services are performed. To date, most of these expenses have been incurred to advance our lead drug candidate stenoparib.

We expect our research and development expenses on stenoparib to increase substantially for the foreseeable future as we continue to invest to accelerate stenoparib in clinical trials designed to attain regulatory approval. Costs related to dovitinib and IXEMPRA will decrease precipitously as these have been deprioritized/ terminated. We expect additional costs in research and development activities as we continue to conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our drug candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our drug candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, facilities costs, depreciation and amortization expenses and professional services expenses, including legal, human resources, audit, and accounting services. Personnel-related costs consist of salaries, benefits, and stock-based compensation. Facilities costs consist of rent and maintenance of facilities. We expect our general and administrative expenses to increase for the foreseeable future due to anticipated increases in headcount to advance our drug candidates and because of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, Nasdaq Stock Market, additional insurance expenses, investor relations activities and other administrative and professional services.

Results of Operations

Comparison of years ended December 31, 2023 and 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022:

	For the years ended December 31,		Increase/
	2023	2022	(Decrease)
	(In thousands)		
Operating expenses:			
Research and development	$ 7,103	$ 6,930	$ 173
Impairment of intangible assets	—	17,571	(17,571)
General and administrative	10,026	9,962	64
Total operating costs and expenses	17,129	34,463	(17,334)
Loss from operations:	$ (17,129)	$ (34,463)	$ (17,334)

Research and Development Expenses

We currently do not track our research and development costs by product candidate. A breakdown by nature of type of expense for the years ended December 31, 2023 and 2022, is provided below.

	For the year ended December 31,		Increase/
	2023	2022	(Decrease)
	(In thousands)		
Research study expenses	$ 2,887	$ 1,847	$ 1,040
Tax credit	(800)	(711)	(89)
Milestone payments	150	1,417	(1,267)
Manufacturing & supplies	2,906	350	2,556
Contractors	996	1,778	(782)
Patents	30	268	(238)
Staffing	873	1,915	(1,042)
Amortization	37	60	(23)
Other	24	6	18
	$ 7,103	$ 6,930	$ 173

For the year ended December 31, 2023, versus December 31, 2022:

The increase of $173 thousand in research and development cost was primarily due to increases of $2.6 million in manufacturing and supplies, increases in research study expenses of $1 million and other of $18 thousand, offset by an increase in tax credit of $89 thousand and decreases in the following: milestone payments of $1.3 million, staffing of $1 million, contractors of $782 thousand, patents of $238 thousand, and amortization of $23 thousand.

Overall, the increase in research and development costs in the year ended December 31, 2023 was because during the year ended December 31, 2023, our research and development activity increased as activity in the clinical trials came back to a pre-pandemic level. Staffing costs decreased in 2023 primarily because stock option grants and bonuses were higher in 2022.

Impairment of Intangible Assets

As a result of both the Company's February 15, 2022, receipt of a Refusal to File ("RTF") from the U.S. Food and Drug Administration regarding the Company's new drug application ("NDA") for Dovitinib, and the depressed state of the Company's stock price, the Company performed an impairment assessments on its individual intangible assets utilizing a discounted cash flow model and recognized an impairment charge of $17.6 million during the year ended December 31, 2022. As of December 31, 2023, because of continued downward pressure on the Company's common stock, we performed an impairment assessment of our intangible assets and determined that no further impairment was required.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, facilities costs, depreciation and amortization expenses and professional services expenses, including legal, human resources, audit, and accounting services. Personnel-related costs consist of salaries, benefits, and stock-based compensation. Facilities costs consist of rent and maintenance of facilities. Legal costs incurred in connection with patents are accounted for as general and administrative expenses. We expect our general and administrative expenses to increase for the foreseeable future due to anticipated increases in headcount to advance our drug candidates and because of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, Nasdaq, additional insurance expenses, investor relations activities and other administrative and professional services.

General and administrative expenses increased by $64 thousand for the year ended December 31, 2023, compared to the year ended December 31, 2022. The increase was primarily due to increased finance expenses of $1.2 million (which were primarily non-cash and related to the value of derivative warrants), increased financial consultant expenses of $160 thousand, communications expenses of $84 thousand, insurance expense of $42 thousand, premises expense of $89 thousand and Delaware franchise tax of $19 thousand, offset by decreases in staffing costs of $1.2 million, audit and legal costs of $264 thousand and other administrative of $105 thousand. Staffing costs decreased primarily because of reduced stock option costs and reduced staff.

Other Income (Expense)

Other income (expense) of $5.3 million recognized in the year ended December 31, 2023, consisted primarily of a $10.4 million fair value adjustment of warrant derivate liabilities, ($4.2) million fair value of inducement warrants, ($591) thousand loss on modification to warrants, foreign exchange gains of $133 thousand, and interest expenses of ($498) thousand, offset by interest income of $22 thousand.

Other income (expense) of $16.9 million recognized in the year ended December 31, 2022, consisted primarily of a $17.1 million fair value adjustment of warrant derivative liabilities, $1.8 million of other income received in connection with the sale of intangible IP assets, and $30 thousand of interest income, offset by ($913) thousand in net foreign exchange losses, ($800) thousand penalty on our Series A preferred stock liability, loss on investment of ($115) thousand, and ($223) thousand in interest expenses.

Changes in the fair value of our derivative and warrant liabilities and convertible debt are measured using level 3 inputs as described in our consolidated financial statements.

Income taxes

During the years ended December 31, 2023, and 2022, we recognized ($83) thousand and $1.5 million in income tax recovery (expense), respectively.

Liquidity, Capital Resources and Plan of Operations

Since our inception through December 31, 2023, our operations have been financed primarily by the sale of preferred stock, convertible promissory notes, and the sale and issuance of our ordinary shares. As of December 31, 2023, we had $166 thousand in cash, and an accumulated deficit of $94.5 million.

In the year ended December 31, 2023, we received $11 million, net from financing activities inclusive of: $19.1 million from equity issuances in April, July and September; $1 million from the issuance of a note to 3i; and $1.1 million from the issuance of Series C Preferred Stock; and we repaid $3.7 million in debt and redeemed $6.7 million in Series A Preferred Stock.

In the year ended December 31, 2022, we received $1.0 million in proceeds from convertible debt. We also paid $1.5 million in cash on the conversion of Series A preferred shares as well as $800 thousand in penalties on the Series A preferred share liability. Our investing activities included the receipt of $809 thousand on the sale of IP and expenditures of $18 thousand on the purchase of property and equipment.

Our primary use of cash is to fund operating expenses, which consist of research and development as well as regulatory expenses related to our most advanced therapeutic candidate, dovitinib, and clinical programs for stenoparib and IXEMPRA®, and to a lesser extent, general and administrative expenses. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

As of December 31, 2023, the Company’s cash deposits of $166 thousand were determined to be insufficient to fund its current operating plan and planned capital expenditures for at least the next 12 months. We estimate that as of the date of this filing, our cash reserves are sufficient for approximately 3 months. These conditions give rise to substantial doubt over the Company’s ability to continue as a going concern.

Management's plans to mitigate the conditions or events that raise substantial doubt include additional funding through public equity, private equity, debt financing, collaboration partnerships, or other sources. There are no assurances, however, that the Company will be successful in raising additional working capital, or if it is able to raise additional working capital, it may be unable to do so on commercially favorable terms. The Company's failure to raise capital or enter into other such arrangements when needed would have a negative impact on its business, results of operations and financial condition and its ability to develop its product candidates.

Cash Flows

The following table summarizes our cash flows for the years indicated:

(In thousands)	Year Ended December 31, 2023	Year Ended December 31, 2022
Net Cash used in operating activities	$ (12,745)	$ (16,817)
Net Cash provided by investing activities	—	791
Net Cash (used in) provided by financing activities	10,995	(1,311)
Effect of foreign exchange rates on cash	(113)	(189)
Net decrease in cash	$ (1,863)	$ (17,526)

Operating Activities

During the year ended December 31, 2023, cash used in operating activities of $12.8 million was attributable to a net loss of $11.9 million, $4.2 million in net non-cash charges, offset by a $3.3 million change in net operating assets and liabilities.

The non-cash of charges consisted of a $4.2 million fair value of inducement warrants, a $591 thousand loss on modification of warrants, non-cash interest of $464 thousand, depreciation and amortization of $37 thousand, offset by a $10.4 million fair value adjustment to derivative liabilities, stock-based compensation of ($71) thousand and unrealized gain on foreign currency of $179 thousand. The change in operating assets and liabilities of $3.3 million was primarily due to a $2.2 million increase in accounts payable, a $1.4 million decrease in other current assets, a $43 thousand decrease in accrued liabilities, and an $18 thousand increase in income taxes payable, offset by an increase of $26 thousand in tax credit receivable, and an $8 thousand decrease in operating lease liability.

During the year ended December 31, 2022, cash used in operating activities of $16.8 million was attributable to a net loss of $16.1 million, $400 thousand in net non-cash charges, and a $300 thousand change in net operating assets and liabilities.

The non-cash charges consisted of intangible asset impairment of $17.6 million, stock-based compensation of $1.7 million, non-cash interest of $138 thousand, loss on investment of $115 thousand, depreciation and amortization of $60 thousand, and unrealized loss on foreign currency of $450 thousand, offset by a $17.1 million fair value adjustment to derivative liabilities, a $1.8 million gain from the sale of IP and deferred tax benefit of $1.6 million. The change in operating assets and liabilities of $300 thousand was primarily due to a $4.7 million decrease in accrued liabilities, an increase in prepaid expenses of $618 thousand, a decrease in income taxes payable of $19 thousand, a $1.1 million increase in other current assets, and a decrease in operating lease liability of $99 thousand, offset by a $6.2 million increase in accounts payable.

Investing Activities

During the year ended December 31, 2023, the Company did not incur any cash flows as a result of investing activities. During the year ended December 31, 2022, the Company received $809 thousand in proceeds from the sale of IP and invested $18 thousand in property and equipment.

Financing Activities

During the year ended December 31, 2023, cash provided by financing activities of $11.0 million consisted of $19.1 million from equity financings in April, July and September, and $1.1 million in net proceeds from the issuance of Series C Preferred, offset by the repayment of $3.7 million in debt and $6.7 million for the redemption of Series A Preferred Stock.

During the year ended December 31, 2022, cash used by financing activities of $1.3 million consisted of $1.0 million in proceeds from the issuance of convertible debt offset by $1.5 million in cash paid on the conversion of Series A preferred shares and $800 thousand in penalties on the Series A preferred share liability.

Contractual Obligations and Commitments

We enter into agreements in the normal course of business with vendors for preclinical studies, clinical trials and other service providers for operating purposes. We have not included these payments in the table of contractual obligations above since these contracts are generally cancellable at any time by us following a certain period after notice and therefore, we believe that our non-cancellable obligations under these agreements are not material.

Operating Capital and Capital Expenditure Requirements

We believe that our existing cash and cash equivalents as of the date of this report, based on our anticipated expenditures and commitments for the next twelve months including contractual obligations for milestone payments, will not enable us to fund our operating expenses and capital expenditure requirements for at least 12 months from the date of this report. Our estimate as to how long we expect our cash to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

In January and February 2024, we entered into a Securities Purchase Agreement with 3i, LP for bridge loans in the total amount of $880 thousand to extend our cash runaway beyond February 29, 2024, in order to provide us more time to complete a financing within Q1 2024.

As previously discussed, we do not have sufficient cash to support our anticipated expenditures and commitments and the Company is seeking capital to support its current and planned operations.

No assurances can be given that any ongoing discussions will be successful or that we will be able to raise additional capital on favorable terms, or at all. Our failure to raise capital or enter into other such arrangements when needed would have a negative impact on our business, results of operations and financial condition and our ability to maintain current operations and develop our product candidates which in turn may force us to seek protection under the U.S. bankruptcy laws. We are actively exploring raising capital through equity and debt financing which may require collateralizing debt financing with our assets. However, if the share increase and/or reverse stock split proposals are not approved by the required stockholder vote, we will be limited in the ways we can raise additional capital.

We expect to incur substantial expenses in the foreseeable future for the development and potential commercialization of our drug candidates and ongoing internal research and development programs. At this time, we cannot reasonably estimate the nature, timing, or aggregate amount of costs for our development, potential commercialization, and internal research and development programs. However, to complete our current and future preclinical studies and clinical trials, and to complete the process of obtaining regulatory approval for our drug candidates, as well as to build the sales, marketing, and distribution infrastructure that we believe will be necessary to commercialize our drug candidates, if approved, we may require substantial additional funding in the future.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based upon our audited consolidated financial statements for the years ended December 31, 2023 and 2022, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting years. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the fair value of the Series A preferred shares, warrants, convertible debt and the accrual for research and development expenses, fair values of acquired intangible assets and impairment review of those assets, share based compensation expense, and income tax uncertainties and valuation allowances. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Estimates are periodically reviewed considering reasonable changes in circumstances, facts, and experience. Changes in estimates are recorded in the period in which they become known and if material, their effects are disclosed in the notes to the consolidated financial statements. Actual results could differ from those estimates or assumptions.

While our significant accounting policies are described in the notes to our consolidated financial statements for the years ended December 31, 2023 and 2022, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting years. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the fair value of the Series A preferred shares, warrants, convertible debt, and the accrual for research and development expenses, fair values of acquired intangible assets and impairment review of those assets, share based compensation expense, and income tax uncertainties and valuation allowances. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Estimates are periodically reviewed considering reasonable changes in circumstances, facts, and experience. Changes in estimates are recorded in the period in which they become known and if material, their effects are disclosed in the notes to the consolidated financial statements. Actual results could differ from those estimates or assumptions.

Acquired in-process research and development (IPR&D)

Acquired IPR&D represents the fair value assigned to research and development assets that the Company acquired as part of a business combination and have not been completed at the acquisition date. The fair value of IPR&D acquired in a business combination is recorded on the consolidated balance sheets at the acquisition-date fair value and is determined by estimating the costs to develop the technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the projected net cash flows to present value. IPR&D is not amortized, but rather is reviewed for impairment on an annual basis or more frequently if indicators of impairment are present, until the project is completed, abandoned, or transferred to a third-party. Management assesses its acquired IPR&D for impairment at year end as well as when events and circumstances indicate there is a potential impairment. Significant quantitative indicators considered are the Company's market capitalization, market share, length of remaining clinical trials, and projected revenue per treatment. The projected discounted cash flow models used to estimate the fair value of partnered assets and cost approach model used to estimate proprietary assets as part of the Company's IPR&D reflect significant assumptions regarding the estimates a market participant would make to evaluate a drug development asset, including the following:

- Estimates of obsolescence of development expenditure;
- Probability of successfully completing clinical trials and obtaining regulatory approval;
- Estimates of future cash flows from potential milestone payments and royalties related to out-licensed product sales; and
- A discount rate reflecting the Company's weighted average cost of capital and specific risk inherent in the underlying assets.

Once brought into use, intangible assets are amortized over their estimated useful economic lives using the economic consumption method if anticipated future revenues can be reasonably estimated. The straight-line method is used when revenues cannot be reasonably estimated. The Company has recorded impairment losses of $17,571 on its intangible assets in the year ended December 31, 2022. During the year ended December 31, 2023, no additional impairment losses were recognized.

Research contract costs and accruals

The Company has entered into various research and development contracts with companies both inside and outside of the United States. These agreements are generally cancellable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Convertible debt instruments

The Company follows ASC 480-10, *Distinguishing Liabilities from Equity* in its evaluation of the accounting for a hybrid instrument. A financial instrument that embodies an unconditional obligation, or a financial instrument other than an outstanding share that embodies a conditional obligation, that the issuer must or may settle by issuing a variable number of its equity shares shall be classified as a liability (or an asset in some circumstances) if, at inception, the monetary value of the obligation is based solely or predominantly on any one of the following: (a) a fixed monetary amount known at inception; (b) variations in something other than the fair value of the issuer's equity shares; or (c) variations inversely related to changes in the fair value of the issuer's equity shares. Hybrid instruments meeting these criteria are not further evaluated for any embedded derivatives and are carried as a liability at fair value at each balance sheet date with remeasurements reported in change on fair value expense in the accompanying Statements of Operations and Comprehensive Loss.

Additionally, the Company accounts for certain convertible debt ("Convertible Notes") issued under the fair value option election of ASC 825, Financial Instruments wherein the financial instrument is initially measured at its issue-date estimated fair value and then subsequently re-measured at estimated fair value on a recurring basis at each reporting period date. The estimated fair value adjustment is recognized as other income (expense) in the accompanying consolidated statements of operations and the portion of the fair value adjustment attributed to a change in the instrument-specific credit risk is recognized as a component of other comprehensive loss. Convertible Notes are settled with shares at fair value of the stock issued with any differences recorded to other income (expense), as a gain or (loss) on extinguishment.

Warrants

When the Company issues warrants it evaluates the proper balance sheet classification to determine classification as either equity or as a derivative liability on the consolidated balance sheets. In accordance with ASC 815-40, Derivatives and Hedging-Contracts in the Entity's Own Equity ("ASC 815-40"), the Company classifies a warrant as equity so long as it is "indexed to the Company's equity" and several specific conditions for equity classification are met. A warrant is not considered indexed to the Company's equity, in general, when it contains certain types of exercise contingencies or adjustments to exercise price. If a warrant is not indexed to the Company's equity or it has net cash settlement that results in the warrants to be accounted for under ASC 480, Distinguishing Liabilities from Equity, or ASC 815-40, it is classified as a derivative liability, which is carried on the Consolidated Balance Sheet at fair value with any changes in its fair value recognized immediately in the Consolidated Statement of Operations and Comprehensive Loss. As of December 31, 2023, and 2022, the Company had warrants outstanding for share-based compensation that were classified as equity, and outstanding investor warrants that were classified as derivative liabilities and classified as "Warrant liabilities" in the Consolidated Balance Sheets.

Derivative financial instruments

The Company does not use derivative instruments to hedge exposures to interest rate, market, or foreign currency risks. The Company evaluates all its financial instruments to determine if such instruments contain features that qualify as embedded derivatives. Embedded derivatives must be separately measured from the host contract if all the requirements for bifurcation are met. The assessment of the conditions surrounding the bifurcation of embedded derivatives depends on the nature of the host contract. Bifurcated embedded derivatives are recognized at fair value, with changes in fair value recognized in the Consolidated Statements of Operations and Comprehensive Loss each reporting period. Bifurcated embedded derivatives are classified as "Derivative liabilities" in the Consolidated Balance Sheets.

Share-based compensation

The Company accounts for share-based compensation in accordance with ASC 718, Compensation — Stock Compensation ("ASC 718"). ASC 718 requires companies to estimate the fair value of equity-based payment awards on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service period in the Company's consolidated statements of operations and comprehensive loss.

The Company records the expense for option awards using either a graded or straight-line vesting method. The Company accounts for forfeitures as they occur. For share-based awards granted to employees, directors and non-employee consultants, the measurement date is the date of grant. The compensation expense is then recognized over the requisite service period, which is the vesting period of the respective award.

The Company reviews stock award modifications when there is an exchange of original award for a new award. The Company calculates the incremental fair value based on the difference between the fair value of the modified award and the fair value of the original award immediately before it was modified. The Company immediately recognizes the incremental value as compensation cost for vested awards and recognizes, on a prospective basis over the remaining requisite service period, the sum of the incremental compensation cost and any remaining unrecognized compensation cost for the original award on the modification date.

The fair value of stock options ("options") on the grant date is estimated using the Black-Scholes option-pricing model using the single-option approach. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions, including the option's expected term and the price volatility of the underlying stock, to determine the fair value of the award. The Company applies the Black-Scholes model as it believes it is the most appropriate fair value method for all equity awards.

Recently Issued Accounting Pronouncements

See the section titled in Note 2*(x)* to the Company's consolidated financial statements for the year ended December 31, 2023, appearing elsewhere herein.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

The Company is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements required by this item begin on page F-1 with the index to financial statements followed by the financial statements.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

Current Auditor

On September 9, 2022, our Audit Committee approved the engagement of Wolf & Company, P.C. as our independent registered public accounting firm. Wolf & Company re-audited our financial statements for the year ended December 31, 2021, and audited our financial statements for the year ended December 31, 2022. During the two fiscal years ended December 31, 2023 and 2022, and through the subsequent interim period to the date of this Form 10-K, neither the Company, nor anyone on its behalf, consulted with Wolf & Company regarding any accounting or auditing issues involving the Company, including (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered with respect to the consolidated financial statements of the Company; or (ii) any matter that was the subject of a "disagreement" (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) or a "reportable event" (as that term is defined in Item 304(a)(1)(v) of Regulation S-K).

Former Auditors

On August 8, 2022, our former independent registered public accounting firm, Marcum LLP ("Marcum") notified us in writing that our client-auditor relationship had ceased to be effective as of August 5, 2022. Marcum's reports on the financial statements for the year ended December 31, 2021, did not contain an adverse opinion or a disclaimer of opinion, nor was it qualified or modified as to uncertainty, audit scope, or accounting principles but it included an explanatory paragraph concerning the uncertainty of the Company's ability to continue as a going concern.

In our Form 8-K filed with the SEC on August 12, 2022, we reported that during the fiscal year ended December 31, 2021, and subsequent interim period preceding Marcum's resignation on August 5, 2022, there were no disagreements with Marcum on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreement(s), if not resolved to the satisfaction of Marcum, would have caused it to make reference to the subject matter of the disagreement(s) in connection with its report. Additionally, during this time period, there were no reportable events as described in Item 304(a)(1)(v) of Regulation S-K, except that, as previously disclosed in our Form 10-K for the year ended December 31, 2021, and Form 10-Q for the quarterly period ended March 31, 2022, we identified material weaknesses in our internal controls over financial reporting because we did not have a formal process for period end financial closing and reporting, we historically had insufficient resources to conduct an effective monitoring and oversight function independent from our operations and we lacked accounting resources and personnel to properly account for accounting transactions such as the issuance of warrants with a derivative liability component.

On August 12, 2022, we provided Marcum with a copy of the disclosures that we were making in response to Item 4.01 on the Form 8-K and requested that Marcum furnish us with a letter addressed to the SEC stating whether it agrees with our statements contained in the Form 8-K and, if not, stating the respects in which it does not agree.

On August 23, 2022, Marcum provided a letter regarding our disclosure contained in our Form 8-K filed on August 12, 2022, which agreed with our statements made in the third sentence of the preceding paragraph regarding the existence of material weaknesses in our internal control over financial reporting; however, Marcum disagreed regarding the description of such material weaknesses. Marcum indicated that the material weaknesses as disclosed in our Form 10-K for the year ended December 31, 2021, and Form 10-Q for the quarterly period ended March 31, 2022, were as follows: (i) a lack of accounting resources required to fulfill GAAP and SEC reporting requirements; (ii) a lack of comprehensive GAAP accounting policies and financial reporting procedures; (iii) lack of adequate procedures and controls to appropriately account for accounting transactions including liability and the valuation allowance on the deferred tax asset relating to the net operating losses; and (iv) a lack of segregation of duties given the size of the finance and accounting team. In addition, Marcum stated that our disclosure did not include any reference to its resignation because of the impairment of its independence. Finally, Marcum indicated that our disclosure did not provide disclosure of a reportable event under Item 304(a)(1)(v)(C) of Regulation S-K, as Marcum indicated that information had come to its attention during the time period covered by Item 304(a)(1)(iv) of Regulation S-K, that if further investigated may have caused Marcum to be unwilling to rely on management's representations or be associated with our financial statements; however, due to the Marcum's resignation as a result of the impairment of its independence, Marcum did not conduct such further investigation.

With regards to Marcum's August 23, 2022, letter as it relates to material weaknesses in our internal controls over financial reporting, we believe that we have provided the information required under Item 304(a)(1)(v)(A) in the Form 8-K. With regards Marcum's statement in its August 23, 2022, letter regarding management's representations, we respectfully disagree that there were events that occurred that rose to a level that would have impaired independence, or there was information, if further investigated, would require disclosure under Item 304(a)(1)(v)(C). Prior to its resignation, Marcum did not inform the Audit Committee of the information stated in their letter and if they had done so, we believe that we would have addressed any issues Marcum would have raised with the Audit Committee to the satisfaction of Marcum. A copy of Marcum's letter to the SEC required by Item 304(a) of Regulation S-K is included as Exhibit 16.1 to the registration statement of which this report forms a part.

Item 9A. Controls And Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, as of the end of the period covered by this report, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Act of 1934. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be included in our SEC reports is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, relating to the Company, including our consolidated subsidiaries, and was made known to them by others within those entities, particularly during the period when this report was being prepared. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2023.

Management's Report on Internal Control over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. As of December 31, 2023, management assessed the effectiveness of the Company's internal control over financial reporting based on the criteria for effective internal control over financial reporting established in "Internal Control - Integrated Framework," issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). A material weakness is a control deficiency (within the meaning of Public Company Accounting Oversight Board (United States) Auditing Standard No. 5) or a combination of control deficiencies that result in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. Based on such assessment, management concluded that as of December 31, 2023, our internal control over financial reporting was effective.

We have implemented and are continuing to implement various measures to address the material weaknesses identified; these measures include:

- as of June 30, 2022, our Director of Financial Reporting, a CPA (Illinois) who is experienced with public company reporting and is conversant in GAAP and SEC accounting issues, was promoted to Interim Chief Financial Officer. Effective January 1, 2023, our Interim Chief Financial Officer was promoted to our full time Chief Financial Officer;
- retaining independent GAAP consulting services to assist with the accounting treatment of complex financial instruments; and
- engaged an independent U.S. based tax consulting firm.

We plan to continue to assess our internal controls and procedures and intend to take further action as necessary or appropriate to address any other matters we identify or are brought to our attention.

We are continuously improving the effectiveness of our internal controls and disclosure controls. The actions that we are taking are subject to ongoing senior management review, as well as audit committee oversight.

This Annual Report on Form 10-K does not include an attestation report of the Company's independent registered public accounting firm regarding the effectiveness of the Company's internal control over financial reporting, as such report is not required due to the Company's status as a smaller reporting company.

Change in Internal Control over Financial Reporting

Except as discussed above, there have been no changes in the Company's internal controls over financial reporting during the quarter ended December 31, 2023, other than as noted above, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information.

As of March 7, 2024, we entered into a Settlement Agreement and General Release ("Settlement Agreement") with James Cullem, our former CEO and director. Pursuant to the terms and conditions outlined in the Settlement Agreement and in exchange for Mr. Cullem's commitments therein, including his general release of claims against us, among other considerations, we agreed to provide Mr. Cullem with an initial settlement payment totaling $70,000 on April 1, 2024. Additionally, we committed to making an installment payment of $179,155, divided equally into 5 monthly payments. Furthermore, we agreed to issue Mr. Cullem 290,000 settlement shares on April 1, 2024. Should the initial settlement payment and issuance of shares not be made to Mr. Cullem in full on April 1, 2024, the Settlement Agreement will be rendered null and void, releasing both parties from any further obligations under the Settlement Agreement unless otherwise mandated by a prior binding contract or agreement. Both parties will retain any and all rights, claims, and causes of action that would have otherwise been released by the Settlement Agreement.

Additionally, Mr. Cullem agreed to act as our consultant and entered into a consulting agreement (the "Consulting Agreement") with us, effective as of March 7, 2024. For the avoidance of doubt, no additional consideration is being paid to Mr. Cullem under the Consulting Agreement. Copies of the Settlement Agreement and Consulting Agreement will be included as exhibits to our Quarterly Report on Form 10-Q for the quarter ending March 31, 2024.

Item 9C. Disclosure Regarding Foreign Jurisdiction that Prevents Inspections.

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 of Form 10-K will be included in our 2024 Proxy Statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for our 2024 Annual Meeting of Stockholders and is incorporated herein by reference. The 2024 Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

Item 11. Executive Compensation.

The information required by this Item 11 of Form 10-K will be included in our 2024 Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 of Form 10-K will be included in our 2024 Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions and Director Independence.

The information required by this Item 13 of Form 10-K will be included in our 2024 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 of Form 10-K will be included in our 2024 Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this annual report on Form 10-K:

(1) Financial Statements

The following financial statements of Allarity, and the Reports of Independent Registered Public Accounting Firms, are included at the end of this report beginning on page F-1:

(2) Financial Statement Schedules

All schedules have been omitted because the required information is included in the financial statements or notes thereto or because they are not required.

(3) Exhibits

The exhibits required by Item 601 of Regulation S-K are listed in subparagraph (b) below.

(b) Exhibits:

The following exhibits are filed as part of this Annual Report.

Exhibit No.	Description
2.1[(e)]	Amended and Restated Plan of Reorganization and Asset Purchase Agreement by and among Allarity Therapeutics, Inc. a Delaware corporation, Allarity Acquisition Subsidiary, a Delaware corporation and Allarity Therapeutics A/S, an Aktieselskab organized under the laws of Denmark, dated as of September 23, 2021
3.1[(a)]	Certificate of Incorporation of Allarity Therapeutics, Inc.
3.2[(b)]	Certificate of Amendment to the Certificate of Incorporation of Allarity Therapeutics, Inc.
3.3[(c)]	Amended and Restated Bylaws of Allarity Therapeutics, Inc.
3.4[(m)]	Amendment No. 1 to Amended and Restated Bylaws of Allarity Therapeutics, Inc.
3.5[(g)]	Certificate of Designations of Allarity Therapeutics, Inc. relating to the Series A Convertible Preferred Stock
3.6[(q)]	Amendment to Certificate of Designation of the Series A Convertible Preferred Stock
3.7[(q)]	Certificate of Designation of the Series B Preferred Stock
3.8[(s)]	Certificate of Designation of the Series C Preferred Stock
3.9[(s)]	Certificate of Amendment to Certificate of Designation of Series C Preferred Stock
3.10[(u)]	Second Certificate of Amendment to Certificate of Incorporation of Allarity Therapeutics, Inc.
3.11[(v)]	Third Certificate of Amendment to Certificate of Incorporation of Allarity Therapeutics, Inc.
3.12[(aa)]	Amended and Restated Certificate of Designations of Series A Convertible Preferred Stock of Allarity Therapeutics, Inc.
3.13[(bb)]	First Certificate of Amendment to Amended and Restated Certificate of Designations of Series A Convertible Preferred Stock
3.14[(cc)]	Fourth Certificate of Amendment to Certificate of Incorporation of Allarity Therapeutics, Inc.
3.15[(dd)]	Second Amendment to Certificate of Designation (Series A Preferred Stock)
3.16[(ff)]	Third Certificate of Amendment to Certificate of Designation (Series A Preferred Stock)
3.17[(hh)]	Fourth Certificate of Amendment (Series A Preferred Stock)
3.18[(jj)]	Fifth Certificate of Amendment (Series A Preferred Stock)
3.19[(ll)]	Sixth Certificate of Amendment (Series A Preferred Stock)
4.1[(b)]	Specimen Common Stock Certificate of Allarity Therapeutics, Inc.
4.2[(aa)]	Warrant to Purchase Common Stock (3i, LP)
4.3[(aa)]	Form of Pre-Funded Warrant (April 2023)
4.4[(aa)]	Form of Common Warrant (April 2023)
4.5[(aa)]	Modification and Exchange Warrant
4.6[(ee)]	Form of Pre-Funded Warrant (July 2023)
4.7[(ee)]	Form of Common Warrant (July 2023)
4.8[(ff)]	Form of Amended and Restated Common Stock Purchase Warrant (July 2023)
4.9[(gg)]	Form of New Warrant

4.10[nn]	Form of Pre-Funded Warrant
4.11[nn]	Form of Series A Common Warrant
4.12[nn]	Form of Series B Common Warrant
4.13[jj]	Senior Convertible Note
4.14[ll]	Senior Convertible Note, dated as of February 13, 2024
10.1#[e]	Allarity Therapeutics, Inc. 2021 Equity Incentive Plan
10.2†[a]	Exclusive License Agreement between Oncology Venture A/S and Smerud Medical Research International As Dated as of June 26, 2020
10.3†[a]	Amended and Restated License Agreement between Allarity Therapeutics A/S and LiPlasome Pharma ApS, dated January 2021
10.4†[a]	Exclusive License Agreement between Oncology Venture, APS and 2-BBB Medicines BV, dated as of March 27, 2017
10.5†[c]	Development, Option and License Agreement between Oncology Venture ApS and R-Pharm US Operating LLC, dated March 1, 2019
10.6†[c]	Exclusive License Agreement between Oncology Venture, ApS and Eisai, Inc., dated as of July 6, 2017
10.7†[c]	License Agreement between Novartis Pharma Ag and Oncology Venture, ApS, dated April 6, 2018
10.8+[a]	Securities Purchase Agreement dated May 20, 2021 between Allarity Therapeutics, Inc. and 3i, LP
10.9[a]	Registration Rights Agreement dated May 20, 2021 between Allarity Therapeutics, Inc. and 3i, LP
10.10†[a]	Asset Purchase Agreement dated July 23, 2021 between Allarity Therapeutics A/S and Lantern Pharma Inc.
10.11[c]	First Amendment to the Exclusive License Agreement between Eisai and Allarity Therapeutics A/S dated December 20, 2020.
10.12[d]	Second Amendment to Exclusive License Agreement between Oncology Venture, ApS and Eisai, Inc. dated as of August 3, 2021.
10.13#[f]	Employment Agreement by and between Allarity Therapeutics, Inc. and James G. Cullem
10.14#[f]	Employment Agreement by and between Allarity Therapeutics, Inc. and Marie Foegh, M.D.
10.15[h]	Asset Purchase Agreement between Allarity Therapeutics, Inc. and Allarity Therapeutics A/S dated December 17, 2021
10.16[k]	Assignment and Assumption Agreement between Allarity Therapeutics, Inc. and Allarity A/S
10.17†[k]	Exclusive License Agreement with Oncoheroes Bioscience, Inc. dated January 2, 2022 (Stenoparib)
10.18†[k]	Exclusive License Agreement with Oncoheroes Bioscience, Inc. dated January 2, 2022 (Dovitnib)
10.19†[k]	Amended and Restated License Agreement among Allarity Therapeutics Europe ApS, LiPlasome Pharma ApS, and Chosa ApS dated March 28, 2022
10.20†[k]	Support Agreement between Allarity Therapeutics A/S and LiPlasome Pharma ApS, dated March 28, 2022
10.21[i]	First Amendment to License Agreement between Novartis Pharma Ag and Allarity Therapeutics Europe ApS
10.22[i]	Convertible Promissory Note
10.23[j]	Forbearance Agreement and Waiver
10.24[l]	First Amendment to Forbearance and Waiver
10.25†#[o]	Separation Agreement with Steve Carchedi
10.26†#[o]	Separation Agreement with Jens Knudsen
10.27[o]	Second Amendment to Development Option & License Agreement
10.28†[p]	Second Amendment to License Agreement with Novartis Pharma AG
10.29[q]	Secured Note Purchase Agreement
10.30[q]	Form of Secured Promissory Note
10.31[q]	Security Agreement
10.32#[r]	Employment Agreement with James G. Cullem
10.33#[r]	Employment Agreement with Joan Brown
10.34[t]	Letter Agreement with 3i, LP dated December 8, 2022
10.35[t]	Letter Agreement with 3i, LP dated January 23, 2023
10.36+[s]	Form of Securities Purchase Agreement Series C Preferred Stock
10.37[s]	Form of Registration Rights Agreement
10.38[s]	Limited Waiver Agreement
10.39[aa]	Form of Securities Purchase Agreement (April Offering)
10.40[y]	Form of Lock- Up Agreement (April Offering)
10.41[z]	First Amendment to Secured Note Purchase Agreement
10.42[z]	First Amendment to Security Agreement
10.43[z]	Form of Secured Promissory Note (2023)

10.44[(aa)]	Secured Promissory Note
10.45[(aa)]	Modification and Exchange Agreement
10.46[(aa)]	Cancellation of Debt Agreement
10.47[(aa)]	First Amendment to Registration Rights Agreement
10.48[(aa)]	Limited Waiver Agreement
10.49[(bb)]	Amendment to Modification and Exchange Agreement
10.50[(ee)]	Form of Securities Purchase Agreement
10.51[(bb)]	Fourth Amendment to the Exclusive License Agreement with Eisai, Inc.
10.52[(ee)]	Third Amendment to the Exclusive License Agreement with Eisai, Inc.
10.53[(ee)]	Form of Limited Waiver and Amendment Agreement
10.54[(ee)]	3i, LP – Limited Waiver and Amendment Agreement
10.55[(dd)]	June 2023 Secured Note Purchase Agreement
10.56[(dd)]	Security Agreement
10.57[(dd)]	Secured Promissory Note
10.58[(ee)]	Form of Lock-Up Agreement
10.59[(gg)]	Form of Inducement Letter
10.60[(gg)]	Limited Waiver between the Company and 3i, LP
10.61[(nn)]	Form of Securities Purchase Agreement
10.62[(mm)]	Form of Lock Up Agreement
10.63#	Employment Agreement (Steen Knudsen)
10.64[(jj)]	Securities Purchase Agreement, dated as of January 18, 2024, by and between the Company and the Purchaser listed on the signature page attached thereto
10.65[(kk)]	Amendment to Securities Purchase Agreement, dated as of January 25, 2024, by and between the Company and the Purchaser listed on the signature page attached thereto
10.66[(ll)]	Limited Waiver Agreement, dated as of February 13, 2024, by and between the Company and the Purchaser listed on the signature page attached thereto
10.67[(oo)]	Amendment to Senior Convertible Notes
16.1[(n)]	Letter from Marcum, LLP dated August 23, 2022, regarding Change in Independent Registered Public Accounting Firm
21	Subsidiaries of the Registrant
31.1	Certifications of the Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act
31.2	Certifications of the Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act
32.1*	Certifications of the Chief Executive Officer under Section 906 of the Sarbanes-Oxley Act
32.2*	Certifications of the Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act
97	Allarity Therapeutics, Inc. Clawback Policy
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

(a) Incorporated by reference from the Registration Statement on Form S-4 filed with the SEC on August 20, 2021.
(b) Incorporated by reference from Amendment No. 1 to Registration Statement on Form S-4 refiled with the SEC on October 20, 2021.
(c) Incorporated by reference from Amendment No. 2 to Registration Statement on Form S-4 refiled with the SEC on October 20, 2021.
(d) Incorporated by reference from Amendment No. 4 to Registration Statement on Form S-4 filed with the SEC on November 2, 2021.
(e) Incorporated by reference from Amendment No. 2 to Registration Statement on Form S-1 filed with the SEC on December 6, 2021.
(f) Incorporated by reference from Form 8-K filed with the SEC on December 10, 2021.
(g) Incorporated by reference from Form 8-K filed with the SEC on December 20, 2021.
(h) Incorporated by reference from Form 8-K filed with the SEC on December 22, 2021.
(i) Incorporated by reference from Form 8-K filed with the SEC on April 18, 2022.

(j) Incorporated by reference from Form 8-K filed with the SEC on May 6, 2022.
(k) Incorporate by reference from Form 10-K filed with the SEC on May 17, 2022.
(l) Incorporated by reference from Form 8-K filed with the SEC on June 10, 2022.
(m) Incorporated by reference from Form 8-K filed with the SEC on July 11, 2022.
(n) Incorporated by reference from Form 8-K filed with the SEC on August 12, 2022, as amended on August 24, 2022.
(o) Incorporated by reference from Form 10-Q filed with the SEC on October 7, 2022.
(p) Incorporated by reference from Form 8-K filed with the SEC on September 30, 2022.
(q) Incorporated by reference from Form 8-K filed with the SEC on November 25, 2022.
(r) Incorporated by reference from Form 8-K filed with the SEC on January 19, 2023.
(s) Incorporated by reference from Form 8-K filed with the SEC on February 28, 2023.
(t) Incorporated by reference from Form 10-K filed with the SEC on March 13, 2023.
(u) Incorporated by reference from Form 8-K filed with the SEC on March 20, 2023.
(v) Incorporated by reference from Form 8-K filed with the SEC on March 24, 2023.
(x) Incorporated by reference from Form S-1 filed with the SEC on March 14, 2023.
(y) Incorporated by reference from Form S-1 filed with the SEC on March 28, 2023.
(z) Incorporated by reference from Form 8-K filed with the SEC on April 12, 2023.
(aa) Incorporated by reference from Form 8-K filed with the SEC on April 25, 2023.
(bb) Incorporated by reference from Form 8-K filed with the SEC on June 1, 2023.
(cc) Incorporated by reference from Form 8-K filed with the SEC on June 28, 2023.
(dd) Incorporated by reference from Form 8-K filed with the SEC on June 30, 2023.
(ee) Incorporated by reference from Amendment No. 1 to Registration Statement on Form S-1 filed with the SEC on June 30, 2023.
(ff) Incorporated by reference from Form 8-K filed with the SEC on July 11, 2023.
(gg) Incorporated by reference from Form 8-K filed with the SEC on September 15, 2023.
(hh) Incorporated by reference to the Company's Form 8-K filed on September 27, 2023.
(ii) Incorporated by reference to the Company's Form S-1 filed on October 30, 2023.
(jj) Incorporated by reference Form 8-K filed with the SEC on January 19, 2024.
(kk) Incorporated by reference Form 8-K filed with the SEC on January 25, 2024.
(ll) Incorporated by reference Form 8-K filed with the SEC on February 14, 2024.
(mm) Incorporated by reference from Amendment No. 3 to Registration Statement on Form S-1 filed with the SEC on December 15, 2023.
(nn) Incorporated by reference from Amendment No. 1 to Registration Statement on Form S-1 filed with the SEC on December 5, 2023.
(oo) Incorporated by reference Form 8-K filed with the SEC on March 1, 2024.

† Certain portions of this exhibit were omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.
* Furnished herewith.
# Indicates a management contract or compensatory plan or arrangement.
+ Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601. The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ALLARITY THERAPEUTICS, INC.

By: /s/ Thomas Jensen
Name: Thomas Jensen
Title: Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Thomas Jensen Thomas Jensen	Chief Executive Officer and Director (*Principal Executive Officer*)	March 7, 2024
/s/ Joan Brown Joan Brown	Chief Financial Officer (*Principal Financial and Accounting Officer*)	March 7, 2024
/s/ Gerald McLaughlin Gerald McLaughlin	Chairman of the Board	March 7, 2024
/s/ Joe Vazzano Joe Vazzano	Director	March 7, 2024
/s/ Dr. Laura Benjamin Dr. Laura Benjamin	Director	March 7, 2024

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of Allarity Therapeutics, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Allarity Therapeutics, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, 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 the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Emphasis of a Matter Regarding Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has recurring losses from operations and accumulated deficit that raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These 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 audit. 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 audits 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 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 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.

/s/ Wolf& Company, P.C.

We have served as the Company's auditor since 2022.

Boston, MA
March 7, 2024

ALLARITY THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
As of December 31, 2023 and 2022
(U.S. dollars in thousands, except for share and per share data*)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash	$ 166	$ 2,029
Other current assets	209	1,559
Prepaid expenses	781	591
Tax credit receivable	815	789
Total current assets	1,971	4,968
Non-current assets:		
Property, plant and equipment, net	20	21
Operating lease right of use assets	—	6
Intangible assets	9,871	9,549
Total assets	$ 11,862	$ 14,544
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 8,416	$ 6,251
Accrued liabilities	1,309	1,904
Warrant derivative liability	3,083	374
Income taxes payable	59	41
Convertible promissory note and accrued interest, net of debt discount	1,300	—
Secured promissory notes	—	2,644
Operating lease liabilities, current	—	8
Total current liabilities	14,167	11,222
Non-current liabilities:		
Convertible promissory note and accrued interest, net of debt discount	—	1,083
Deferred tax	446	349
Total liabilities	14,613	12,654
Commitments and contingencies (Note 17)		
Redeemable preferred stock (500,000 shares authorized)		
Series A Preferred Stock $0.0001 par value (20,000 shares designated) shares issued and outstanding at December 31, 2023 and 2022, were 1,417 and 13,586, respectively (liquidation preference of $17.54 at December 31, 2023)	—	2,001
Series B Preferred Stock $0.0001 par value (200,000 shares designated); shares issued at December 31, 2023 and 2022, were 0 and 190,786, respectively (liquidation preference of $0 at December 31, 2023)	—	2
Series C Convertible Preferred stock $0.0001 par value (50,000 and 0 shares designated at December 31, 2023 and 2022, respectively); shares issued and outstanding at December 31, 2023 were 0	—	—
Total redeemable preferred stock	—	2,003
Stockholders' (deficit) equity		
Series A Preferred stock $0.0001 par value (20,000 shares designated) shares issued and outstanding at December 31, 2023 and 2022, were 1,417 and 13,586, respectively (liquidation preference of $17.54 at December 31, 2023)	1,742	—
Common Stock, $0.0001 par value (750,000,000 and 30,000,000 shares authorized, at December 31, 2023 and 2022, respectively); shares issued and outstanding at December 31, 2023 and 2022, were 5,886,934 and 11,356, respectively	—	—
Additional paid-in capital	90,369	83,158
Accumulated other comprehensive loss	(411)	(721)
Accumulated deficit	(94,451)	(82,550)
Total stockholders' deficit	(2,751)	(113)
Total liabilities, preferred stock and stockholders' (deficit) equity	$ 11,862	$ 14,544

* All common share data has been retroactively adjusted to effect reverse stock splits in 2023 (see Notes 1 and 10.)

See report of independent registered public accounting firm and accompanying notes to consolidated financial statements.

ALLARITY THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
For the years ended December 31, 2023 and 2022
(U.S. dollars in thousands, except for share and per share data*)

	2023	2022
Operating expenses:		
Research and development	$ 7,103	$ 6,930
Impairment of intangible assets	—	17,571
General and administrative	10,026	9,962
Total operating expenses	17,129	34,463
Loss from operations	(17,129)	(34,463)
Other income (expenses)		
Income from the sale of IP	—	1,780
Interest income	22	30
Interest expenses	(498)	(223)
Loss on investment	—	(115)
Foreign exchange gains (losses)	133	(913)
Fair value of inducement warrants	(4,189)	—
Loss on modification of warrants	(591)	—
Change in fair value adjustment of warrant derivative liabilities	10,434	17,125
Penalty on Series A Preferred stock liability	—	(800)
Net other income, net	5,311	16,884
Net loss before tax recovery (expense)	(11,818)	(17,579)
Deferred income tax (expense) benefit	(83)	1,521
Net loss	(11,901)	(16,058)
Cash payable on converted Series A Preferred Stock	—	(3,421)
Deemed dividends on Series A Preferred Stock	(8,392)	—
Deemed dividend of on Series C Preferred Stock	(123)	(1,572)
Net loss attributable to common stockholders	$ (20,416)	$ (21,051)
Basic and diluted net loss per common stock	$ (10.26)	$ (3,093.42)
Weighted average number of common stock outstanding, basic and diluted	1,990,748	6,805
Other comprehensive loss, net of tax:		
Net loss	$ (11,901)	$ (16,058)
Change in cumulative translation adjustment	310	(121)
Comprehensive loss attributable to common stockholders	$ (11,591)	$ (16,179)

* All common share data has been retroactively adjusted to effect reverse stock splits in 2023 (see Notes 1 and 10.)

See report of independent registered public accounting firm and accompanying notes to consolidated financial statements.

ALLARITY THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
For the years ended December 31, 2023 and 2022
(U.S. dollars in thousands, except for share data*)

	Series A Convertible Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, December 31, 2021 carried forward	19,800	$ 632	—	$ —	5,783	$ 1	$ 85,243	$ (600)	$ (66,492)	$ 18,152
Conversion of Series A Preferred Stock into common stock, net	(6,214)	(203	—	—	5,573	1	202	—	—	203
Floor price liability			—	—	—	—	(3,421)	—	—	(3,421)
Reclassification of derivative liabilities related to converted preferred stock	—	—	—	—	—	—	954	—	—	954
Deemed dividend of 8% on preferred stock		1,572	—	—	—	—	(1,572)	—	—	(1,572)
Series B preferred stock dividend	—	—	190,786	2	—	—	(2)	—	—	(2)
Stock based compensation	—	—	—	—	—	—	1,752	—	—	1,752
Cumulative translation adjustment	—	—	—	—	—	—	—	(121)	—	(121)
Net loss	—	—	—	—	—	—	—	—	(16,058)	(16,058)
Balance, December 31, 2022	13,586	$ 2,001	190,786	$ 2	11,356	$ 2	$ 83,158	$ (721)	$ (82,550)	$ (113)

* All common share data has been retroactively adjusted to effect reverse stock splits in 2023 (see Notes 1 and 10.)

See report of independent registered public accounting firm and accompanying notes to consolidated financial statements.

ALLARITY THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
For the years ended December 31, 2023 and 2022
(U.S. dollars in thousands, except for share data*)

	Series A Preferred Stock		Series B Preferred Stock		Series C Convertible Preferred Stock		Series A Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Number	Value	Number	Value	Number	Value	Number	Value	Number	Value				
Balance, December 31, 2022	13,586	$ 2,001	190,786	$ 2	—	$ —	—	—	11,356	$ —	$ 83,158	$ (721)	$ (82,550)	$ (113)
Issuance of Series C Convertible Preferred Stock, net	—	—	—	—	50,000	1,160	—	—	—	—	—	—	—	—
Deemed dividend of 5% and accretion of Series C Convertible Preferred Stock to redemption value	—	—	—	—	—	164	—	—	—	—	(164)	—	—	(164)
Round up of common shares issued as a result of 1-for-35 and 1-for-40 reverse stock splits	—	—	—	—	—	—	—	—	351	—	—	—	—	—
Conversion of Series A Preferred Stock into common stock, net	(9,347)	(1,377)	—	—	—	—	(2,705)	(2,522)	241,893	—	3,899	—	—	1,377
Redemption of Series B Preferred Stock	—	—	(190,786)	(2)	—	—	—	—	—	—	2	—	—	2
Issuance of common stock, net, April 2023 Financing	—	—	—	—	—	—	—	—	250,000	—	6,815	—	—	6,815
Fair value of April Warrants allocated to liabilities, net of financing costs	—	—	—	—	—	—	—	—	—	—	(3,772)	—	—	(3,772)
Deemed dividends on Series C Preferred Stock	—	—	—	—	—	123	—	—	—	—	(123)	—	—	(123)
Elimination of Series A redemption rights	(4,239)	(624)	—	—			4,239	3,952	—	—	(3,328)	—	—	624
Issuance of Series A Preferred Stock as repayment of debt	—	—	—	—	—	—	486	453	—	—	—	—	—	453
Deemed dividend on redemption of Series A Preferred Stock and cancellation of debt in conjunction with April 2023 financing	—	—	—	—	—	—	(1,550)	(1,445)	—	—	(207)	—	—	(1,652)
Deemed dividend on exchange of Series C Preferred stock for Series A Preferred stock	—	—	—	—	(50,000)	(1,447)	5,577	5,199	—	—	(3,752)	—	—	1,447
Deemed dividend on July 10, 2023 modification of Series A Preferred stock	—	—	—	—	—	—	—	206	—	—	(206)	—	—	—
Issuance of common stock, net July 2023 financing	—	—	—	—	—	—	—	—	2,444,445	—	10,080	—	—	10,080
Fair value of July Warrants allocated to liabilities, net of financing costs	—	—	—	—	—	—	—	—		—	(6,254)	—	—	(6,254)
Deemed dividend on redemption of Series A Preferred Stock in conjunction			—	—	—	—	(4,630)	(4,474)	—	—	(526)	—	—	(5,000)

with July 2023 financing														
September 2023 warrants exercised on inducement, net	—	—	—	—	—	—	—	—	2,438,889	—	2,962	—	—	2,962
Reclassification of derivative liabilities related to September 2023 warrants exercised	—	—	—	—	—	—	—	—	—	—	1,056	—	—	1,056
Cashless exercise of Exchange Warrants	—	—	—	—	—	—	—	—	500,000	—	1,031	—	—	1,031
Deemed dividend on September 2023 modification of Series A Preferred shares	—	—	—	—	—	—	—	373	—	—	(373)	—	—	—
Stock based compensation	—	—	—	—	—	—	—	—	—	—	71	—	—	71
Currency translation adjustment	—	—	—	—	—	—	—	—	—	—	—	310	—	310
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(11,901)	(11,901)
Balance, December 31, 2023	—	$ —	—	$ —	—	$ —	1,417	$ 1,742	5,886,934	$ —	$ 90,369	$ (411)	$ (94,451)	$ (2,751)

* All common share data has been retroactively adjusted to effect reverse stock splits in 2023 (see Notes 1 and 10.)

See report of independent registered public accounting firm and accompanying notes to consolidated financial statements.

ALLARITY THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the years ended December 31, 2023 and 2022
(U.S. dollars in thousands*)

	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (11,901)	$ (16,058)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain from the sale of IP	—	(1,780)
Depreciation and amortization	37	60
Intangible asset impairment	—	17,571
Stock-based compensation	(71)	1,752
Unrealized foreign exchange (gain) loss	(179)	450
Non-cash interest expense	464	138
Non-cash finance expense	1,110	—
Fair value of inducement warrants	4,189	—
Loss on modification of warrants	591	—
Loss on investment	—	115
Change in fair value of warrant derivative liabilities	(10,434)	(17,125)
Deferred income taxes	97	(1,612)
Changes in operating assets and liabilities:		
Other current assets	1,350	(1,077)
Tax credit receivable	(26)	—
Prepaid expenses	(190)	(618)
Accounts payable	2,165	6,207
Accrued liabilities	43	(4,722)
Income taxes payable	18	(19)
Operating lease liability	(8)	(99)
Net cash used in operating activities	(12,745)	(16,817)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of IP	—	809
Purchase of property and equipment	—	(18)
Net cash provided by investing activities	—	791
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from Series C Convertible Preferred Stock issuance, net	1,160	—
Proceeds from 3i promissory notes	1,050	1,000
Repayment of 3i debt	(3,699)	—
Net proceeds from common stock and pre-funded warrant issuance	16,895	—
Net proceeds from warrants exercised in conjunction with price & warrant inducement	2,243	—
Redemption of Series A Preferred Stock	(6,652)	—
Redemption of Series B Preferred Stock	(2)	—
Cash paid in connection with conversion of Series A Preferred Stock	—	(1,511)
Penalty on Series A Preferred Stock liability	—	(800)
Net cash provided by (used in) financing activities	10,995	(1,311)
Net decrease in cash	(1,750)	(17,337)
Effect of exchange rate changes on cash	(113)	(189)
Cash, beginning of year	2,029	19,555
Cash, end of year	$ 166	$ 2,029

* All common share data has been retroactively adjusted to effect reverse stock splits in 2023 (see Notes 1 and 10.)

See report of independent registered public accounting firm and accompanying notes to consolidated financial statements.

ALLARITY THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (cont.)
For the years ended December 31, 2023 and 2022
(U.S. dollars in thousands)

	2023	2022
Supplemental disclosure of cash flow information		
Cash paid for income taxes	$ 6	$ 12
Cash paid for interest	$ 34	$ 85
Supplemental disclosure of non-cash investing and financing activities:		
Offset of payable against receivable from sale of IP	$ —	$ 971
Conversion of Series A Redeemable Preferred Stock to equity	$ 3,899	$ 1,157
Issuance of Series A Preferred Stock in Exchange for Series C Preferred Stock	$ 5,199	$ —
Issuance of Series A Preferred Stock to extinguish 3i Promissory Note	$ 453	$ —
Redemption of Series A Preferred Stock as repayment of debt	$ 1,445	—
Deemed dividends on Series A Preferred Stock	$ 8,392	$ 1,572
Deemed dividend on Series C Convertible Preferred Stock, and accretion of Series C Preferred Stock to redemption value	$ 123	—
Cashless exercise of 3i LP Exchange Warrants in exchange for common stock	$ 1,031	$ —
Deemed dividend on redemption of Series B Preferred Stock	$ —	$ 2
Conversion of floor price liability to convertible debt	$ —	$ 1,667
Reclassification of derivative liabilities related to converted Preferred Stock	$ —	$ 954

See report of independent registered public accounting firm and accompanying notes to consolidated financial statements.

1. Organization, Principal Activities, and Basis of Presentation

Allarity Therapeutics, Inc. and Subsidiaries (the "Company") is a clinical stage pharmaceutical company that develops drugs for the personalized treatment of cancer using drug specific companion diagnostics generated by its proprietary drug response predictor technology, DRP®. Additionally, the Company, through its Danish subsidiary, Allarity Denmark (previously Oncology Venture ApS), specializes in the research and development of anti-cancer drugs.

The Company's principal operations are located at Venlighedsvej 1, 2970 Horsholm, Denmark. The Company's business address in the Unites States is located at 24 School Street, 2nd Floor, Boston, MA 02108.

(a) Reverse Stock Splits

On June 28 and March 24, 2023, the Company effected a 1-for-40 reverse stock split and a 1-for-35 reverse stock split, respectively, of the shares of common stock of the Company (collectively, the "Reverse Stock Splits"). All historical share and per share amounts reflected throughout the financial statements (as defined below in 1(b) and these notes to the financial statements have been adjusted to reflect both of the Reverse Stock Splits. See Note 10(a).

(b) Liquidity and Going Concern

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The accompanying consolidated financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

Pursuant to the requirements of Accounting Standard Codification (ASC) 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date of these financial statements, and (1) is probable that the plan will be effectively implemented within one year after the date the financial statements are issued, and (2) it is probable that the plan, when implemented, will mitigate the relevant condition or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date the financials are issued. Certain elements of the Company's operating plan to alleviate the conditions that raise substantial doubt are outside of the Company's control and cannot be included in the management's evaluation under the requirements of ASC 205-40.

Since inception, the Company has devoted substantially all its efforts to business planning, research and development, clinical expenses, recruiting management and technical staff, and securing funding via collaborations. The Company has historically funded its operations with proceeds received from its collaboration arrangements, sale of equity capital and proceeds from sales of convertible notes.

The Company has incurred significant losses and has an accumulated deficit of $94.5 million as of December 31, 2023. As of December 31, 2023, our cash deposits of $166 are insufficient to fund our current operating plan and planned capital expenditures for the next 12 months. These conditions give rise to substantial doubt over the Company's ability to continue as a going concern.

1. Organization, Principal Activities, and Basis of Presentation *(cont.)*

Management's plans to mitigate the conditions or events that raise substantial doubt include additional funding through public equity, private equity, debt financing, collaboration partnerships, or other sources.

Considering the Company's cash position as of March 7, 2024, the Company does not have sufficient funds for its current operations and planned capital expenditures. As discussed above the Company intends to seek capital through the sale of its securities or other sources. There are no assurances, however, that the Company will be successful in raising additional working capital, or if it is able to raise additional working capital, it may be unable to do so on commercially favorable terms. The Company's failure to raise capital or enter other such arrangements if and when needed would have a negative impact on its business, results of operations and financial condition and its ability to develop its product candidates.

Although management continues to pursue its funding plans, there is no assurance that the Company will be successful in obtaining sufficient funding to fund continuing operations on terms acceptable to the Company, if at all. Accordingly, based upon cash on hand at the issuance date of these financial statements the Company does not have sufficient funds to finance its operations for at least twelve months from the issuance date and therefore has concluded that substantial doubt exists about the Company's ability to continue as a going concern.

(c) Risks and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry, including but not limited to, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval for any drug product candidate that it may identify and develop, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel and collaboration partners, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations, and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval prior to commercialization. Even if the Company's research and development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

(d) Emerging Growth Companies

Section 102(b)(1) of the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has chosen not to make an election to opt out of new or revised accounting standards.

2. Summary of Significant Accounting Policies

(a) Basis of Presentation

The accompanying consolidated financial statements have been prepared on an accrual basis of accounting, in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the ASC and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

2. Summary of Significant Accounting Policies *(cont.)*

(b) Organization and Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries:

Name	Country of Incorporation
Allarity Acquisition Subsidiary Inc.	United States
Allarity Therapeutics Europe ApS (formerly Oncology Venture Product Development ApS)	Denmark
Allarity Therapeutics Denmark ApS (formerly OV-SPV2 ApS)	Denmark
MPI Inc.*	United States
OV US Inc.**	United States

* In the process of being dissolved because inactive.
** OV US Inc. was dissolved effective November 15, 2023.

All intercompany transactions and balances, including unrealized profits from intercompany sales, have been eliminated upon consolidation.

(c) Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting years. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the fair value of the Series A preferred shares, warrants, 3i Exchange Warrants, convertible debt, and the accrual for research and development expenses, fair values of acquired intangible assets and impairment review of those assets, share based compensation expense, and income tax uncertainties and valuation allowances. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Estimates are periodically reviewed considering reasonable changes in circumstances, facts, and experience. Changes in estimates are recorded in the period in which they become known and if material, their effects are disclosed in the notes to the consolidated financial statements. Actual results could differ from those estimates or assumptions.

(d) Foreign currency and currency translation

The functional currency is the currency of the primary economic environment in which an entity's operations are conducted. The Company and its subsidiaries operate mainly in Denmark and the United States. The functional currencies of the Company's subsidiaries are their local currency.

The Company's reporting currency is the U.S. dollar. The Company translates the assets and liabilities of its Denmark subsidiaries into the U.S. dollar at the exchange rate in effect on the balance sheet date. Revenues and expenses are translated at the average exchange rate in effect during each monthly period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the consolidated statements of changes in redeemable convertible preferred stock and stockholders' equity as a component of accumulated other comprehensive loss.

Monetary assets and liabilities denominated in currencies other than the functional currency are remeasured into the functional currency at rates of exchange prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are re-measured into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions are included in the determination of net loss for the respective periods.

Adjustments that arise from exchange rate translations are included in other comprehensive income (loss) in the consolidated statements of operations and comprehensive loss as incurred. The Company recorded a foreign exchange translation gain (loss) of $309 and ($121), included in accumulated other comprehensive loss for the years ended December 31, 2023 and 2022, respectively.

2. Summary of Significant Accounting Policies *(cont.)*

(e) Concentrations of credit risk and of significant suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash. The Company maintains its cash in financial institutions in amounts that could exceed government-insured limits. The Company does not believe it is subject to additional credit risks beyond those normally associated with commercial banking relationships. The Company has not experienced losses on its cash accounts and management believes, based upon the quality of the financial institutions, that the credit risk regarding these deposits is not significant. The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply its requirements for supplies and raw materials related to these programs. These programs could be adversely affected by a significant interruption in these manufacturing services or the availability of raw materials.

(f) Cash

Cash consists primarily of highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. The Company had no cash equivalents or restricted cash on December 31, 2023 and 2022.

(g) Property, plant and equipment

Property, plant, and equipment are stated at cost, less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful lives of the respective assets as follows:

	Estimated Useful Economic Life
Laboratory equipment	5 years
Furniture and office equipment	3 years

Upon retirement or sale, the cost of assets disposed of, and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations. As of December 31, 2023 and 2022, there have been no significant asset retirements to date. Expenditures for repairs and maintenance that do not improve or extend the lives of the respective assets are charged to expense as incurred.

(h) Impairment of long-lived assets

Long-lived assets consist of property, plant and equipment, and intangible assets. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. An impairment loss would be recognized as a loss from operations when estimated undiscounted future cash flows expected to result from the use of an asset group or the estimated return on investment are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flow or return on investment calculations.

(i) Acquired patents

Acquired patents are measured in the balance sheet at the lower of cost less accumulated amortization and impairment charges, if any. The legal costs incurred to renew or extend the term of the acquired patents are expensed as incurred. Cost comprises the acquisition price and the depreciation period are estimated at approximately 5 years with no residual value. Depreciation methods, useful lives and residual values are reviewed every year.

2. Summary of Significant Accounting Policies *(cont.)*

(j) Acquired in-process research and development (IPR&D)

Acquired IPR&D represents the fair value assigned to research and development assets that the Company acquired as part of a business combination and have not been completed at the acquisition date. The fair value of IPR&D acquired in a business combination is recorded on the consolidated balance sheets at the acquisition-date fair value and is determined by estimating the costs to develop the technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the projected net cash flows to present value. IPR&D is not amortized, but rather is reviewed for impairment on an annual basis or more frequently if indicators of impairment are present, until the project is completed, abandoned, or transferred to a third-party. Management assesses its acquired IPR&D for impairment at year end date as well as when events and circumstances indicate there is a potential impairment. Significant quantitative indicators considered are the Company's market capitalization, market share, length of remaining clinical trials, and projected revenue per treatment. The projected discounted cash flow models used to estimate the fair value of partnered assets and cost approach model used to estimate proprietary assets as part of the Company's IPR&D reflect significant assumptions regarding the estimates a market participant would make to evaluate a drug development asset, including the following:

- Estimates of obsolescence of development expenditure;
- Probability of successfully completing clinical trials and obtaining regulatory approval;
- Estimates of future cash flows from potential milestone payments and royalties related to out-licensed product sales; and
- A discount rate reflecting the Company's weighted average cost of capital and specific risk inherent in the underlying assets.

Once brought into use, intangible assets are amortized over their estimated useful economic lives using the economic consumption method if anticipated future revenues can be reasonably estimated. The straight-line method is used when revenues cannot be reasonably estimated. In the years ended December 31, 2023 and 2022, the Company has recorded impairment losses of $0 and $17,571 respectively on its intangible assets.

(k) Fair value measurements of financial instruments

The carrying value of the Company's financial instruments of cash, other current assets, accounts payable and accrued liabilities, approximate their fair value due to their short-term nature. The Company's other financial instruments include an equity investment, preferred shares, convertible debt, and warrant derivative liabilities. The equity investment is adjusted to fair market value at the end of every period based upon unadjusted quoted prices. The convertible debt and derivative liabilities that are freestanding equity-linked financial instruments are fair valued at the end of every period using level 3 inputs.

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. ASC Topic 820, Fair Value Measurement ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes between the following:

- Level 1 — defined as observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.

2. Summary of Significant Accounting Policies *(cont.)*

- Level 2 — defined as inputs other than quoted prices in active markets that are either directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and

- Level 3 — defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

In some circumstances, the inputs used to measure fair value might be categorized within different levels of the fair value hierarchy. In those instances, the fair value measurement is categorized in its entirety in the fair value hierarchy based on the lowest level input that is significant to the fair value measurement.

(l) Segment and geographic information

Operating segments are defined as components of a business for which separate discrete financial information is available for evaluation by the chief operating decision maker in deciding how to allocate resources and assess performance. The Company and its chief operating decision maker, the Company's Chief Executive Officer, view the Company's operations and manage its business as a single operating segment. The Company operates in two geographic areas: Denmark and the United States.

(m) Research contract costs and accruals

Research and development costs are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries, share-based compensation and benefits, facilities costs and laboratory supplies, depreciation, amortization and impairment expense, manufacturing expenses and external costs of outside vendors engaged to conduct preclinical development activities and clinical trials. Typically, upfront payments and milestone payments made for the licensing of technology are expensed as research and development in the period in which they are incurred.

The Company has entered into various research and development contracts with companies in Europe, the United States, and other countries. These agreements are generally cancellable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

(n) Research and development incentives and receivable

Denmark Tax Incentives

Denmark allows loss making companies the opportunity to apply for a payment equal to the tax value (22%) of negative taxable income related to R&D costs. The negative taxable income is calculated on the total negative income of the companies participating in the joint taxation. Tax payment according to this rule cannot exceed an amount of DKK 5.5 million, corresponding to a tax loss relating to R&D expenditure of DKK 25 million. The tax credit is recorded as tax receivable and other income within research and development expenses. In the years ended December 31, 2023 and 2022, the Company recorded $800 and $711 in tax credits, respectively, thereby reducing research and development expenses.

2. Summary of Significant Accounting Policies *(cont.)*

European Agency Grants

The Company, through its subsidiaries in Denmark, from time-to-time receives reimbursements of certain research and development expenditures as part of a European agency's research and development cost relief program. Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the research and development incentive program described above. At each period end, management estimates the reimbursement available to the Company based on available information at the time. The Company records these research and development expense reimbursements as a reduction to research and development expenses in the consolidated statements of operations and comprehensive loss, as the research and development cost reimbursements are not dependent on the Company generating future taxable income, the Company's ongoing tax status, or tax position. The Company recognizes a receivable for the research and development incentives when the relevant expenditure has been incurred, the associated conditions have been satisfied and there is reasonable assurance that the reimbursement will be received. During the years ended December 31, 2023 and 2022, the Company has not received or recorded government grants receivable.

(o) Convertible debt instruments

The Company follows ASC 480-10, *Distinguishing Liabilities from Equity* in its evaluation of the accounting for a hybrid instrument. A financial instrument that embodies an unconditional obligation, or a financial instrument other than an outstanding share that embodies a conditional obligation, that the issuer must or may settle by issuing a variable number of its equity shares shall be classified as a liability (or an asset in some circumstances) if, at inception, the monetary value of the obligation is based solely or predominantly on any one of the following: (a) a fixed monetary amount known at inception; (b) variations in something other than the fair value of the issuer's equity shares; or (c) variations inversely related to changes in the fair value of the issuer's equity shares. Hybrid instruments meeting these criteria are not further evaluated for any embedded derivatives and are carried as a liability at fair value at each balance sheet date with remeasurements reported in change on fair value expense in the accompanying Consolidated Statements of Operations and Comprehensive Loss.

Additionally, the Company accounts for certain convertible debt ("Convertible Notes") issued under the fair value option election of ASC 825, Financial Instruments wherein the financial instrument is initially measured at its issue-date estimated fair value and then subsequently re-measured at estimated fair value on a recurring basis at each reporting period date. The estimated fair value adjustment is recognized as other income (expense) in the accompanying consolidated statements of operations and the portion of the fair value adjustment attributed to a change in the instrument-specific credit risk is recognized as a component of other comprehensive loss. Convertible Notes are settled with shares at fair value of the stock issued with any differences recorded to other income (expense), as a gain (loss) on extinguishment.

(p) Warrants

When the Company issues warrants it evaluates the proper balance sheet classification to determine classification as either equity or as a derivative liability on the consolidated balance sheets. In accordance with ASC 815-40, Derivatives and Hedging-Contracts in the Entity's Own Equity ("ASC 815-40"), the Company classifies a warrant as equity so long as it is "indexed to the Company's equity" and several specific conditions for equity classification are met. A warrant is not considered indexed to the Company's equity, in general, when it contains certain types of exercise contingencies or adjustments to exercise price. If a warrant is not indexed to the Company's equity or it has net cash settlement that results in the warrants to be accounted for under ASC 480, Distinguishing Liabilities from Equity, or ASC 815-40, it is classified as a derivative liability, which is carried on the Consolidated Balance Sheet at fair value with any changes in its fair value recognized immediately in the Consolidated Statement of Operations and Comprehensive Loss. As of December 31, 2023 and 2022, the Company had warrants outstanding for share-based compensation that were classified as equity, and outstanding investor warrants that were classified as derivative liabilities and classified as "Warrant liabilities" in the Consolidated Balance Sheets.

2. Summary of Significant Accounting Policies *(cont.)*

(q) Derivative financial instruments

The Company does not use derivative instruments to hedge exposures to interest rate, market, or foreign currency risks. The Company evaluates all its financial instruments to determine if such instruments contain features that qualify as embedded derivatives. Embedded derivatives must be separately measured from the host contract if all the requirements for bifurcation are met. The assessment of the conditions surrounding the bifurcation of embedded derivatives depends on the nature of the host contract. Bifurcated embedded derivatives are recognized at fair value, with changes in fair value recognized in the Consolidated Statements of Operations and Comprehensive Loss each reporting period.

(s) Share-based compensation

The Company accounts for share-based compensation in accordance with ASC 718, Compensation — Stock Compensation ("ASC 718"). ASC 718 requires companies to estimate the fair value of equity-based payment awards on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service period in the Company's Consolidated Statements of Operations and Comprehensive Loss.

The Company records the expense for option awards using either a graded or straight-line method. The Company accounts for forfeitures as they occur. For share-based awards granted to both employee and non-employee consultants, the measurement date for non-employee awards is the date of grant. The compensation expense is then recognized over the requisite service period, which is the vesting period of the respective award.

The Company reviews all stock award modifications including when there is an exchange of original award for a new award. In the case of stock award modifications, the Company calculates for the incremental fair value based on the difference between the fair value of the modified award and the fair value of the original award immediately before it was modified. The Company immediately recognizes the incremental value as compensation cost for vested awards and recognizes, on a prospective basis over the remaining requisite service period, the sum of the incremental compensation cost and any remaining unrecognized compensation cost for the original award on the modification date.

The fair value of stock options ("options") on the grant date is estimated using the Black-Scholes option-pricing model using the single-option approach. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions, including the option's expected term and the price volatility of the underlying stock, to determine the fair value of the award. The Company applies the Black-Scholes model as it believes it is the most appropriate fair value method for all option awards. The Black-Scholes model requires several assumptions, of which the most significant are the share price, expected volatility and the expected award term.

Expected term of options granted is calculated using the simplified method being the average between the vesting period and the contractual term to the expected term of the options in effect at the time of grant. The Company has historically not paid dividends and has no foreseeable plans to pay dividends and, therefore, uses an expected dividend yield of zero in the option pricing model. The risk-free interest rate is based on the yield of U.S. treasury bonds with equivalent terms.

The Company classifies share-based compensation expense in its Consolidated Statements of Operations and Comprehensive Loss in the same way the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

2. Summary of Significant Accounting Policies *(cont.)*

(t) Accumulated other comprehensive loss

Accumulated other comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with shareholders. The Company records unrealized gains and losses related to foreign currency translation and instrument specific credit risk as components of other accumulated comprehensive loss in the Consolidated Statements of Operations and Comprehensive Loss. For the years ended December 31, 2023 and 2022, the Company's other comprehensive loss was comprised of currency translation adjustments and fair value adjustments attributable to instrument specific credit risk.

(u) Contingencies

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. At each reporting date, the Company evaluates whether a potential loss amount or a potential loss range is probable and reasonably estimable under the provisions of the authoritative guidelines that address accounting for contingencies. The Company expenses costs as incurred in relation to such legal proceedings as general and administrative expense within the Consolidated Statements of Operations and Comprehensive Loss.

(v) Income taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined based on the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not-to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that will more likely than not be realized upon ultimate settlement. Any provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits that are considered appropriate. The Company recognizes interest and penalties related to uncertain tax positions in other (income) expenses.

(w) Computation of loss per share

Basic net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common stock and common stock equivalents outstanding for the period. The Company adjusts net loss to arrive at the net loss attributable to common stockholders to reflect the amount of dividends accumulated during the period on the Company's redeemable convertible preferred stock, if any. The treasury stock method is used to determine the dilutive effect of the Company's stock option grants and warrants and the if-converted method is used to determine the dilutive effect of the Company's redeemable convertible preferred stock and Convertible Notes. For the years ended December 31, 2023 and 2022, the Company had a net loss attributable to common stockholders, and as such, all outstanding stock options, shares of redeemable convertible preferred stock, and warrants were excluded from the calculation of diluted loss per share. Under the if-converted method, convertible instruments that are in the money, are assumed to have been converted as of the beginning of the period or when issued, if later.

2. Summary of Significant Accounting Policies *(cont.)*

(x) Recently issued accounting pronouncements

Changes to GAAP are established by the FASB in the form of ASUs to the FASB's Accounting Standards Codification. The Company considers the applicability and impact of all ASUs. All other ASUs issued through the date of these financial statements were assessed and determined not to be applicable or are expected to have minimal impact on the Company's consolidated financial position and results of operations.

3. Other Current Assets

The Company's other current assets are comprised of the following:

	December 31,	
	2023	**2022**
Deposits	$ 56	$ 51
Salary deposit	22	85
Value added tax ("VAT") receivable	131	82
Deferred consulting costs	—	81
Deferred Directors & Officers insurance expense	—	1,260
	$ 209	$ 1,559

4. Intangible assets

Intangible assets, impairment charges and adjustments are summarized as follows:

	IPR&D Assets December 31,	
	2023	**2022**
Opening balance	$ 9,549	$ 28,135
Impairment recognized during the period	—	(17,571)
Foreign translation adjustment	322	(1,015)
Ending balance	$ 9,871	$ 9,549

As of the year ended December 31, 2023, because of continuing downward pressure on the Company's common stock, we performed an impairment assessment and determined that no further impairment of our intangible assets is required as of December 31, 2023.

As a result of both the Company's February 15, 2022, receipt of a Refusal to File ("RTF") from the U.S. Food and Drug Administration regarding the Company's new drug application ("NDA") for Dovitinib, and the current depressed state of the Company's stock price, the Company has performed an impairment assessment on its individual intangible assets utilizing a discounted cash flow model with a weighted average cost of capital ("WACC") of 16%, and recognized an impairment charge of $14,007 during the quarter ended March 31, 2022. During the quarter ended December 31, 2022, because of continued downward pressure on the Company's common stock, we performed a further impairment assessment on the Company's individual intangible asset utilizing a discounted cash flow model with a WACC of 26% and recognized a further impairment charge of $3,564.

The Company's IPR&D assets have been classified as indefinite-lived intangible assets. Our individual material development project in progress, Stenoparib, is recorded at $9,871 and $9,549 on December 31, 2023 and 2022, respectively.

5. Accrued liabilities

The Company's accrued liabilities are comprised of the following:

	December 31,	
	2023	2022
Development cost liability	$ 114	$ 964
Accrued interest on milestone liabilities	101	—
Payroll accruals	398	221
Accrued Board member fees	60	91
Accrued consulting fees	150	—
Accrued audit and legal	425	239
Other	61	389
	$ 1,309	$ 1,904

6. Convertible promissory note and accrued interest, net

On April 12, 2022, Allarity Denmark re-issued a Convertible Promissory Note (the "Promissory Note") to Novartis Pharma AG, a company organized under the laws of Switzerland ("Novartis," and together with Allarity Therapeutics Europe ApS ("Allarity Europe"), the "License Parties") in the principal amount of $1,000. The Promissory Note was re-issued pursuant to the First Amendment to License Agreement, with an effective date of March 30, 2022 (the "First Amendment"), entered into by and between the License Parties, which amended the License Agreement dated April 6, 2018 (the "Original Agreement") previously entered into by the License Parties relating to the Compound (as defined in the Original Agreement). The First Amendment amends and restates Section 11.7 of the Original Agreement to add the revised Note to the list of enforceable claims in the second paragraph of Section 11.7 making the revised Note enforceable under New York law as a legal obligation of Allarity Denmark ApS (formerly OV-SPV2 ApS). All other provisions of the Original Agreement and Promissory Note were unchanged and remain in full force and effect. The Promissory Note pays simple interest on the outstanding principal amount from the date until payment in full, which interest shall be payable at the rate of 5% per annum. Interest shall be calculated on the basis of a 360-day year for the actual number of days elapsed. Due to the Company's inability to meet its milestone payment commitments to Novartis, effective January 26, 2024, the Company has received a Termination Notice of all agreements with Novartis resulting in the promissory note and accrued interest in the amount of $300 becoming immediately due and payable. Accordingly, $1.3 million has been recorded as a current liability as of December 31, 2023.

During the years ended December 31, 2023 and 2022, the Company recorded $217 and $104, respectively, to interest expense and increased the convertible promissory note liability by the same amount. The roll forward of the Promissory Note as of December 31, 2023 and 2022, is as follows:

	December 31, 2023	December 31, 2022
Convertible promissory note	$ 1,083	$ 1,000
Less debt discount, opening	(232)	(215)
Plus, accretion of debt discount, interest expense	51	53
Convertible promissory note, net of discount	889	838
Interest accretion, opening	245	194
Interest accrual, expense	166	51
Convertible promissory note – net, ending balance	$ 1,300	$ 1,083

7. Secured Promissory Notes

On November 22, 2022, the Company entered into a Secured Note Purchase Agreement ("Purchase Agreement") with 3i, LP ("Holder", or "3i"), whereby the Company authorized the sale and issuance of three Secured Promissory Notes (each a "Note" and collectively, the "Notes"). Effective November 28, 2022, the Company issued: (1) a Note in the principal amount of $1,667 as payment of $1,667 due to 3i, LP in Alternative Conversion Floor Amounts that began to accrue on July 14, 2022; and (2) a Note in the principal amount of $350 in exchange for cash. Effective December 30, 2022, the Company issued an additional Note in the principal amount of $650 in exchange for cash. Each Note matures on January 1, 2024, carries an interest rate of 5% per annum, and is secured by all of the Company's assets pursuant to a security agreement (the "Security Agreement"). In addition, the Holder may exchange the Notes for the Company's common stock at an exchange price equal to the lowest price per share of the equity security sold to other purchasers, rounded down to the nearest whole share, if the Company concludes a future equity financing prior to the maturity date or other repayment of such promissory note. Lastly, each Note and interest earned thereon may be redeemed by the Company at its option at any time or the holder may demand redemption if a) the Company obtains gross proceeds of at least $5 million in a financing in an amount of up to 35% of the gross proceeds of the financing or b) there is an Event of Default (as defined in the Note agreement).

On April 19, 2023, 3i, provided the Company with a loan for $350, which was evidenced by a Secured Promissory Note dated April 19, 2023 (the "April Note").

On April 20, 2023, the Company entered into a Cancellation of Debt Agreement with 3i, which became effective as of the April Offering Closing. Upon the closing, pursuant to the terms of the Cancellation of Debt Agreement, all of the Company's outstanding indebtedness under the Notes (as defined therein) and the Alternative Conversion Amount (as defined therein) due by the Company to 3i were paid in full. Accordingly, any and all obligations in connection therewith were extinguished without any additional further action on the part of 3i upon payment of $3,348 in cash from a portion of the proceeds from the April Offering.

On June 29, 2023, the Company entered into a Secured Note Purchase Agreement with 3i, (the "June 2023 Purchase Agreement"), pursuant to which, on June 30, 2023, 3i purchased a secured promissory note for a principal amount of $350 (the "June Note"). Such note matured on July 31, 2023, and carried an interest rate of 5% per annum, and is secured by all of the Company's assets pursuant to that certain security agreement dated June 29, 2023 (the "Security Agreement"). As contemplated by the June 2023 Purchase Agreement, the Company filed the Second Certificate of Amendment with the Delaware Secretary of State on June 30, 2023. From the proceeds of the July Offering, on July 10, 2023, the Company redeemed the June Note for $351 in cash.

The roll forward of, the April Note and the June Note as of December 31, 2023 and 2022, is as follows:

	December 31, 2023	December 31, 2022
Secured promissory notes	$ 2,644	$ 2,667
Less debt discount, opening	—	(35)
Plus, accretion of debt discount, interest expense	—	2
Carrying value of the Notes	2,644	2,634
Interest accretion, opening	10	—
Interest accrual, expense	33	10
	$ 2,687	$ 2,644
Less: repayment April 10, 2023	(2,687)	—
Plus: June 2023 Promissory Note proceeds and interest	351	—
Less: July 10, 2023 repayment	(351)	—
Secured promissory note, ending balance	$ —	$ 2,644

8. Preferred Stock

A. Series A Preferred Stock and Common Stock Purchase Warrants

(a) Amendments to Series A Preferred Stock

On November 22, 2022, the Company amended Section 12 of the Certificate of Designation of Series A Convertible Preferred Stock ("Series A Preferred Stock") to provide for voting rights. Subject to a 9.99% beneficial ownership limitation, the holders of Series A Preferred Stock shall have the right to vote on all matters presented to the stockholders for approval together with the shares of common stock, voting together as a single class, on an "as converted" basis using the "Conversion Price" (initially $9.906 per share before any adjustment) (rounded down to the nearest whole number and using the record date for determining the stockholders of the Company eligible to vote on such matters), except as required by law (including without limitation, the DGCL) or as otherwise expressly provided in the Company's Certificate of Incorporation or the Certificate of Designations of Series A Convertible Preferred Stock. The voting rights described above expired on February 28, 2023, and thereafter holders of preferred stock shall not have voting rights except as required by law.

On December 9, 2022, the Company and 3i entered into a letter agreement which provided that pursuant to Section 8(g) of the Certificate of Designations for the Series A Preferred Stock, the parties agreed that the Conversion Price was modified to mean the lower of: (i) the Closing Sale Price on the trading date immediately preceding the Conversion Date and (ii) the average Closing Sale Price of the common stock for the five trading days immediately preceding the Conversion Date, for the Trading Days through and inclusive of January 19, 2023. Any conversion which occurs shall be voluntary at the election of the Holder, which shall evidence its election as to the Series A being converted in writing on a conversion notice setting forth the then Minimum Price. Management determined that the adjustment made to the Conversion Price is not a modification of the COD which allows for adjustments to the Conversion Price at any time by the Company and the other terms of the Certificate of Designations remained unchanged.

On January 23, 2023, we and 3i amended the letter agreement entered into on December 8, 2022, to provide that the modification of the term Series A Preferred Stock Conversion Price ("Series A Preferred Stock Conversion Price") to mean the lower of: (i) the Closing Sale Price (as defined in the Certificate of Designations of Series A Preferred Stock ("Series A Certificate of Designations")) on the trading date immediately preceding the Conversion Date (as defined in the Series A Certificate of Designations and (ii) the average Closing Sale Price of the common stock for the five trading days immediately preceding the Conversion Date, for the Trading Days (as defined in the Series A Certificate of Designations) will be in effect until terminated by us and 3i.

On April 20, 2023, the Company entered into a certain Modification and Exchange Agreement (the "Exchange Agreement") with 3i pursuant to which the parties agreed to, among other things, subject to the April Offering Closing, (i) amend the Certificate of Designations for the Series A Convertible Preferred Stock (the "Amended COD"), which among other things, eliminates the Series A Preferred Stock redemption right and dividend (except for certain exceptions as specified in the Amended COD), and provides for the conversion of Series A Preferred Stock into Common Stock at a conversion price of $0.75 which is equal to the price for a share of Common Stock sold in the April Offering, (ii) exchange 50,000 shares of Series C Preferred Stock (the "Series C Shares") beneficially owned by 3i for 5,577 shares of Series A Preferred Stock (the "Exchange Shares"), (iii) exchange a warrant to purchase common stock issued on December 20, 2021 to 3i (the "Original Warrant") for a new warrant (the "Exchange Warrant"), which reflects an exercise price of $30.00 (the "New Exercise Price") and represents a right to acquire 315,085 shares of Common Stock (the "New Warrant Shares"). In addition to the satisfaction or waiver of customary and additional closing conditions set forth in the Exchange Agreement, the transactions contemplated by the Exchange Agreement were subject to (a) the occurrence of the closing of the Offering and (b) the filing of the Amended COD with the Delaware Secretary of State. On April 21, 2023, the closing of the transactions contemplated by the Exchange Agreement occurred and the Exchange Warrant and the Exchange Shares were issued to 3i, and the Original Warrant and the Series C Shares were cancelled. In addition, on April 21, 2023, the Amended COD was filed with the Delaware Secretary of State.

8. Preferred Stock *(cont.)*

On April 20, 2023, the Company also entered into a Cancellation of Debt Agreement as described in Note 7. Pursuant to such agreement, 1,550 shares of Series A Preferred Stock (the "Redemption Shares") beneficially owned by 3i were redeemed in full for a purchase price of $1,652, which redemption price was paid in cash from the portion of the proceeds from the April Offering. The Company also entered into the First Amendment to the Registration Rights Agreement dated May 20, 2023 (the "RRA"), which became effective upon the April Offering Closing, to amend certain defined terms under the RRA to include the Exchange Shares, the New Warrant Shares and the Note Conversion Shares.

On April 21, 2023, in connection with the transactions contemplated under the Exchange Agreement, the Company filed an Amended and Restated Certificate of Designations of Series A Convertible Preferred Stock of the Company (the "Amended and Restated Series A COD") with the Delaware Secretary of State. The Amended and Restated Series A COD eliminates the Series A Preferred Stock redemption right and dividend (except for certain exceptions as specified therein) and provides for the conversion of Series A Preferred Stock into Common Stock at a conversion price equal to the price for a share of Common Stock sold in the April Offering, $30.00 per share, and based on a stated value of $1,080 per share. As a result of the Amended and Restated Series A COD, the Company determined that the Series A Preferred Stock met the definition of equity and reclassified it from mezzanine equity.

On May 30, 2023, the Company filed an amendment to the Amended and Restated Certificate of Designations for the Series A Preferred Stock with the Delaware Secretary of State (the "Amended COD") to amend the voting rights of the Series A Preferred Stock which among other things provided additional voting rights to the Series A Preferred Stock.

Under the Amended COD, holders of the Series A Preferred Stock have the following voting rights: (1) holders of the Series A Preferred Stock have a right to vote on all matters presented at the Special Meeting together with the Common Stock as a single class on an "as converted" basis using the conversion price of $30.00 and based on stated value of $1,080 subject to a beneficial ownership limitation of 9.99%, and (2), in addition, holders of Series A Preferred Stock have granted the Board the right to vote, solely for the purpose of satisfying quorum and casting the votes necessary to adopt a reverse stock split of the Company's issued and outstanding shares of Common Stock (the "Reverse Stock Split Proposal") and to adjourn any meeting of stockholders called for the purpose of voting on reverse stock split (the "Adjournment Proposal") under Delaware law, that will "mirror" the votes cast by the holders of shares of Common Stock and Series A Preferred Stock, voting together as a single class, with respect to the Reverse Stock Split Proposal and the Adjournment Proposal.

The number of votes per each share of Series A Preferred Stock that may be voted by the Board shall be equal to the quotient of (x) the sum of (1) the original aggregated stated value of the Series A Preferred Stock when originally issued on December 20, 2021 (calculated based on the original stated value of $1,000 of the Series A Preferred Stock multiplied by 20,000 shares of Series A Preferred Stock) and (2) $1,200, which represents the purchase price of the Series C Preferred Stock when originally issued; divided by (y) the conversion price of $30.00. If the Board decides to cast the vote, it must vote all votes created by the Amended COD in the same manner and proportion as votes cast by the holders of Common Stock and Series A Preferred Stock, voting as single class. The Series A Preferred Stock voting rights granted to the holders thereof relating to the Reverse Stock Split Proposal and the Adjournment Proposal 2 expired automatically on July 31, 2023.

In addition, among other things, the Reverse Stock Split Proposal, the effectuation of the June Reverse Stock Split, and the amendment to the Company's Certificate of Incorporation, are subject to the consent by the holders of a majority of the then outstanding shares of Series A Preferred Stock. Such consent was received on June 27, 2023.

The Series A Preferred Stock has a liquidation preference equal to an amount per Series A Preferred Stock equal to the sum of (i) the Black Scholes Value (as defined in the Warrants, which was sold concurrent with the Series A Preferred Stock) with respect to the outstanding portion of all Warrants held by such holder (without regard to any limitations on the exercise thereof) as of the date of such event and (ii) the greater of (A) 125% of the Conversion Amount of such Series A Preferred Stock on the date of such payment and (B) the amount per share such holder would receive if such holder converted such Series A Preferred Stock into Common Stock immediately prior to the date of such payment, and will be entitled to convert into shares of Common Stock at an initial fixed conversion price of $30.00 per share, subject to a beneficial ownership limitation of 9.99%.

8. Preferred Stock *(cont.)*

If certain defined "triggering events" defined in the Series A COD, as amended and restated and further amended, occur, or our failure to convert the Series A Preferred Stock into Common Stock when a conversion right is exercised, failure to issue our Common Stock when the Exchange Warrant is exercised, failure to declare and pay to any holder any dividend on any dividend date, then we may be required to pay a dividend on the stated value on the Series A Preferred Stock in the amount of 18% per annum, but paid quarterly in cash, so long as the triggering event is continuing.

On June 6, 2023, 3i and the Company entered into a separate limited waiver and amendment agreement whereby 3i ("3i Waiver Agreement") agreed to waive certain rights granted under a Series A Preferred Stock securities purchase agreement dated December 20, 2021, the Exchange Agreement, and the securities purchase agreement related to the April Offering in exchange for, among other things, amending the conversion price of the Series A Preferred Stock to equal the public offering price of the shares of Common Stock in the July Offering. Upon the consummation of the July Offering, the conversion price of the Series A Preferred Stock was reduced to $4.50. On July 10, 2023, the Company filed a Third Certificate of Amendment to the Amended and Restated Certificate of Designations of Series A Preferred Stock ("Third Amendment") to effect the change to conversion price.

In connection with the September 2023 Inducement Letter and the transactions contemplated therein, the Company and 3i, LP entered into a limited waiver agreement (the "Waiver") pursuant to which 3i, LP agreed to allow the filing of the Resale Registration Statement not otherwise permitted under certain agreements with 3i, LP. In consideration of entering in the Waiver, the Company agreed to amend the "Conversion Price" of the Series A Convertible Preferred Stock to equal $1.00 as soon as practicable. On September 22, 2023, the Company filed the Fourth Certificate of Amendment to the Amended and Restated Certificate of Designations of Series A Convertible Preferred Stock ("Fourth Amendment") with the Secretary of State of the State of Delaware to reflect the new conversion price of the Series A Preferred Stock of $1.00. Subsequent to December 31, 2023, the Series A Preferred Stock conversion price was reduced (see Note 18(c)).

(b) Series A Preferred Stock Triggering Event

As more specifically discussed below, a "Triggering Event" under the COD occurred on April 29, 2022, under Section 5(a)(ii) of the COD, which would have resulted in the following unless 3i, agreed to forebear and/or waive its rights under the COD:

1. An 18% per annum dividend will start to accrue on the stated value of all outstanding Preferred Shares and will continue to accrue until the Triggering Event has been cured. The accrued dividend is added to the stated value prior to the Dividend Payment Date and paid in cash on the first trading day of the Company's next fiscal quarter. A "Late Charge" in the amount of 18% per annum will accrue on any amounts due to be paid to holders of the Preferred Shares if not paid when due, including payments that may be owed under Section (e) of the Registration Rights Agreement ("RRA").

2. A "Triggering Event Redemption Right" will commence and remain open for a period of 20 trading days from the later of the date either the Triggering Event is cured or the receipt by 3i of the Triggering Event Notice. Under the Triggering Event Redemption Right, if elected by the holder of the Preferred Shares, the Company would be obligated to redeem all or a portion of the Preferred Shares for a minimum of 125% of the stated value of the Preferred Shares. Concurrently, under the provisions of the PIPE Warrant, if elected by 3i, the Company would be obligated to redeem the PIPE Warrant for the Black Sholes Triggering Event Value as defined in the warrant agreement.

3. A "Registration Delay Payment" will accrue on April 22, 2022 (the expiration of the Allowable Grace Period under the RRA) in the amount of 2% of 3i's "Purchase Price" as defined in the Securities Purchase Agreement which is approximately 2% of $20 million, or $400 and will continue to accrue at 2% every 30 days thereafter. Additionally, a late charge of 2% per month will accrue on any payments that are not paid when due. The Registration Delay Payments will stop accruing when the post-effective amendment is declared effective by the SEC at which time the registration statement and its prospectus will again be available for the resale of common stock.

8. Preferred Stock *(cont.)*

As a result of the Company's delay in filing its periodic reports with the SEC in 2022, a "triggering event" under Section 5(a)(ii) of the Original Series A COD, occurred on or about April 29, 2022, and because of the delay the Company was obligated to pay (i) registration delay payments under the RRA, (ii) additional amounts under the Original Series A COD, and (iii) legal fees incurred in the preparation of the Forbearance Agreement and Waiver to 3i in an aggregate amount of $539 which was paid pursuant to that certain Forbearance Agreement and Waiver with 3i.

On May 4, 2022, the Company and 3i entered into a Forbearance Agreement and Waiver, dated April 27, 2022, wherein 3i confirmed that no Triggering Event as defined under the COD has occurred prior to April 27, 2022, that a Triggering Event under Section 5(a)(ii) will and has occurred on April 29, 2022, and that in consideration for the Registration Delay Payments the Company is obligated to pay under the RRA, and additional amounts the Company is obligated to pay under the COD and 3i's legal fees incurred in the preparation of the Forbearance Agreement and Waiver in the aggregate of $539 paid upon execution of the Forbearance Agreement and Waiver, and so long as the Company pays the Registration Delay Payments that become due and payable under the RRA after the execution of the Forbearance Agreement and Waiver, 3i has agreed to forbear exercising any rights or remedies that it may have under the COD that arises as a result of a Triggering Event under Section 5(a)(ii) of the COD and Section 4(c)(ii) of the PIPE Warrant until the earlier to occur of (i) the date immediately prior to the date of occurrence of a Bankruptcy Triggering Event, (ii) the date of occurrence of any other Triggering Event under Section 5(a) of the COD (excluding any Triggering Event arising solely as a result of Section 5(a)(ii) of the COD and Section 4(c)(ii) of the PIPE Warrant), (iii) the time of any breach by the Company under the Forbearance Agreement and Waiver, (iv) the Resale Availability Date as defined therein and (v) June 4, 2022 (such period, the "Forbearance Period"). Provided that the Company is not in breach of its obligations under Forbearance Agreement and Waiver, effective as of the Trading Day immediately following the date the Company cures the Triggering Event under Section 5(a)(ii) of the COD, 3i agrees to waive any rights or remedies that it may have under the COD that arises as a result of a Triggering Event under Section 5(a) of the COD and Section 4(c)(ii) of the PIPE Warrant that may have arisen prior to the date of the Forbearance Agreement and Waiver.

(c) 3i Warrants

Effective April 21, 2023, pursuant to the terms of an Exchange Agreement, the PIPE Warrant was exchanged for an Exchange Warrant representing a right to acquire 315,085 shares of Common Stock, exercisable at $30.00 per share. The number of shares exercisable under the Exchange Warrant and the exercise price was subsequently adjusted in July 2023 to the right to acquire 9,452,667 shares of Common Stock, exercisable at $1.00 per share.

Effective July 10, 2023, upon the closing of the July Offering, the number of shares exercisable under the Exchange Warrant and the exercise price was adjusted to 2,100,565 shares of Common Stock and $4.50 per share, respectively. Subsequently on July 26, 2023, pursuant to Section 2(e) of the Exchange Warrant, due to the event market price on the 16th day after the June Reverse Stock Split being less than the exercise price of the Exchange Warrant then in effect, the number of shares exercisable under such Warrant and the exercise price was further adjusted to 3,134,693 shares and $3.0155 per share, respectively.

Effective September 14, 2023, the date of the September Induced Warrant offering, the number of shares exercisable under the Exchange Warrant and the exercise price was adjusted to 9,452,667 shares of Common Stock and $1.00 per share, respectively. On December 5, 2023, 3i exercised 5,045,466 Exchange Warrants on a cashless basis in exchange for 500,000 common shares. As of December 31, 2023, there were 4,407,201 Exchange Warrants, exercisable at $1.00, outstanding. After December 31, 2023, the exercise price of the Exchange Warrants was reduced (see Note 18(c)).

(d) Accounting

i. Series A Preferred Stock

The Company evaluated the Series A Preferred Stock under ASC 480-10 to determine whether it represents an obligation that would require the Company to classify the instrument as a liability and determined that the Series A Preferred Stock is not a liability pursuant to ASC 480-10. Management then evaluated the instrument pursuant to ASC 815 and determined that because the holders of the Series A Preferred Stock may be entitled to receive cash, the Series A Preferred stock should be recorded as mezzanine equity given the cash redemption right that is within the holder's control.

8. Preferred Stock *(cont.)*

Generally, preferred stock that are currently redeemable should be adjusted to their redemption amount at each balance sheet date. If it is probable that the equity instrument will become redeemable, the Company has the option to either accrete changes in the redemption value over the period from the date of issuance (or from the date that it becomes probable that the instrument will become redeemable, if later) to the earliest redemption date of the instrument or to recognize changes in the redemption value immediately as they occur and adjust the carrying amount of the instrument to equal the redemption value at the end of each reporting period. The Company recognizes changes in redemption value when redemption becomes probable to occur.

Through December 9, 2022, the derivative scope exception under ASC 815 was not met because a settlement contingency was not indexed to the Company's stock. Therefore, the redemption feature (derivative liability) was bifurcated from the Series A Preferred Stock and recorded as a derivative liability. The fair value of the Series A Preferred Stock Redemption Feature (the "Redemption Feature") derivative is the difference between the fair value of the Series A Preferred Stock with the Redemption Feature and the Series A Preferred Stock without the Redemption Feature. The Series A Preferred Stock Redemption Feature has been valued with a Monte Carlo Simulation model, using the inputs as described in Note 9(b).

Subsequent to December 9, 2022, because of the agreed conversion price adjustment, although bifurcation of the conversion feature is still required, the value of the derivative has been determined to be immaterial since the conversion price will always be at market. Additionally, because the Series A redemption terms were amended to be entirely within the Company's control, they have now been classified as permanent equity. Management has fair valued the Series A Preferred Stock prior to and after its modification and because the change in fair value was greater than 10%, has made a policy election to treat the amendment as an extinguishment. Accordingly, the difference in fair value has been recorded as a deemed dividend and reduction in additional paid in capital.

Deemed Dividends

In the year ended December 31, 2023, the Company, has recorded $8,392 in deemed dividends resulting from using the Black-Scholes model to determine the fair value the Company's Series A Preferred shares as follows:

i. $3,328 on the elimination of Series A redemption rights as of April 21, 2023,
ii. $3,959 on the Exchange of 50,000 Series C Preferred Stock for 5,577 Series A Preferred Stock;
iii. $206 on the July 10, 2023, modification of Series A Preferred Stock;
iv. $526 on the redemption of Series A Preferred Stock; and
v. $373 on the September 14, 2023 modification of Series A Preferred Stock.

As of the dates noted below, the Company used the Black-Scholes option pricing model to determine the fair values using the following inputs:

	Series A Preferred Shares September 14, 2023	Series A Preferred Shares July 10, 2023
Number of shares valued	1,417	6,047
Stock Price	$ 1.00	$ 3.40
Exercise price pre-modification	$ 4.50	$ 8.00
Exercise price post-modification	$ 1.00	$ 4.50
Risk fee rate	5.37%	5.28%
Dividend	0%	0%
Volatility	119%	140%

8. Preferred Stock *(cont.)*

During the year ended December 31, 2023, the Company used the Black-Scholes option pricing model to determine the fair values using the following inputs:

	Original Series A Preferred Shares	Debt Settled for Series A Preferred Shares	Series C Preferred Shares Exchanged for Series A Preferred Shares
Number of shares valued	4,239	5,577	486
Stock Price at April 21, 2023 post 40 to 1 split	$ 20.40	$ 20.40	$ 20.40
Exercise price	$ 30.00	$ 30.00	$ 30.00
Risk fee rate	5.1%	5.1%	5.1%
Dividend	0%	0%	0%
Expected liquidity event	September 15, 2023	September 15, 2023	September 15, 2023
Volatility	156%	156%	156%

ii. 3i Warrants

The 3i Warrants were identified as a freestanding financial instrument and meet the criteria for derivative liability classification, initially measured at fair value. Subsequent changes in fair value are recognized through earnings for as long as the contracts continue to be classified as a liability. The measurement of fair value is determined utilizing an appropriate valuation model considering all relevant assumptions current at the date of issuance and at each reporting period (i.e., share price, exercise price, term, volatility, risk-free rate and expected dividend rate).

(f) Series A Preferred Stock Conversions

i. Year ended December 31, 2023

During the year ended December 31, 2023, 3i exercised its option to convert 12,052 shares of Series A Preferred stock for 241,893 shares of common stock at the fair value of $3,899. From the proceeds of the July Offering, on July 10, 2023, the Company redeemed (i) 4,630 shares of Series A Preferred Stock held by 3i, for $5,000, and (ii) the 3i June Promissory Note (as defined below) for $351 in cash. As a result of the payment, the 3i June Promissory Note was paid in full on July 10, 2023. As of December 31, 2023, the Company had 1,417 shares of Series A Preferred Stock issued and outstanding. (See Note 18(b).)

ii. Year ended December 31, 2022

During the year ended December 31, 2022, 3i exercised its option to convert 6,214 shares of Series A Preferred stock for 5,573 shares of common stock. As of December 31, 2022, we had 13,586 shares of Series A Preferred Stock issued and outstanding. The fair value of the derivative liability associated with the Series A Preferred Stock converted during the year ended December 31, 2022, as determined by Monte Carlo simulations, was $954.

Because the latest nine conversions in the period January 1, 2022, through December 9, 2022, were completed at less than the agreed floor price, we recorded a floor price liability and recognized a corresponding reduction of additional paid in capital, as follows:

i. During the six months ended June 30, 2022, $1,511 (paid in cash prior to June 30, 2022);

ii. During the three months ended September 30, 2022, $1,646 (see Note 9(b));

iii. On December 9, 2022, we issued 86 shares of Common Stock to the Investor upon the conversion of 222 Conversion Shares and recorded a floor price liability of $264.

8. Preferred Stock *(cont.)*

Additionally, because the Company's average daily dollar volume of stock trading was less than $2.5 million during a ten-day period in January 2022, the Company has recorded a one-time deemed dividend of 8% in the amount of $1,572 on preferred stock converted between February 1, 2022 and March 31, 2022 and the balance of Series A Preferred Stock outstanding as at March 31, 2022 as an increase to the value of the Series A Preferred Stock and a reduction of additional paid in capital. In addition, under the terms of the Registration Rights Agreement ("RRA"), during the year ended December 31, 2022, the Company has also paid 3i an additional $800 in Registration Delay Payments.

The accounting for the Series A Preferred Stock and 3i Exchange Warrants is illustrated in the table below:

	Consolidated Balance Sheets				Consolidated Statement of Operations & Comprehensive Loss
	3i Exchange Warrant liability	Series A Convertible Preferred Stock – Mezzanine Equity	Series A Preferred Stock	Additional paid-in capital	Fair value adjustment to derivative and warrant liabilities
Balances at December 31, 2022	$ 374	$ 2,001	$ —	$ (3,756)	$ —
Conversion of 9,247 Series A Preferred Stock, net	—	(1,377)	(2,522)	3,909	—
Elimination of redemption rights on Series A Preferred stock; deemed dividend of $3,328	—	(624)	3,952	(3,328)	—
Redemption of 6,180 Series A Preferred Stock, deemed dividend of $526	—	—	(5,919)	(526)	—
Issuance of 486 Series A Preferred stock as repayment of $350 debt; $103 charged to interest expense	—	—	453	—	—
Exchange of 50,000 Series C Preferred Stock for 5,577 Series A Preferred Stock; deemed dividend of $3,959	—	—	5,199	(3,959)	—
Deemed dividend on July 10, 2023 modification	—	—	206	(206)	—
Deemed dividend on September 14, 2023 modification	—	—	373	(373)	—
Cashless redemption of 5,045,446 Exchange Warrants for 500,000 common shares	(1,031)	—	—	1,031	—
Fair value adjustment	1,477	—	—	—	(1,477)
Balances, December 31, 2023	$ 820	$ —	$ 1,742	$ (7,208)	$ (1,477)

8. Preferred Stock *(cont.)*

The accounting for the Series A Preferred Stock and 3i Exchange Warrants is illustrated in the table below:

	Consolidated Balance Sheets				Consolidated Statement of Operations & Comprehensive Loss
	3i Exchange Warrant liability	Series A Convertible Preferred Stock – Mezzanine Equity	Series A Preferred Stock	Additional paid-in capital	Fair value adjustment to derivative and warrant liabilities
Balances at December 31, 2021	$ 11,273	$ 7,181	$ 632	$ 80	$ —
Conversion of 6,214 shares of Series A Preferred stock into common stock	—	—	(203)	203	—
Reclassification of derivative liability relating to converted Series A Preferred Stock	—	(954)	—	954	—
Floor price adjustment on conversion of shares of Series A Preferred Stock	—	—	—	(3,421)	—
8% deemed dividend on Preferred Stock	—	—	1,572	(1,572)	—
Fair value adjustment	(10,899)	(6,227)	—	—	17,125
Balances, December 31, 2022	$ 374	$ —	$ 2,001	$ (3,756)	$ 17,125

* Valuation of the Series A Preferred Derivative Liability is discussed in Note 9(b).

B. Series C Convertible Preferred Stock

On February 28, 2023, the Company entered into a Securities Purchase Agreement (the "SPA") with 3i, L.P. for the purchase and sale of 50,000 shares of Series C Convertible Redeemable Preferred Stock ("Series C Preferred Stock") at a purchase price of $24.00 per share, for a subscription receivable in the aggregate amount equal to the total purchase price of $1.2 million (the "Offering"). The 50,000 shares of Series C Preferred Stock (the "Shares") are convertible into shares of the Company's common stock, subject to the terms of the COD. The conversion price for the Series C Preferred Stock is initially equal the lower of: (i) $0.182 ($6.37 post reverse stock split), which is the official closing price of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) on the Trading Day (as defined in the COD) immediately preceding the Original Issuance Date (as defined in the COD); and (ii) the lower of: (x) the official closing price of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) on the Trading Day immediately preceding the Conversion Date or such other date of determination; and (y) the average of the official closing prices of the Common Stock on the Nasdaq Global Market (as reflected on Nasdaq.com) for the five Trading Days immediately preceding the Conversion Date (as defined in the COD) or such other date of determination, subject to adjustment (the "Conversion Price"). In no event will the Conversion Price be less than $0.0370 ($1.295 post reverse stock split) (the "Floor Price").

8. Preferred Stock *(cont.)*

In the event that the Conversion Price on a Conversion Date would have been less than the applicable Floor Price if not for the immediately preceding sentence, then on any such Conversion Date the Company will pay the Holder an amount in cash, to be delivered by wire transfer out of funds legally and immediately available therefor pursuant to wire instructions delivered to the Company by the Holder in writing, equal to the product obtained by multiplying (A) the higher of (I) the highest price that the Common Stock trades at on the Trading Day immediately preceding such Conversion Date and (II) the applicable Conversion Price and (B) the difference obtained by subtracting (I) the number of shares of Common Stock delivered (or to be delivered) to the Holder on the applicable Share Delivery Date with respect to such conversion of Series C Preferred Stock from (II) the quotient obtained by dividing (x) the applicable Conversion Amount that the Holder has elected to be the subject of the applicable conversion of Series C Preferred Stock, by (y) the applicable Conversion Price without giving effect to clause (x) of such definition. The Offering closed on February 28, 2023.

In connection with the Offering, concurrently with the SPA, the Company entered into a registration rights agreement with 3i (the "RRA") pursuant to which the Company is required to file a registration statement with the SEC to register for resale the shares of Common Stock that are issued upon the potential conversion of the Shares. Under the terms of the RRA, if the Company fails to file an Initial Registration Statement (as defined in the RRA) on or prior to its Filing Date (as defined in the RRA), or fail to maintain the effectiveness of the registration statement beyond defined allowable grace periods set forth in the RRA, we will incur certain registration delay payments, in cash and as partial liquidated damages and not as a penalty, equal to 2.0% of 3i's subscription amount of the Shares pursuant to the SPA. In addition, if we fail to pay any partial liquidated damages in full within seven days after the date payment, we will have to pay interest at a rate of 18.0% per annum, accruing daily from the date such partial liquidated damages are due until such amounts, plus all such interest thereon, are paid in full. The Company has also agreed to pay all fees and expenses incident to the performance of the RRA, except for any broker or similar commissions. In connection with the Offering, the Company and 3i entered into a limited waiver agreement (the "Waiver") pursuant to which 3i confirmed that the sale and issuance of the Shares will not give rise to any, or trigger any, rights of termination, defaults, amendment, anti-dilution or similar adjustments, acceleration or cancellation under agreements with 3i.

The Company has evaluated the terms of the Series C Preferred Stock as required pursuant to ASC 570, 480, 815 and ASU 2020-06, and concluded the Series C Preferred Stock will be recorded at fair value of $1,200, net of share issuance costs of $40, and accreted dividends at 5% to redemption value of $1,446 on April 21, 2023, using the effective interest method. Effective April 21, 2023, all of the 50,000 shares of Series C Preferred stock were exchanged for 5,577 shares of Series A Preferred Stock at an agreed value of $1,652.

The Company has treated the exchange of Series C Preferred Stock for Series A Preferred Stock as an extinguishment as there has been a fundamental change in the nature of the instrument and has applied the derecognition accounting model in ASC 260-10-S99-2. Accordingly, the Company has recognized the difference between (1) the fair value of the consideration transferred to the holders of the preferred shares of $5,200, and (2) the carrying amount of the preferred shares (net of issuance costs), of $1,240 as a deemed dividend of $3,959 that is deducted from additional paid in capital and subtracted from net income to arrive at income available to common stockholders in the calculation of loss per common share.

The roll forward of the Series C Preferred Stock as of December 31, 2023, is as follows:

	December 31, 2023
Opening balance at January 1, 2023	$ —
Series C Preferred Stock, cash received	1,200
Less debt discount, opening	(40)
Plus, 5% dividend and accretion	286
	1,446
Exchange of Series C Preferred stock for Series A Preferred stock	(1,446)
Series C Preferred Stock – net, ending balance	$ —

9. Derivative Liabilities

(a) Continuity of Warrant Derivative Liabilities

The derivative liabilities are measured at fair value at each reporting period and the reconciliation of changes in fair value in the years ended December 31, 2023 and 2022, is presented in the following tables:

	Common Share Purchase Warrants	3i Exchange Warrants	3i Fund Series A Redemption Feature
		Issued December 20, 2021	
Balance as of January 1, 2022	$ —	$ 11,273	$ 7,181
Change in fair value	—	(10,899)	(6,227)
Amount transferred to Equity	—	—	(954)
Balance as of December 31, 2022	$ —	$ 374	$ —
Fair value per 3i Warrant / Series A Preferred share issuable at period end	$ —	$ 6.48	$ —
Balance as of January 1, 2023	$ —	$ 374	$ —
Issuance date fair value of April, July & September 2023 Common share purchase warrants	15,161	—	—
Modifications to fair value upon exercise	592	—	—
Fair value adjustments	(11,911)	1,477	—
Amount transferred to Equity	(1,579)	(1,031)	—
Balance as of December 31, 2023	$ 2,263	$ 820	$ —
Fair value per Common warrant / 3i Warrant / Series A Preferred share issuable at period end	$ 0.44	$ 0.19	$ —

(b) Series A Preferred Stock Conversion Feature – Valuation Inputs

The following inputs were used for the Series A Preferred Stock conversions recorded in the year ended December 31, 2022, and the fair value of the Series A Preferred derivative liability determined at September 30, 2022:

	January 1, 2022 – September 30, 2022*
Initial exercise price	$9.05 - $9.91
Stock price on valuation date	$1.10 - $10.75
Risk-free rate	1.03% - 4.23%
Time to exercise (years)	2.22 - 2.96
Equity volatility	70% - 114%
Probability of volume failure	93% - 99%
Rounded 10-day average daily volume (in 1,000's)	$297 - $873

* The agreed conversion price adjustment (see Note 8(d) i.) resulted in the Series A Preferred liability value derivative being valued at zero at December 9, 2022. Consequently, there were no conversions subsequent to September 30, 2022, which impacted the Series A derivative liability.

(c) 3i Warrants – Valuation Inputs

On December 5, 2023, 3i converted 5,045,446 Exchange Warrants on a cashless basis for 500,000 shares of our Common Stock. Therefore, we utilized the reset strike options Type 2 model by Espen Garder Haug and Black-Scholes Merton models to estimate the fair value of the outstanding 9,452,667 Exchange Warrants immediately before 3i's conversion to be approximately $1,931 as of December 5, 2023. Accordingly, we recorded a $2,015 reduction in the fair value of the 9,452,667 Exchange Warrants as a credit to change in fair value of warrants in our consolidated statement of comprehensive loss and $1,031, being the fair value of the 5,045,446 converted Exchange Warrants, was recorded as a credit to additional paid in capital.

9. Derivative Liabilities *(cont.)*

On December 31, 2023 and 2022, the Company utilized the reset strike options Type 2 model by Espen Garder Haug and Black-Scholes Merton models to estimate the fair value of the 3i Exchange Warrants to be approximately $820 and $374, respectively.

The 3i Exchange Warrants were valued at December 31, 2023, December 5, 2023, and December 31, 2022, using the following inputs:

	December 31, 2023	December 5, 2023	December 31, 2022
Exercise price	$ 1.00	$ 1.00	$ 9.91
Stock price on valuation date	$ 0.55	$ 0.58	$ 0.29
Risk-free rate	4.71%	4.92%	4.33%
Expected life of the Warrant to convert (years)	0.97	1.04	1.97
Rounded annual volatility	127%	123%	131%
Timing of liquidity event	Q1 - 2024	March 31, 2024	March 15, 2023
Expected probability of event	10%	10%	100%

10. Stockholders' Equity

(a) Amendments to Certificate of Incorporation and Reverse Stock Splits

On March 20, 2023, an amendment to Allarity Therapeutics, Inc.'s Certificate of Incorporation, as amended (the "Certificate of Incorporation"), to increase the number of authorized shares from 30,500,000 to 750,500,000, and to increase the number of shares of common stock (the "Common Stock") from 30,000,000 to 750,000,000 (the "Share Increase") was approved by the stockholders of record entitled to vote in person or by proxy at the Special Meeting of Stockholders on March 20, 2023 (the "2023 Special Meeting"). Upon receipt of the required stockholder approval, on March 20, 2023, Allarity Therapeutics, Inc. (the "Company"), filed a Third Certificate of Amendment to the Certificate of Incorporation (the "Certificate of Amendment") with the Secretary of State of the State of Delaware (the "Delaware Secretary of State") to effect the Share Increase. On March 23, 2023, the Company filed a Third Certificate of to the Certificate of Incorporation with the Delaware Secretary of State to effect a 1-for-35 share consolidation of our common stock on March 24, 2023 ("March Reverse Stock Split"). No fractional shares were issued in connection with the March Reverse Stock Split. If, as a result of the March Reverse Stock Split, a stockholder would otherwise have been entitled to a fractional share, each fractional share was rounded up to the next whole number. The March Reverse Stock Split resulted in a reduction of our outstanding shares of common stock from 34,294,582 to 979,846.

As a result of the filing of the Certificate of Amendment, the Company is authorized to issue 750,500,000 shares, consisting of (i) 750,000,000 shares of common stock, par value $0.0001 per share, and (ii) 500,000 shares of preferred stock, par value of $0.0001 per share.

On June 23, 2023, we held a Special Meeting of Stockholders (the "Special Meeting") for our stockholders of record of our outstanding shares of Common Stock and Series A Preferred Stock. At the Special Meeting, the stockholders of Common Stock and Series A Preferred Stock approved an amendment to our Certificate of Incorporation, to, at the discretion of the board, effect a reverse stock split with respect to our issued and outstanding Common Stock at a ratio between 1-for-15 and 1-for-50 (the "June Reverse Stock Split Proposal"). Upon stockholder approval, the Board of Directors determined a ratio of 1-for-40 for the reverse stock split (the "June Reverse Stock Split"). On June 28, 2023, the Company filed a Fourth Certificate of Amendment of the Certificate of Incorporation to effect the June Reverse Stock Split on June 28 2023 (the "June Share Consolidation"). No fractional shares were issued in connection with the June Share Consolidation. If, as a result of the June Share Consolidation, a stockholder would otherwise have been entitled to a fractional share, each fractional share was rounded up to the next whole number. The June Share Consolidation resulted in a reduction of our outstanding shares of Common Stock from 20,142,633 to approximately 503,566. The par value of our authorized stock remained unchanged at $0.0001.

As of the date of these financial statements all references to our common stock have been retrospectively adjusted to reflect both the March Share Consolidation and the June Share Consolidation (the "Share Consolidations"), unless otherwise noted.

10. Stockholders' Equity *(cont.)*

(b) Redemption of Series B Preferred Stock

Upon conclusion of the 2023 Annual Meeting of Stockholders on February 3, 2023, all the 190,786 shares of Series B Preferred Stock outstanding were automatically redeemed, with the holders of the Series B Preferred Stock only having a right to receive the purchase price for the redemption, which was $0.01 per share of Series B Preferred Stock.

(c) Series C Preferred Stock

On February 24, 2023, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Redeemable Preferred Stock (the "Series C COD") with the Delaware Secretary of State designating 50,000 shares of its authorized and unissued preferred stock as Series C Preferred Stock with a stated value of $27.00 per share. On February 28, 2023, the Company filed a Certificate of Amendment to the Series C COD (the "COD Amendment") to clarify the terms of conversion price and floor price based on definitions provided in the Series C COD (the COD Amendment, together with the Series C COD, the "COD"). Each share of Series C Preferred Stock has 620 votes and is subject to certain redemption rights and voting limitations.

Pursuant to the terms of a Modification and Exchange Agreement dated April 20, 2023, by and between 3i and the Company, effective April 21, 2023, 3i exchanged 50,000 shares of Series C Preferred Stock (the "Series C Shares") beneficially owned by 3i for 5,577 shares of Series A Preferred Stock.

(d) Common Share, Pre-Funded Warrant and Common Share Purchase Warrant issuances

In April 2023, the Company issued 71,734 shares of our Common Stock and 71,734 common stock purchase warrants, each exercisable for one share of Common Stock, at a combined public offering price of $30.00, and 178,267 pre-funded warrants, each exercisable for one share of Common Stock, and 178,267 common stock purchase warrants, each exercisable for one share of common stock only (the common stock purchase warrants sold in the public offing hereinafter referred to as the "April 2023 Common Warrants") at a combined public offering price of $30.00 less the $0.001 for the pre-funded warrants, for aggregate gross proceeds of approximately $7.5 million, before deducting placement agents fees and offering expenses payable by the Company, or the April Offering. The Common Stock, pre-funded warrant and April 2023 Common Warrants were sold pursuant to a securities purchase agreement with the purchaser signatory thereto or pursuant to the prospectus which was part of an effective registration statement on Form S-1 filed with the SEC. The Common Stock, pre-funded warrants and April 2023 Common Warrants are immediately separable and were issued separately in the offering. As of June 30, 2023, all pre-funded warrants from the April Offering were exercised in exchange for 178,267 common shares.

In July 2023, the Company issued 357,223 shares of our Common Stock pre-funded warrants to purchase up to 2,087,222 shares of common stock (the "July Pre-Funded Warrants"), and common warrants to purchase up to 2,444,445 shares of Common Stock (the "2023 July Common Warrants") at an effective combined purchase price of $4.50 per share and related common stock purchase warrants for aggregate gross proceeds of approximately $11 million, before deducting placement agent fees and offering expenses payable by the Company of approximately $920 on July 10, 2023 ("July Offering"). The securities in the July Offering were registered pursuant to the registration statement on Form S-1, as amended (File No. 333-272469). The purchase price of each July Pre-Funded Warrant and 2023 July Common Warrant was equal to $4.50 less the $0.001 per share exercise price of each Pre-Funded Warrant. Such securities were sold pursuant to a securities purchase agreement with the purchaser signatory thereto or pursuant to the prospectus which was part of an effective registration statement on Form S-1 filed with the SEC. As of September 30, 2023, all July Pre-Funded Warrants were exercised prior in exchange for 2,087,222 common shares.

10. Stockholders' Equity *(cont.)*

In September 2023, the Company entered into an Inducement Letter dated September 14, 2023 (the "Inducement Letter") with each of Armistice Capital Master Fund Ltd. and Sabby Volatility Warrant Master Fund, Ltd. ("September Investors") who were the holders of existing common stock purchase warrants issued (i) in the April Offering (the "April Warrants") and (ii) in the July Offering (the "July Warrants" and together with the April Warrants, the "Existing Warrants"). Pursuant to the Inducement Letter, the September Investors agreed to exercise for cash their respective Existing Warrants to purchase an aggregate of up to 2,438,889 shares of the Company's Common Stock (the "Existing Warrant Shares"), at a reduced exercise price of $1.00 per share, in consideration for the Company's agreement to issue a new unregistered common stock purchase warrant to purchase up to a number of shares of Common Stock equal to 200% of the number of Existing Warrant Shares issued, or the Inducement Warrants, pursuant to each Existing Warrant exercise (the "Inducement Warrant Shares"), exercisable for 5 years and six months from the issue date, at an exercise price of $1.00, subject to adjustment. Upon execution of the Inducement Letter by each of the September Investors the Company issued the Inducement Warrants to the September Investors pursuant to a private placement (the "September Private Placement"). As of December 31, 2023, the Company received approximately $2,962 million, net of costs in exchange for the exercise of 2,438,889 Existing Warrants.

(e) April 2023, July 2023 and September 2023 Common Warrants

Subject to certain ownership limitations, the April 2023 Common Warrants are exercisable immediately from the date of issuance. The April 2023 Common Warrants have an exercise price of $34.00 per share and expire on the 5 year anniversary of the date of issuance, April 21, 2023, unless otherwise agreed upon by us and holder of the warrant. The exercise price of the April 2023 Common Warrants is subject to certain adjustments, including stock dividends, stock splits, combinations and reclassifications of the Company's Common Stock. In the event of a fundamental transaction, as described in the April 2023 Common Warrants, each of the holders of the April 2023 Common Warrants will have the right to exercise its April 2023 Common Warrant and receive the same amount and kind of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder had been, immediately prior to such fundamental transaction, the holder of shares of the Company's Common Stock issuable upon the exercise of its April 2023 Common Warrant. Additionally, in the event of a fundamental transaction within the Company's control, as described in the April 2023 Common Warrants, each holder of the April 2023 Common Warrants will have the right to require the Company to repurchase the unexercised portion of its April 2023 Common Warrant at its fair value using a variant of the Black Scholes option pricing formula. In the event of a fundamental transaction that is not within the Company's control, each holder of the April 2023 Common Warrants will have the right to require the Company or a successor entity to redeem the unexercised portion of its April 2023 Common Warrant for the same consideration paid to the holders of the Company's Common Stock in the fundamental transaction at the unexercised April 2023 Common Warrant's fair value using a variant of the Black Scholes option pricing formula.

Pursuant to a securities purchase agreement entered into with certain investors in the April Offering, we agreed that for a period of 90 days from the close of the April Offering, that we would not issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or securities convertible or exercisable into Common Stock or file a registration statement with the SEC to register our securities, subject to certain exceptions. The investors to the securities purchase agreement in the April Offering, excluding 3i, have agreed to waive that provision and permit the July offering of our Common Stock, pre-funded warrants and common warrants ("Offering Waiver") in exchange for (i) the repricing of the exercise price of the April 2023 Common Warrant to the exercise price of the common warrant offered in the July Offering if the exercise price of the common warrant is lower than the then-current April 2023 Common Warrant exercise price; and (ii) extending the termination date of the April 2023 Common Warrant to the date of termination of the common warrants offered in the July Offering As a result of the July Offering, investors to the securities purchase agreement in the April Offering, excluding 3i, had the exercise price of their April 2023 Common Warrant reduced to $4.50 per share and the exercise period extended to on or around July 10, 2028. 3i and the Company entered into a separate limited waiver and amendment agreement, as discussed above. We used the Black-Scholes option pricing model to fair value the April Common Warrants as of July 10, 2023, using the Black-Scholes option pricing model and recorded the incremental value of $202 as a fair value modification cost in other income (expenses).

10. Stockholders' Equity *(cont.)*

Management considered the September, July and April Common Warrants, which do not represent outstanding shares, and determined that they contain certain contingent redemption features, outside of the Company's control and at the election of the Holder, which may require the Company to repurchase the September, July and April Common Warrants or Warrant Shares in exchange for cash (i.e., puttable) in an amount as defined in the Warrant Agreements. The Company concluded that the September, July, and April Common Warrants represent liabilities under ASC 480. Accordingly, the September, July and April Common Warrants have been initially recorded at their fair value of $4,189, $6,824, and $4,148 respectively using the Black-Scholes option pricing model and as a reduction of additional paid in capital. Additionally, the total July financing cost of $902 has been proportionately allocated to financing costs and additional paid in capital in the amounts of the amount of $571 and $349, respectively; and the total April financing cost of $679 has been proportionately allocated to the finance expense and additional paid in capital in the amounts of $376 and $303, respectively. The September financing cost of $198 has been allocated to a finance expense in general and administration costs.

On September 14, 2023, the exercise prices of the July and April Common Warrants were reduced to $1.00 per share and the exercise period extended to on or about September 14, 2028. We used the Black-Scholes option pricing model to fair value the July and April Common Warrants as of September 14, 2023, using the Black-Scholes option pricing model and recorded the incremental value of $389 as a fair value modification cost in other income (expenses).

On November 8, December 1, and December 5, 2023, a total of 373,000, 266,000 and 1,373,534 July warrants were exercised, respectively, and we used the Black-Scholes option pricing model to fair value the July warrants at $143, $124, and $233, respectively. On December 5, 2023, a total of 83,333 April warrants were exercised, and we used the Black-Scholes option pricing model to fair value the April warrants at $22. As of December 31, 2023, we used the Black-Scholes option pricing model to fair value the outstanding September, July, and April Common share purchase warrants of 4,877,778, 222,223, and 33,333, respectively, at $2,154, $95 and $14, respectively.

Inputs used in the above noted Black-Scholes valuation models for the April, July and September Common Warrants are as follows:

	December 5, 2023	December 1, 2023	November 8, 2023
Initial exercise price	$ 1.00	$ 1.00	$ 1.00
Stock price on valuation date	$ 0.58	$ 0.59	$ 0.50
Risk-free rate	4.14%	4.14%	4.14%
Term of Warrant (in years)	4.60	4.61	4.67
Rounded annual volatility	123%	122%	122%

	December 31, 2023	September 14, 2023	July 10, 2023	April 21, 2023
Initial exercise price	$ 1.00	$ 1.00 - $4.50	$ 4.50 - $34.00	$ 34.00
Stock price on valuation date	$ 0.55	$ 1.00	$ 3.40	$ 20.40
Risk-free rate	3.84%	4.32% - 4.35%	4.16% - 4.19%	3.70%
Term of Warrant (in years)	4.53 - 5.20	4.82	4.78 - 5.00	5.00
Rounded annual volatility	125%	127%	122% - 140%	126%

10. Stockholders' Equity *(cont.)*

ii. Establishment of Series B Preferred Stock

On November 22, 2022, the Company's Board of Directors established the Series B Preferred Stock, par value $0.0001 per share ("Series B Preferred Stock"). Following is a summary of the terms of the Series B Preferred Stock:

a. The number of shares designated as Series B Preferred Stock is 200,000;

b. The holders of Series B Preferred Stock shall not be entitled to receive dividends of any kind;

c. Each outstanding share of Series B Preferred Stock shall have 400 votes per share;

The Series B Preferred Stock shall rank senior to the Common Stock, but junior to the Series A Preferred stock, as to any distribution of assets upon a liquidation, dissolution or winding up of the Company, whether voluntarily or involuntarily.

All shares of Series B Preferred Stock that are not present in person or by proxy through the presence of such holder's shares of Common Stock or Series A Preferred Stock, in person or by proxy, at any meeting of stockholders held to vote on the Reverse Stock Split, the Share Increase Proposal and the Adjournment Proposal as of immediately prior to the opening of the polls at such meeting (the "Initial Redemption Time") shall automatically be redeemed by the Company at the Initial Redemption Time without further action on the part of the Company or the holder thereof (the "Initial Redemption");

Any outstanding shares of Series B Preferred Stock that have not been redeemed pursuant to an Initial Redemption shall be redeemed in whole, but not in part, (i) if such redemption is ordered by the Board of Directors in its sole discretion, automatically and effective on such time and date specified by the Board of Directors in its sole discretion or (ii) automatically upon the approval by the Company's stockholders of the Reverse Stock Split and the Share Increase Proposal at any meeting of stockholders held for the purpose of voting on such proposals; and

Each share of Series B Preferred Stock redeemed in any Redemption shall be redeemed in consideration for the right to receive an amount equal to $0.01 in cash for each one whole share of Series B Preferred Stock as of the applicable Redemption Time.

iii. Issuance of Series B Preferred Stock Dividend

Effective December 5, 2022, the Company issued a stock dividend to be distributed as follows to stockholders of record as of close of business on December 5, 2022: (i) 0.016 shares of Series B Preferred Stock for each outstanding share of common stock; and (ii) 1.744 shares of Series B Preferred Stock for each outstanding share of Series A Preferred Stock. Effective February 3, 2023, the Company redeemed 190,786 shares of Series B Preferred stock in exchange for $0.01 per share.

iv. Share issuances

During the year ended December 31, 2023, the Company issued 241,893 shares of common stock valued at $3,899 upon the conversion of 9,347 shares of Series A Preferred Stock; 250,000 shares of Common Stock as a result of its April Public Offering of 71,733 shares of common stock and the exercise of 178,267 pre-funded warrants, described above in exchange for $6,815, net of costs; 2,444,445 shares of Common Stock, net of costs as a result of its July Public Offering of 357,223 shares of common stock and the exercise of 2,087,222 pre-funded warrants, described above in exchange for $10,080; 2,438,889 shares of Common Stock as a result of its September Inducement Letter, as described above in exchange for $2,962, net of costs, and 500,000 common shares as a result of a cashless exercise of 5,045,446 3i Exchange Warrants.

During the year ended December 31, 2022, the Company issued 5,573 common shares valued at $1,156 gross and ($2,265) net of the $3,421 floor price adjustments upon the conversion of 6,214 shares of Series A Preferred Stock.

11. Share-based payments

As of December 31, 2023 and 2022, the Company's total issued and outstanding common shares were 5,886,934 and 11,356, respectively, with a par value of $0.0001. The shares are fully paid in. The shares are not divided into classes, and no shares enjoy special rights.

2021 Equity Incentive Plan

Our 2021 Equity Incentive Plan became effective on December 20, 2021. It was approved by shareholders in connection with the Recapitalization Share Exchange. Our 2021 Plan authorizes the award of stock options, Restricted Stock Awards ("RSAs"), Stock Appreciation Rights ("SARs"), Restricted Stock Units ("RSUs"), cash awards, performance awards and stock bonus awards. We initially reserved 1,211,374 shares of our common stock under the 2021 Plan. The number of shares reserved for issuance under our 2021 Plan will increase automatically on January 1 of each of 2022 through 2031 by the number of shares equal to the lesser of 5% of the aggregate number of outstanding shares of our common stock as of the immediately preceding December 31, or a number as may be determined by our board of directors.

During the years ended December 31, 2023, and 2022, the total charge to profit or loss amounted to $71 and $1,752, respectively of which $47 and $1,156, respectively, are recognized as general and administrative expenses and $24 and $596, respectively, are recognized as research and development expenses. As of December 31, 2023, total unrecognized compensation cost relating to unvested options granted was $72 and is expected to be realized over a period of 1.75 years. The Company will issue shares upon exercise of options from shares reserved under our 2021 Plan.

The table below summarizes the number of options that were outstanding, their weighted average exercise price and contractual term as of December 31, 2023, as well as the movements during the period.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)
Balance on January 1, 2023	483	$ 9,174	4.14
Forfeited	(101)	13,996	—
Outstanding as of December 31, 2023	382	$ 7,876	3.16
Options exercisable at December 31, 2023	341	$ 5,320	3.18

A total of 101 options were forfeited and no options expired or were exercised in the year ended December 31, 2023. In the year ended December 31, 2022, 389 options were forfeited and none expired or were exercised. The intrinsic value of all stock options outstanding at December 31, 2023 and 2022, was $0. The weighted average exercise price for options outstanding at the end of 2023 is $7,876. The total fair value of options vested during the year ended December 31, 2023, was $845.

No options were granted in the year ended December 31, 2023. The weighted average grant date fair value per share of options granted in 2022 was $1.19. The estimate of the grant date fair value of each option issued is based on a Black-Scholes model. The assumptions used in our valuations for the year ended December 31, 2022, are summarized as follows:

	Year ended December 31, 2022
Expected volatility	105.85% - 120.22%
Weighted average share price	$ 1.19
Expected life (in years)	5
Expected dividend yield	0%
Risk-free interest rate	3.05% - 4.09%

11. Share-based payments *(cont.)*

Expected Term — The expected term is based upon the historical exercise patterns of options.

Expected Volatility — Was determined based upon the expected term of the options which is based upon the historical exercise patterns of options.

Risk-Free Interest Rate — The risk-free interest rate is based on the 5 years government bond yield rate of Denmark at the date of grant maturities approximately equal to the options' expected term.

Dividend Rate — The expected dividend is zero as the Company has not paid nor does it anticipate paying any dividends on its common stock in the foreseeable future.

Fair Value of Common Stock — The quoted prices of the Company's common stock is used to estimate the fair value of the share-based awards at grant date.

12. License and Development Agreements

(a) License Agreement with Novartis for Dovitinib

On January 26, 2024, we received a Termination Notice from Novartis due to a material breach of our license agreement. Accordingly, under the terms of the Agreement (i) we shall cease all development and commercialization activities with respect to all licensed products; (ii) all rights and licenses granted by Novartis to Allarity shall revert to Novartis; and all liabilities due to Novartis became immediately due and payable in the amount of $5,001 inclusive of interest which is continuing to accrue at 5% per annum. As of December 31, 2023, the liability is recorded as a current liability on our Consolidated Balance Sheets as follows: $3,600 in accounts payable, $1,300 convertible promissory note and accrued interest, net of discount, and $101 in accrued liabilities.

(b) License Agreement with Eisai Inc. for Stenoparib

We hold the exclusive worldwide rights to all preventative, therapeutic and/or diagnostic uses related to cancer in humans and by amendment to the agreement on December 11, 2020, viral infections in humans (including, but not limited to, coronaviruses) for stenoparib from Eisai, Inc. ("Eisai") pursuant to a license agreement. Pursuant to the license agreement, we are solely responsible for the development of stenoparib during the term of the agreement. The agreement also provides for a joint development committee consisting of six members, three appointed by us and three appointed by Eisai. One of our members of the joint development committee is designated chair of the committee and has the power to break any deadlock in decisions by the committee that must be made by a majority vote with each representative having one vote. The purpose of the committee is to implement and oversee development activities for stenoparib pursuant to the clinical development plan, serving as a forum for exchanging data, information and development strategy.

Effective July 12, 2022, the Company's July 6, 2017 Exclusive License Agreement with Eisai Inc. (the "Third Amendment"), the terms of the original exclusive license were further amended in order to (1) further postpone the due date of the Extension Payment and extend the deadline for the Company's successful completion of its first Phase 1b or Phase 2 clinical trial for Stenoparib (the "Product") beyond December 31, 2022; and (2) amend terms related to Eisai's right of termination of development.

On May 26, 2023, the Company and Eisai entered into a fourth amendment to the Exclusive License Agreement with an effective date of May 16, 2023, to postpone the extension payment, restructure the payment schedule and extend the deadline to complete enrollment in a further Phase 1b or Phase 2 Clinical Trial for the Stenoparib (the "Product"). The Company agreed to pay Eisai in periodic payments as follows: (i) $100 which has been paid; (ii) $50 within 10 days of execution of the fourth amendment which has been paid; (iii) $100 upon completion of a capital raise (paid on July 18, 2023); and (iv) $850 on or before March 1, 2024. As of the date of this filing, the Company is currently negotiating a fifth amendment to the extend the timeframe of periodic payments due.

12. License and Development Agreements *(cont.)*

Once the extension payment is paid in full, the Company shall have until April 1, 2024, to complete enrollment in a further Phase 1b or Phase 2 Clinical Trial of the Product. If the Company has not achieved successful completion of a further Phase 1b or Phase 2 Clinical Trial of the Product prior to April 1, 2024, Eisai may terminate this Agreement in its entirety, in its sole discretion on at least 120 days prior written notice.

Development Milestone Payments

Pursuant to the agreement, we have agreed to make milestone payments to Eisai in connection with the development of stenoparib by us or our affiliates, or by a third-party Program Acquirer that assumes control of the stenoparib development program from us corresponding to: (i) successful completion of a Phase 2 clinical trial; (ii) Upon dosing of the first patient in the first Phase 3 clinical trial; (iii) upon submission of the first NDA with the FDA; (iv) submission of an MAA to the EMA; (v) submission of an NDA to the MHLW in Japan; (vi) upon receipt of authorization by the FDA to market and sell a licensed product; (vii) upon receipt of approval of an MAA by the EMA for a licensed product; and (viii) upon receipt of approval by the MHLW in Japan for a licensed product. If all milestones have been achieved, we may be obligated to pay Eisai up to a maximum of $94 million. In addition, we have agreed to pay Eisai a one-time sales milestone payment in the amount of $50 million the first time our annual sales of licensed product is $1 billion or more.

Royalty Payments

In addition to the milestone payments described above, we have agreed to pay Eisai royalties based on annual incremental sales of product derived from stenoparib in an amount between 5% and 10% of annual sales of between $0 and $100 million, between 6% and 10% of annual sales between $100 million and $250 million, between 7% and 11% of annual sales between $250 million and $500 million, and between 11% and 15% of annual sales in excess of $500 million.

We are obligated to pay royalties under the agreement on a country-by-country and product-by-product basis for a period that commences with the first commercial sale of a product until the later of (i) the expiration of the last to expire valid claim of any licensed patent covering such licensed product in such country; or, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country or (iii) the 15 year anniversary of the date of first commercial sale of such licensed product in such country. However, the agreement may be terminated sooner without cause by us upon 120 days prior written notice, or upon written notice of a material breach of the agreement by Eisai that is not cured within 90 days (30 days for a payment default). Eisai also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 90 days (30 days for a payment default) or if we file for bankruptcy. By an amendment effective as of August 3, 2021, and executed by Eisai on August 23, 2021, Eisai also has the right to terminate the agreement if we do not complete a Phase 2 clinical trial before December 31, 2022, unless we elect to pay a $1,000 extension payment (“Extension Payment”). Notwithstanding the foregoing, in the event we fail to enroll and dose at least 30 patients with the first dose of cancer drug in the ongoing Phase 2 Ovarian Cancer Clinical Trial by July 1, 2022, then the Extension Payment will be due and payable in fully by July 30, 2022. In addition, if we fail to achieve successful completion of first Phase 2 Clinical Trial prior to December 31, 2022, and do not elect to pay the Extension Payment then Eisai may terminate the agreement in its sole discretion pursuant to the terms of the amendment.

12. License and Development Agreements *(cont.)*

Option to Reacquire Rights to Stenoparib

For the period commencing with enrollment of the first five patients in a Phase 2 clinical trial pursuant to the clinical development plan and ending 90 days following successful completion of such Phase 2 clinical trial, Eisai has the option to reacquire our licensed rights to develop stenoparib for a purchase price equal to the fair market value of our rights, giving effect to the stage of development of stenoparib that we have completed under the agreement. We commenced a Phase 2 clinical trial April 15, 2019, and as of the date of these consolidated financial statements, Eisai has not indicated an intention to exercise its repurchase option.

(c) Development, Option and License Agreement with R-Pharm for IXEMPRA®

On March 1, 2019, the Company entered into an option to in-license the rights to any and all therapeutic and/or diagnostic uses in humans for IXEMPRA® in the European Union (Great Britain but excluding Switzerland and Lichtenstein) (the "Territory") from R-Pharm U.S. Operating, LLC ("R-Pharm"), pursuant to a Development, Option and License Agreement (the "Option"). By an amendment to the agreement dated August 4, 2022, for no consideration, the term of the option will expire on September 1, 2023, if not exercised by us before then. The agreement provides a right of extension, should we elect, for an additional $250. As of the date of this filing, we have not extended the option with R-Pharm.

(d) Development costs and Out-License Agreement with Smerud

In June of 2020 (the "June 2020 Out-License Agreement"), as amended March 28, 2022 (the "Amended License Agreement"), the Company out-licensed its secondary LiPlaCis® and 2X-111 programs to Smerud Medical Research International, the Company's long-time CRO partner in Europe, for further Phase 2 clinical development of each program together with its DRP® companion diagnostic. Pursuant to the terms of the Amended License Agreement, Chosa ApS, a company organized under the laws of Denmark ("Chosa"), replaced us as the exclusive licensee to the LiPlaCis® technology. In addition, we also granted Chosa an exclusive, royalty-free, transferable and sublicensable license for (i) our DRP® Companion Diagnostics that are specific for Cisplatin or LiPlaCis® (a liposomal formulation of Cisplatin) for the research and development of LiPlaCis® products, and (ii) the use of any and all know-how and intellectual property rights owned by us for Chosa's use of our DRP® Companion Diagnostics that are specific for Cisplatin or LiPlaCis® (a liposomal formulation of Cisplatin) for the development and commercialization of LiPlaCis® products, as contemplated in the Amended License Agreement.

12. License and Development Agreements *(cont.)*

LiPlaCis Support Agreement with Smerud, Chosa and LiPlasome

On March 28, 2022, concurrent with the entry into the Amended License Agreement, we entered into the LiPlaCis Support Agreement with Allarity Europe, Smerud, Chosa and LiPlasome (the "Support Agreement"). Pursuant to the terms of the Support Agreement, we agreed (i) to pay to LiPlasome a certain percentage of the Commercialization Proceeds received from Smerud by way of debt cancellation relating to prior work on LiPlaCis® by Smerud, which obligation was to be satisfied by the payment of $338 to LiPlasome upon execution of the Support Agreement, (ii) to equally share the milestone payments under the terms of the License Agreement, pursuant to which it was contemplated that upon the achievement of all the milestones, our pro rata share of the Milestone Payments would be up to $3.5 million, (iii) to amend and restate the Original License Agreement, and (iv) to terminate the 2020 Sublicense Agreement as contemplated by the parties pursuant to the terms of the Support Agreement.

Development costs

Under the terms of the June 2020 Sublicense agreement (the "2020 Sublicense Agreement") between the Company and Smerud Medical Research International AS (Norway) ("Smerud"), the Company is liable for development costs incurred by Smerud in the approximate amount of $1,264, which has been accrued as of December 31, 2021, as payable to Smerud. However, effective March 28, 2022, the Company terminated its LiPlasome rights through the following agreements:

A Letter Agreement between Chosa Oncology Ltd. (England), Chosa ApS (Denmark) (collectively "Chosa"), Smerud, and the Company, which references the following agreements:

Development costs

a. The 2022 Amended and Restated License Agreement between LiPlasome Pharma Aps (Denmark) ("LiPlasome"), Chosa, and the Company's subsidiary Allarity Therapeutics ApS, which amended the original February 15, 2016, LiPlasome License Agreement (as amended January 27, 2021), whereby Chosa replaced the Company as licensee of LiPlasome in exchange for Smerud's cancellation of the Company's $1,309 liability to Smerud and the Company's agreement to pay $338 to LiPlasome. Consequently, in 2022, the Company recorded a balance due to LiPlasome of $338 in accrued liabilities (paid on April 1, 2022) and recorded other income of $971, which was recognized as a gain on sale of IP.

b. The LiPlacis Support Agreement between Allarity Therapeutics Europe, Smerud, Chosa and LiPlasome. Terms of the Support Agreement provide that each of Smerud and the Company agreed that the 2022 Sublicense Agreement is terminated in its entirety.

12. License and Development Agreements *(cont.)*

(e) Oncoheroes

Effective January 2, 2022, the Company entered into an Exclusive License Agreement with Oncoheroes Biosciences Inc. (the "Oncoheroes Agreement") to grant Oncoheroes an exclusive royalty-bearing global license to both dovitinib and stenoparib in pediatric cancers. Oncoheroes will take responsibility for pediatric cancer clinical development activities for both clinical-stage therapeutics. The Company will support Oncoheroes' pediatric clinical trials by providing clinical-grade drug inventory at cost and by facilitating DRP® companion diagnostic screening of pediatric patients for each drug. Under the licenses, Oncoheroes will receive commercialization rights for pediatric cancers, subject to the Company's first buy-back option for each program, and the Company will receive an upfront license fee and regulatory milestones for for stenoparib, as follows:

i. A one-time upfront payment of $250 for stenoparib, within 5 business days after January 2, 2022 ($350 received as of April 4, 2022) and recorded in other income as a gain on sale of IP; and

ii. two milestone payments of $1 million each due and payable upon receipt of regulatory approval of a product in the United States, and of a product in Europe, respectively.

Pursuant to the Oncoheroes Agreement the Company is also entitled to tiered royalties on aggregate net product sales ("Sales") of between 7% and 12% on net sales of products as follows: 7% on Sales less than $100 million; 10% on Sales of greater than $100 million and less than $200 million; and 12% on Sales greater than $200 million.

(f) Lantern Pharma, Inc. – Irofulven Agreement

On July 23, 2021, we entered into an Asset Purchase Agreement with Lantern Pharma, Inc. relating to our inventory of Irofulven active pharmaceutical ingredients, our clinical research data relating to Irofulven developed by us during the drug development program under the May 2015 Drug License and Development Agreement for Irofulven and terminated our obligation to further advance the development of Irofulven under the May 2015 agreement. Under the Asset Purchase Agreement, Lantern Pharma agreed to pay us $1 million on closing of the transaction, and additional amounts:

(i) when the inventory of Irofulven API is recertified with a longer shelf life;

(ii) upon the initiation of treatment of the first patient in an investigator-led "compassionate use" ERCC2/3 mutation subgroup study using Irofulven in certain agreed upon investigators;

(iii) upon the initiation of treatment of the first patient within twenty-four months after the closing of the transaction in any human clinical trial of Irofulven initiated by Lantern Pharma; and

(iv) upon the initiation of treatment of the second patient within an agreed upon time period after the closing of the transaction in any human clinical trial of Irofulven initiated by Lantern Pharma.

In addition to the sale of our inventory of Irofulven API and Data to Lantern Pharma, we also granted Lantern Pharma a non-exclusive, worldwide license to use our putative Irofulven DRP® companion diagnostic to advance the development and commercialization of Irofulven and other Illudins (sesquiterpenes with anti-tumor properties produced by some mushrooms). We have also agreed not to engage in any drug development program for Illudins or any of its analogues or any use thereof for a period of five years.

Effective March 18, 2022, pursuant to clause (i) the inventory was recertified with a longer shelf life and as of March 31, 2022, we received $459 which was recorded in other income as a gain on sale of IP.

13. Tax

The reconciliation of the statutory rate to the effective tax rate is as follows:

Reconciliation of effective tax rate:	**2023**	**2022**
Tax computed on the loss before tax at a tax rate of 21.0% for the years ended December 31, 2023 and 2022	$ (2,482)	$ (3,692)
Foreign rate differential	(73)	(260)
Non-deductible expenses, other	—	1
Tax value of derivative warrants	(1,187)	(3,597)
Special tax deduction on research and development expenses	(559)	(754)
Loss offset to research and development incentive	798	609
Other adjustments	17	(1)
Adjustment of tax concerning previous years	45	(871)
Change in valuation allowance	3,524	7,044
Effective tax rate	$ 83	$ (1,521)

The components of net loss before income taxes were as follows:

	Year ended December 31,	
	2023	**2022**
Denmark	$ (6,234)	$ (25,336)
Sweden	—	(3)
United States	(5,584)	7,760
	$ (11,818)	$ (17,579)

The components of the provision for income taxes from operations were as follows:

	Year ended December 31,	
	2023	**2022**
Current:		
Denmark	$ —	$ —
Sweden	—	—
United States	—	—
Total	—	—
Deferred:		
Denmark	83	(1,521)
Sweden	—	—
United States	—	—
Total	83	(1,521)
	$ 83	$ (1,521)

13. Tax *(cont.)*

Deferred tax comprises:	**2023**	**2022**
Property, plant and equipment	$ (25)	$ 20
Intangible assets	(1,405)	(1,160)
Stock compensation	790	1,152
Other accruals	16	(44)
Net operating losses	16,952	12,981
Total deferred tax	16,328	12,949
Valuation allowance	(16,774)	(13,298)
Net deferred tax liabilities	$ (446)	$ (349)

Tax on profit/loss for the year:	**2023**	**2022**
Current income tax (benefit) expense	$ —	$ —
Change in deferred tax	83	(1,521)
Adjustment of tax concerning previous years	—	—
Tax (benefit) expense	$ 83	$ (1,521)

Tax losses carried forward of approximately $78.1 million can be carried forward indefinitely. Deferred tax has been provided corresponding to the statutory tax rate applied.

The statute of limitations for re-assessment of tax returns in Denmark is three years and five years for transfer pricing. As of December 31, 2023, the tax years that remain subject to examination by the major tax jurisdictions, under the statute of limitations, are from the year ended December 31, 2018, forward. The Company does not believe it has any uncertain tax positions that would result in the Company having a liability to the taxing authorities.

14. Related parties

During the years ended December 31, 2023 and 2022, a Director of the Company was paid $127 and $269, respectively, in fees as a consultant.

15. Basic and diluted net loss per share

Basic and diluted net loss per share attributable to common shareholders was as follows:

	Years Ended December 31,	
	2023	**2022**
Numerator:		
Net loss attributable to common shareholders	$ (20,416)	$ (21,051)
Denominator:		
Weighted average common shares outstanding – basic and diluted	1,990,748	6,805
Net loss per share attributable to common shareholders – basic and diluted	$ (10.26)	$ (3,093.42)

15. Basic and diluted net loss per share *(cont.)*

The Company's potentially dilutive securities, which include warrants and shares issuable upon conversion of convertible debt, have been excluded from the computation of diluted net loss per share attributable to common shareholders as the effect would be to reduce the net loss per share attributable to common shareholders. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common shareholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common shareholders for the periods indicated because including them would have had an anti-dilutive effect:

	As of December 31,	
	2023	**2022**
Warrants and stock options	9,540,951	2,695,907
Series A Convertible Preferred stock	1,530,360	7,406,057
Convertible debt*	—	9,071,430
	11,071,311	19,173,394

* Estimated based on $2,667 at $0.1825 per share.

16. Financial Instruments

The following tables present information about the Company's financial instruments measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values:

	Fair Value Measurements as of December 31, 2023, Using:			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities:				
Warrant liability	$ —	$ —	$ (2,263)	$ (2,263)
Derivative warrant liability	—	—	(820)	(820)
	$ —	$ —	$ (3,083)	$ (3,083)

	Fair Value Measurements as of December 31, 2022, Using:			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities:				
Derivative warrant liability	$ —	$ —	$ (374)	$ (374)
	$ —	$ —	$ (374)	$ (374)

Methods used to estimate the fair values of our financial instruments, not disclosed elsewhere in these consolidated financial statements, are as follows:

When available, our marketable securities are valued using quoted prices for identical instruments in active markets. If we are unable to value our marketable securities using quoted prices for identical instruments in active markets, we value our investments using broker reports that utilize quoted market prices for comparable instruments. Accordingly, our investment is considered a Level 1 financial asset. We have no financial assets or liabilities measured using Level 2 inputs. Financial assets and liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies, or similar techniques, and at least one significant model assumption or input is unobservable.

16. Financial Instruments *(cont.)*

The Company recognizes its derivative liabilities as level 3 and values its derivatives using the methods discussed below. While the Company believes that its valuation methods are appropriate and consistent with other market participants, it recognizes that the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date. The primary assumptions that would significantly affect the fair values using terms in the notes that are subject to volatility and market price of the underlying common stock of the Company.

The Company reviews the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy. The Company's policy is to recognize transfers into and out of levels within the fair value hierarchy at the date the actual event or change in circumstances that caused the transfer occurs. When a determination is made to classify an asset or liability within Level 3, the determination is based upon the significance of the unobservable inputs to the overall fair value measurement. There were no transfers between level 1 or level 2 during the years ended December 31, 2023, or 2022.

During the years ended December 31, 2023, and 2022, the Company utilized the reset strike options Type 2 model by Espen Garder Haug and Black-Scholes Merton models to measure the fair value of the 3i Exchange Warrant derivative liability at $820 and $374, respectively. All changes in fair value were recorded in the Consolidated Statements of Operation and Comprehensive Loss during the corresponding period. Fluctuations in the Company's stock price are a primary driver for the changes in the derivative valuations during each reporting period. During the years ended December 31, 2023, and 2022, the Company's stock price decreased from its initial valuation. As the stock price decreases for each of the related derivative instruments, the value to the holder of the instrument generally decreases. Stock price is one of the significant unobservable inputs used in the fair value measurement of each of the Company's derivative instruments.

17. Commitments and Contingencies

License Agreement with 2-BBB Medicines B.V. for Stenoparib ("2X-111")

On March 27, 2017, we in-licensed the exclusive worldwide rights to the central nervous system ("CNS") and/or cerebrocardiovascular drug application, including the (preventive) treatment of peripheral effects of agents causing CNS disease or symptoms, including cancer, for 2X-111 from 2-BBB Medicines B.V. ("2-BBB") pursuant to a license agreement. Upon execution of the agreement, we paid 2-BBB a one-time, non-refundable, non-creditable payment of $500. Pursuant to the agreement, we are solely responsible for the development of 2X-111 during the term of the agreement.

Development and Sales Milestone Payments

Pursuant to the agreement, we have agreed to make milestone payments to 2-BBB in connection with the development of 2X-111 by us or our affiliates, or by a third-party (a "Program Acquirer") that assumes control of the 2X-111 development program from us corresponding to: (i) upon enrollment of the first ten patients required in a Phase 2 clinical trial; (ii) upon the successful completion of a Phase 2 clinical trial; (iii) upon dosing of the first patient in the first Phase 3 clinical trial; (iv) upon submission of the first NDA with the FDA; (v) submission of an MAA to the EMA in the European Union; (vi) upon submission of an NDA in the first of either China or India; (vii) upon receipt of the first authorization by the FDA to market and sell a licensed product; (viii) upon receipt of a MAA for a licensed product in the European Union; and (ix) upon receipt of regulatory approval in the first of either China or India. If all development milestones have been achieved, we may be obligated to pay 2-BBB up to a maximum of $27.75 million which could increase to $55.5 million if 2-BBB successfully expands the field of our license agreement to include all preventative, therapeutic and/or diagnostic uses related to cancer in humans. In addition to the development milestones described above, we have agreed to make a mid-level seven figure one-time payment upon our sales of a licensed product reaching $500 million annually and a low eight figure payment upon the first and second time our sales of a licensed product reaches $1 Billion annual. If all sales milestones have been achieved, we would be obligated to pay 2-BBB up to a maximum of $22.5 million which could increase to $45 million if 2-BBB successfully expands the field of our license agreement to include all preventative, therapeutic and/or diagnostic uses related to cancer in humans.

17. Commitments and Contingencies (cont.)

Royalty Payments

In addition to the milestone payments described above, we have agreed to pay 2-BBB royalties based on annual incremental sales of product derived from 2X-111 in an amount between 5% and 10% of annual sales of between $0 and $100 million, between 6% and 13% of annual sales between $100 million and $250 million, and between 7% and 13% of annual sales in excess of $250 million. We are obligated to pay royalties under the agreement on a product-by-product and country-by-country basis, from the period of time commencing on the first commercial sale of any product in such country and expiring upon the latest of (a) the expiration of the last valid claim of a patent within (i) the 2-BBB intellectual property and/or (ii) the joint intellectual property in such country (if, but only if, such joint intellectual property arose from activities under the clinical development plan), or (b) the 10^{th} anniversary of the date of first commercial sale of such product in such country. However, the agreement may be sooner terminated without cause by us upon 120 days prior written notice, or upon written notice of a material breach of the agreement by 2-BBB that is not cured within 90 days. 2-BBB also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 90 days (30 days for a payment default) or if we file for bankruptcy. 2-BBB also has the right to terminate the agreement in the event we challenge a 2-BBB patent and we have the right to terminate the agreement upon 30 days' notice for specified safety reasons.

18. Subsequent Events

(a) 3i LP Securities Purchase Agreement

On January 18th, 2024, we entered into a Securities Purchase Agreement with 3i, pursuant to which we issued and sold 3i a senior convertible promissory notes in an aggregate principal amount of $440 due on January 18, 2025 (the "First Note", and together with the Purchase Agreement, the "Transaction Documents") for an aggregate purchase price of $400, representing an approximate 10% original issue discount (the "Transaction"). We agreed to use the net proceeds from the sale of the Note for accounts payable and working capital purposes. Unless the Transaction Documents state otherwise, we may not prepay any portion of the principal amount of the Note without the Purchaser's prior written consent.

On February 13, 2024 (the "Second Closing"), the Parties entered into a Limited Waiver Agreement (the "Waiver Agreement") and agreed that the Second Closing can be consummated prior to the 30th calendar day following January 18, 2024. The Parties further waive any rights or remedies that they may have under Section 2.3 of the Purchase Agreement, solely in connection with the Second Closing, including any rights of termination, defaults, amendment, acceleration or cancellation that be triggered under the Purchase Agreement solely as a result of accelerating the Second Closing. As of the Second Closing, we issued and sold to the Purchaser a senior convertible promissory note in an aggregate principal amount of $440 (the "Principal Amount") due on February 13, 2025 (the "Second Note," and together with the First Note dated January 18, 2024, and Purchase Agreement, the "Transaction Documents") for an aggregate purchase price of $400, representing an approximately 10% original issue discount (the "Transaction"). We agreed to use the net proceeds from the sale of the Second Note for accounts payable and working capital purposes. Unless the Transaction Documents state otherwise, we may not prepay any portion of the principal amount of the Second Note without the Purchaser's prior written consent.

Subject to the satisfaction (or express waiver) of the conditions set forth in the Purchase Agreement, the Purchaser shall also have the right to require us to consummate one or more additional closings of up to an additional $600 of notes in the aggregate.

18. Subsequent Events *(cont.)*

Interest

We agreed to pay interest to 3i on the aggregate unconverted and then outstanding principal amount of the First and Second Notes at the rate of 8% per annum. The first interest payment on the First Note is due on February 1, 2024, and has been deferred to March 1, 2024, with subsequent payments on the 1st of each month, starting from March 1, 2024, until the First Note is fully redeemed. The first interest payment on the Second Note is due on March 1, 2024, with subsequent payments on the 1st of each month, starting from April 1, 2024, until the Second Note is fully redeemed. The interest on each of the First and Second Notes is payable in cash or, at the Purchaser's option, in shares of our common stock, par value $0.0001 (the "Common Stock"), at the 90% of the lowest VWAP during the previous ten trading days that is immediately prior to the interest payment dates. Under the terms of the Note, 3i has the exclusive right to choose whether to receive interest payments in cash or as shares of our Common Stock.

Conversion of the First and Second Notes

From the First Closing Date until the First Note is fully paid off, it can be converted, partially or entirely, into Common Stock at 3i's discretion (subject to limits specified in the Note). We have committed to keeping enough of our authorized but unissued shares of Common Stock available exclusively for conversion of the Note. The set conversion price is $0.4476 per share. The number of shares to be issued upon conversion of the Note will be calculated by dividing the outstanding principal amount of the Note to be converted by $0.4476.

From the Second Closing until the Second Note is fully paid off, it can be converted, partially or entirely, into Common Stock at the Purchaser's discretion (subject to limits specified in the Second Note). We have committed to keeping enough of our authorized but unissued shares of Common Stock available exclusively for conversion of the Second Note. The set conversion price is $0.405 per share. The number of shares to be issued upon conversion of the Second Note will be calculated by dividing the outstanding principal amount of the Second Note to be converted by $0.405.

3i's ownership percentage of our Common Stock is limited to no more than 4.99%, as determined according to Section 13(d) of the Securities Exchange Act of 1934, as amended, and its accompanying rules. Additionally, we cannot issue shares of our Common Stock in relation to the Transaction, including shares due upon the First and Second Note conversion or otherwise, that exceed 19.99% of our total outstanding shares of Common Stock, unless otherwise permitted by the Transaction documents.

Redemption

Subject to the provisions of the First and Second Notes, if, at any time while the First and Second Notes are outstanding, we engage in one or more subsequent financings, 3i may require us to first use up to 100% of the gross proceeds of such financing to redeem all or a portion of the First and Second Notes. However, if we raise capital in an ATM offering, 3i may request up to 20% of the proceeds to redeem the Series A Convertible Preferred Stock (the "Series A Preferred Stock") at the stated value.

Events of Default

The First and Second Notes include customary event of default provisions and provide for a mandatory default provision. Upon the occurrence of an event of default, the Purchaser may require us to pay in cash the "Mandatory Default Amount" which is defined in the Note to mean the sum of (a) the greater of (i) the outstanding principal amount of the First and Second Note, plus all accrued and unpaid interest hereon, divided by the lesser of (i) 0.4476 in the case of the First Note and $0.405 in the case of the Second Note, or (ii) 85% of the average of the three lowest VWAPs during the 10 trading days ending on the trading day that is immediately prior to the applicable date the Mandatory Default Amount is either (A) demanded or otherwise due or (B) paid in full, whichever has a lower conversion price, multiplied by the highest closing price for our shares of Common Stock on the trading market during the period beginning on the date of first occurrence of the event of default and ending on the date the Mandatory Default Amount is paid in full, or (ii) 130% of the sum of the outstanding principal amount of the First and Second Note, plus accrued and unpaid interest hereon, and (b) all other amounts, costs, expenses and liquidated damages due in respect of the First and Second Note.

18. Subsequent Events *(cont.)*

Negative Covenants

While any part of the First and Second Notes are outstanding, without prior written consent from the Purchaser and holders of at least 50.01% of the outstanding Second Note, we are restricted from (i) incurring any debt exceeding $250 in total; (ii) creating any liens on their property, except for permitted ones; (iii) making amendments to their charter documents that adversely affect the Purchaser's rights; (iv) repurchasing our Common Stock or equivalents, except under specific conditions related to conversion shares under the Second Note and equity incentives for departing officers and directors, capped at $50 in total; (v) repurchasing or acquiring any indebtedness other than the First and Second Note, unless it is done pro-rata; (vi) paying cash dividends or distributions on their equity securities; (vii) engaging in transactions with any affiliates or related parties, unless permitted by the Purchase Agreement; and (viii) entering into agreements related to the above restrictions.

Registration Rights

We agreed to register with the Securities and Exchange Commission the resale of our shares of the Common Stock issuable upon conversion of the First and Second Note pursuant to the Purchase Agreement. We agreed to reimburse the Purchaser of reasonable attorneys' fees and expenses incurred by the Purchaser for significant work in connection with the First and Second Closing. The Purchase Agreement also provides for indemnification of the Purchaser if it incurs losses, liabilities, obligations, claims, contingencies, damages, costs and expenses related to, among other things, a breach by us of any of our representations, warranties or covenants under the Purchase Agreement.

(b) Series A Preferred Stock Conversions

On February 8, 2024, pursuant to the exercise of conversion by the 3i, we issued 291,958 shares of Common Stock to 3i upon the conversion of 121 shares of Series A Preferred Stock based on a conversion price of $0.4476. No proceeds were received by the Company upon such conversion. As of the date of these financial statements, we had 1,296 shares of Series A Preferred Stock issued and outstanding.

(c) Modification to Conversion Price of Series A Preferred Stock and 3i Exchange Warrants

On January 14, 2024, pursuant to the terms of the January 14th, 2024, 3i LP Bridge Loan, the Company modified the conversion price of the 3i Exchange Warrants from $1.00 to $0.4476, thereby increasing the number of Exchange Warrants outstanding from 4,407,221 at December 31, 2023 to 9,846,339 outstanding at January 14, 2024. Also on January 14, 2024, the conversion price of the outstanding 1,417 shares of Series A Preferred Stock was revised from $1.00 to $0.4476. We filed the Fifth Certificate of Amendment to Amended and Restated Certificate of Designations of Series A Convertible Preferred Stock (the "Fifth Amendment") with the Secretary of State of the State of Delaware to reflect the new conversion price of the Series A Preferred Stock of $0.4476. At a stated value of $1,080 for each share of Series A Preferred Stock, the revised price of $0.4476 per share results in the 1,417 shares being convertible into 3,419,035 common shares as of January 14, 2024.

On February 13, 2024, pursuant to the terms of the February 13, 2024, Bridge Loan, the Company modified the conversion price of the 3i Exchange Warrants from $0.4476 to $0.4050 and thereby increased the number of Exchange Warrants outstanding from 9,846,339 on January 18, 2024, to 10,882,028 on February 13, 2024. The Company also agreed to amend the conversion price of the Series A Preferred Stock to equal $0.405 as soon as practicable. We filed the Sixth Certificate of Amendment to Amended and Restated Certificate of Designations of Series A Convertible Preferred Stock (the "Sixth Amendment") with the Secretary of State of the State of Delaware to reflect the new conversion price of the Series A Preferred Stock of $0.405. At a stated value of $1,080 for each share of Series A Preferred Stock, the revised price of $0.405 per share results in the 1,296 shares being convertible into 3,456,000 common shares.

(d) Nasdaq Hearing

On February 1, 2024 we attended a de-listing appeal hearing with Nasdaq, the outcome of which is pending as of the date of this filing.

(e) Settlement Agreement (with J.Cullem)

As of March 7, 2024, we entered into a Settlement Agreement and General Release ("Settlement Agreement") with James Cullem, our former CEO and director. Pursuant to the terms and conditions outlined in the Settlement Agreement and in exchange for Mr. Cullem's commitments therein, including his general release of claims against us, among other considerations, we agreed to provide Mr. Cullem with an initial settlement payment totaling $70,000 on April 1, 2024. Additionally, we committed to making an installment payment of $179,155, divided equally into 5 monthly payments. Furthermore, we agreed to issue Mr. Cullem 290,000 settlement shares on April 1, 2024. Should the initial settlement payment and issuance of shares not be made to Mr. Cullem in full on April 1, 2024, the Settlement Agreement will be rendered null and void, releasing both parties from any further obligations under the Settlement Agreement unless otherwise mandated by a prior binding contract or agreement. Both parties will retain any and all rights, claims, and causes of action that would have otherwise been released by the Settlement Agreement.

Additionally, Mr. Cullem agreed to act as our consultant and entered into a consulting agreement (the "Consulting Agreement") with us, effective as of March 7, 2024. For the avoidance of doubt, no additional consideration is being paid to Mr. Cullem under the Consulting Agreement. Copies of the Settlement Agreement and Consulting Agreement will be included as exhibits to our Quarterly Report on Form 10-Q for the quarter ending March 31, 2024.