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, 2024

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 28, 2024, the last business day of the registrant's most recently completed second fiscal quarter, was $7,460,532 (based on the closing price for shares of the registrant's common stock as reported by the Nasdaq Capital Market on June 28, 2024). 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 31, 2025, there were 17,014,737 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2025 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The registrant's definitive proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

ALLARITY THERAPEUTICS, INC.

ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2024

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When used herein, unless the context requires otherwise, references to the "Company," "Allarity," "we," "our" and "us" refer to Allarity Therapeutics, Inc., a Delaware corporation. References in this Annual Report to "our therapeutic candidate," "our therapeutic candidate, stenoparib," or "stenoparib" refer to our sole current therapeutic candidate, stenoparib.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "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 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;
- our ability to indemnify third parties pursuant to contractual agreements;
- our ability to satisfy the Nasdaq Capital Market continued listing requirements;
- 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 stenoparib;
- 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;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;

- 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 stenoparib;
- our expectations regarding the potential market size and the rate and degree of market acceptance of stenoparib;
- 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 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 third party manufacturers to produce clinical and commercial supplies of API for stenoparib;
- our ability to obtain, maintain, protect and enforce sufficient patent and other intellectual property rights for stenoparib;
- 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 Annual Report, including those set forth in the section titled “Risk Factors” as set forth in this Annual Report, which is incorporated herein by reference.

These forward-looking statements are based on information available as of the date of this Annual 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

We are a clinical-stage, precision medicine pharmaceutical company focused on developing novel anti-cancer therapeutics for patients with high unmet medical need. We were founded on the innovation of our novel Drug Response Predictor (DRP®) platform. The DRP® technology is designed to define the gene expression signatures in cancer cells that predict the cancer cell's sensitivity to a specific cancer therapeutic. Once defined, the DRP® gene expression signature can then be assessed in cancer tissue biopsies from patients to identify those cancers that share this signature of drug sensitivity, and by extension, to identify those patients who may then be most likely to receive benefit from that specific anti-cancer therapeutic. We have developed and published DRP® signatures for dozens of anti-cancer therapeutics. Ideally, by using DRP to identify the patients most likely to benefit clinically from a given therapeutic, clinical development of that therapeutic can be focused on a smaller, more responsive patient population, which would allow for smaller, cheaper and quicker trials while also enhancing the probability of clinical and regulatory success for that therapeutic. Historically, we have generated DRP signatures for numerous anti-cancer therapeutics and had in-licensed numerous assets for DRP-guided development, including Liposomal CisPlatin (LiPlaCis), Irofulven and dovitinib as well as the novel PARP/tankyrase inhibitor, stenoparib.

In the second half of 2023, we seated two new independent directors to our board of directors, Laura E. Benjamin, PhD and Joseph W. Vazzano, CPA. Along with the chairman of the board, Gerald W. McLaughlin, Dr. Benjamin and Mr. Vazzano took the decision to replace the prior CEO, Mr. James Cullem, with Thomas H. Jensen as interim CEO. Mr. Jensen is a co-founder of Allarity and has extensive experience not only with the core DRP® platform technology but also with capital fund raising. Mr. Jensen was tasked with streamlining the organization and its finances. In June 2024, Mr. Jensen was permanently installed as our CEO. In the second half of 2024, we added a new Chief Financial Officer, Mr. Alexander Epshinsky, who comes to us after serving in accounting and controller roles in a series of small cap biotech companies. To help Mr. Jensen re-focus our clinical development program, we also added a new President and Chief Development Officer, Jeremy R. Graff, PhD, who was brought in with deep experience in cancer drug development, including nearly 17 years at Eli Lilly and Company and 10 more years in various C-suite roles in biotech.

We are now singularly focused on the development of stenoparib and the parallel development of the stenoparib DRP® as a companion diagnostic. All other assets including dovitinib, Irofulven and LiPlaCis, were terminated and are no longer part of our portfolio. Stenoparib was in-licensed with exclusive world-wide rights from the Japanese Pharmaceutical company, Eisai Pharmaceuticals. Stenoparib is a novel, dual inhibitor of poly-ADP-ribose polymerase (PARP1/2) as well as tankyrases, enzymes critically important in the WNT cancer cell survival pathway. Stenoparib is currently being explored in a phase 2 clinical trial in patients with advanced, recurrent ovarian cancer who have been pre-selected for enrollment using the stenoparib-DRP®. Emerging clinical data from this ongoing trial in heavily pre-treated, advanced ovarian cancer patients show promising clinical benefit including a patient with a complete, confirmed response (i.e., absence of active disease by RECISTv1.1 criteria) as well as a patient with primary platinum refractory disease who stayed on therapy more than 10 months and two additional patients with ongoing stable disease still on therapy more than 17 months. These compelling data in heavily pre-treated ovarian cancer patients have now prompted us to design a new clinical protocol, guided by key gynecologic oncology experts, to deepen and enrich the understanding of the clinical benefit from stenoparib treatment while also advancing the stenoparib-DRP® as a companion diagnostic used to select patients for stenoparib treatment.

Allarity's DRP® Companion Diagnostic Platform

Our patented DRP® platform is a proprietary technology that enables the development of cancer drug-specific companion diagnostics that may be used to identify patients most likely to benefit from a particular cancer therapy. Accordingly, using DRP to enrich for patients more likely to get benefit from a particular anti-cancer therapy can help to accelerate clinical development as trial sizes can be smaller with an anticipation of higher clinical benefit rates.

Our patented DRP® platform is a powerful bioinformatic engine based on advanced systems biology used to assess the cancer's transcriptome - the entire library of genes that are transcribed, or expressed, in a cancer. To create a new, drug-specific DRP®, we first assess the transcriptome from an established panel of cancer cell lines which have been treated with the cancer drug or therapeutic candidate. We then correlate the gene expression profile of these cell lines that are either sensitive or resistant to the drug or therapeutic candidate. In our development of a companion diagnostic, we typically use the well-known collection of 60 human tumor cell lines from the National Cancer Institute known as the "NCI-60" panel. We may 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 the specific RNA changes (i.e., gene expression changes) that correlate with either drug response or resistance. The totality 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 cancers (from patients), thereby reducing background "noise" from our observations. This process generates a putative DRP® companion diagnostic, specific for the drug or therapeutic candidate, which identifies and ring-fences those cancer patients most likely to get benefit from that specific drug. Typically, between 50 and 400 biomarkers (i.e., expressed genes) comprise a putative DRP® companion diagnostic for any specific drug or therapeutic candidate.

Before we can confidently use the DRP® as a companion diagnostic, we must retrospectively validate the predictive power of the DRP® for that drug by accessing gene expression data from tumor biopsy tissues collected from prior clinical trials of that drug. Then, in a blinded manner, the DRP data are retrospectively used to "predict" which patients received clinical benefit. Unblinding the clinical benefit data and then comparing to the "prediction" made using the DRP allows us to assess the utility of DRP for potential patient selection. At this stage, we can assess clinical benefit against a range of DRP scores to begin to establish a cutoff score for the putative DRP® companion diagnostic - i.e., a score above which patients would be putatively enrolled in a prospective trial and below which patients would be excluded. Ideally, the DRP companion diagnostic will be used to screen patients before treatment for inclusion into a trial and this enriched population would show substantially elevated clinical benefit when compared to standard of care therapy in unselected patients. 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.

Our DRP® platform has been evaluated for multiple anti-cancer drugs using retrospective observational studies in 35 clinical trials that were conducted or sponsored by other companies for those drugs. 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, showing the broad potential applicability of the DRP technology. Patent applications for our DRP® companion diagnostics have been submitted for more than 70 anticancer agents. 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.

In contrast with other 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 in retrospective studies has been successful in more than 35 clinical trials.

- ***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 have 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® to pre-select patients for clinical trials.

We have a broad intellectual property portfolio comprised of 18 granted DRP® patents covering 70 different cancer drugs, and another 9 DRP® patent applications pending covering 3 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.

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 LiPlaCis® leveraging a platinum-specific DRP® companion diagnostic for development in partnership with Chosa Oncology. 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. We have previously developed and retrospectively assessed a DRP® companion diagnostic specific for cisplatin, which may enable us to identify and treat the patients most likely to respond to this therapeutic candidate.

In 2024, we signed service agreements with external biotech clients for both DRP® analysis and gene expression services. Leveraging our gene expression and diagnostic capabilities, our laboratory will provide the services to the external clients. We have received down payments in 2024 totaling approximately $0.2 million, are actively preparing the laboratory and required samples, and expect to start recognizing revenue in 2025.

Stenoparib: Allarity's Novel, Dual Inhibitor of PARP and Tankyrases

Our 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, notably ovarian cancers. Tankyrases are enzymes involved in the stabilization and maintenance of telomeres (the ends of chromosomal DNA) during cell replication. Tankyrases and the WNT pathway also enable cancer cell survival and are commonly upregulated in advanced, chemo- and radio-resistant cancers including ovarian as well as colon and other cancers.

There are multiple PARP inhibitors currently approved and used for the treatment of cancers, primarily ovarian and breast cancers but now also pancreatic and prostate cancers. PARP inhibitors disable DNA repair. Tumors with genetic defects in DNA damage repair (e.g., tumors with BRCA mutations) are particularly vulnerable to the added effect of PARP inhibition. Coupling PARP inhibition to in-born defects in DNA Damage Repair creates "Synthetic Lethality," selectively killing cancer cells while theoretically sparing most normal cells (as most normal cells have intact DNA repair mechanisms). Stenoparib is distinct from other PARP inhibitors in that it not only potently inhibits PARP but also the PARP family enzymes known as Tankyrases. Tankyrases are key enzymes whose activation drives WNT pathway activity, enabling cancer cell survival, invasion, metastasis and therapeutic resistance. Moreover, there is evidence that WNT pathway inhibition may itself disable or diminish DNA Damage Repair creating a "BRCA-mutant like" state in cancer cells that may not typically be susceptible to PARP inhibitor-induced death. Additionally, preclinical data suggest that stenoparib may cross the blood-brain barrier (BBB) — potentially suggesting stenoparib use 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 PARP inhibitors.

Pre-Clinical Studies

PARP utilizes nicotinamide adenine dinucleotide (NAD) as substrate to catalyze the polymerization and transfer of poly (ADP-ribose) (PAR) to substrate 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, trapping PARP on DNA to restrict cancer cell growth and survival. 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 suggesting that PgP-mediated drug resistance, which is common for many cancer drugs, may not be an issue for 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 and reduction in disease, which translated to a statistically significant survival benefit.

In addition to activity as monotherapy, stenoparib used in combination potentiated the anti-tumor effects of common chemotherapeutics Temozolomide (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 suspend the clinical development of E7449 (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 Adverse Events (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.

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 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). Retrospectively, both PRs were "predicted" by the DRP® for stenoparib after analyzing biopsies from 13 of the patients.

Development of Our Lead Clinical Asset, Stenoparib

Stenoparib is a novel inhibitor of the key DNA damage repair enzyme PARP. Distinct from most 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 formerly known as E7449, was originally developed by Eisai, Inc. (Eisai) through Phase 1 clinical trials. The phase 1 Eisai trial was run in cancer patients regardless of cancer type (i.e., an "all-comers" trial; Plummer et al, 2020) and showed Partial Responses by RECIST criteria, especially in 2 ovarian cancer patients. Allarity had developed a DRP for stenoparib and engaged Eisai to assess whether that stenoparib-DRP would, in a retrospective assessment of the Eisai clinical data, identify the responsive patients. The success of doing so then prompted Allarity to in-license exclusive world-wide rights to develop, commercialize and market stenoparib. Consequently, Allarity 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.

Stenoparib is currently in a Phase 2 clinical trial for the treatment of ovarian cancer patients who have had at least 3 prior lines of therapy. The trial has been running at numerous trial sites in the U.S. and Europe. The trial was expressly designed to enroll patients based on a stenoparib-DRP score above 50 (i.e., DRP+ patients) using the stenoparib-specific DRP® companion diagnostic for which the FDA has previously approved an Investigational Device Exemption (IDE). The first cohort was administered 600 mg stenoparib once daily - the Maximum Tolerated Dose assigned by Eisai in the original dose escalation phase 1 study. Cohort 2 was designed to enroll only DRP+ patients with 600 mg stenoparib being orally administered twice daily (200 mg dose in the morning and a 400 mg dose in the evening). Cohort 2 in particular has provided promising clinical efficacy data showing durable clinical benefit in multiple patients including one confirmed, complete response (by RECIST v1.1 criteria) as well as 1 platinum refractory patient remaining on the drug more than 10 months and 2 additional patients with extended stable disease continuing on treatment now beyond 17 months.

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 of 1933, as amended (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

We were founded in Denmark in 2004 by our chief scientific officer, Steen Knudsen, Ph.D., and our Chief Executive Officer, Thomas H. 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.

We were incorporated in Delaware in 2021. 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.

Our principal executive offices are located at 24 School Street, 2nd Floor, Boston, MA 02108. Our telephone number is (401) 426-4664, and our email address is info@allarity.com. Our corporate website address is *www.allarity.com*. Information contained on or accessible through our website is not a part of this Annual Report, and the inclusion of our website address in this Annual 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 Annual 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 Annual 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 candidate, stenoparib, 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 Business

Our DRP® companion diagnostic platform has been retrospectively evaluated 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*. 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.

Throughout 2024, a deep dive review of our development programs, clinical progress, likelihood of clinical and regulatory success and an evaluation of commercial plausibility prompted new our management to terminate all development candidates except that of stenoparib. Not only does this streamline the focus on our most promising asset, but it also enabled critical cost saving measures. Stenoparib continues in phase 2 clinical studies for patients with advanced, recurrent ovarian cancer showing promising, durable clinical benefit in patients with limited alternative treatment options other than more chemotherapy. These data continue to mature and have prompted us to work with Key Opinion Leaders (KOLs) in gynecologic oncology to devise and finalize a follow-on clinical trial in advanced ovarian cancer patients that will more aggressively advance stenoparib toward regulatory approval.

Overview of Ovarian Cancer

Ovarian Cancer (OC) is a lethal disease with a 5-year survival rate of 20-30% for advanced OC. 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).

The peak incidence of BC occurred in the 41-50-year age group (28.3 per 1,000 person-years) for BRCA1 and in the 51-60-year group (30.6 per 1,000 person-years) 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.

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 FDA-approved PARP inhibitors were approximately $9.0 billion in 2023 and are forecasted to be over $21.0 billion by 2031.

Despite the commercial success of PARP inhibitors, broader adoption is limited by their high rates of GI and bone marrow/ myelo-toxicity. 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 does not show the myelotoxicity common among first generation PARP inhibitors.
- 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 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.

Overview of Our PRP® (Patient Response Predictor)

Collections of drug-specific, putative DRP® companion diagnostics can be grouped together to form a panel of 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® 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:

- 18 DRP® companion diagnostics patents granted covering 70 different cancer drugs, including 8 issued patents in the U.S. and 5 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.

- 9 DRP® companion diagnostics patent applications pending covering 3 drugs, including pending applications in the U.S., China, Japan, Canada, India, and Australia. Our pending patent applications cover, among others, DRP® companion diagnostics for 2X-111 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).

- 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.

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.

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.

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 ("Eisai License Agreement"). Upon the execution of the Eisai License Agreement in 2017, we paid Eisai a one-time, non-refundable, and non-creditable payment of $1 million. Pursuant to the Eisai License Agreement, we are solely responsible for the development of stenoparib during the term of the Eisai License Agreement. The Eisai License 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.

On July 12, 2022, we amended the terms of the Eisai License Agreement with Eisai in order to (1) further postpone the due date of the extension payment and extend the deadline for our successful completion of its first Phase 1b or Phase 2 clinical trial for stenoparib beyond December 31, 2022; and (2) amend terms related to Eisai’s right of termination of development.

On May 26, 2023, we entered into a fourth amendment with Eisai to the Eisai 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. We agreed to pay Eisai in periodic payments as follows: (i) $100,000, which has been paid; (ii) $50,000 within 10 days of execution of the fourth amendment, which has been paid; (iii) $100,000 upon completion of a capital raise, which has been paid; and (iv) $850,000 on or before March 1, 2024.

On February 26, 2024, in exchange for an additional $200,000, paid as of May 1, 2024, we entered into a fifth amendment to the Eisai License Agreement with Eisai to postpone the payment of $850,000. We agreed to make a one-time payment to Eisai of $850,000 upon completion of a ten-million-dollar capital raising campaign, no later than September 1, 2024. We paid Eisai $850,000 on August 20, 2024 and no payments are currently outstanding.

On August 2, 2024, we entered into a sixth amendment to the Eisai License Agreement with Eisai in order to (1) amend the definition of a successful completion and (2) amend the terms related to Eisai's right of termination for development.

Development Milestone Payments

Pursuant to the Eisai License Agreement, as amended, 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.

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, 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 Annual Report, Eisai has not indicated an intention to exercise its repurchase option.

LiPlaCis Support Agreement with Smerud, Chosa and LiPlasome

Pursuant to the terms of the amendment on March 28, 2022 to the out-license agreement with Smerud Medical Research International (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. On March 28, 2022, and concurrent with the entry into the Amended License Agreement with LiPlasome Pharma ApS and Chosa, 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 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.

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 (especially with inhibitory activity against the WNT pathway), with or without its Stenoparib-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 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 candidate, stenoparib, is considered a small molecule drug and must be approved by the FDA through the new drug application ("NDA"), and similarly by the EMA under an equivalent process, before it 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 an 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 stenoparib 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.

- Pivotal or 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 stenoparib. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that stenoparib does not undergo unacceptable deterioration over its 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.

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 Patient Protection and Affordable Care Act ("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, extended 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 having gone 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 U.S., 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. 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.

Human Capital

As of December 31, 2024, we had 7 employees, 6 of whom were full-time and 1 half-time; and most of whom 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 in Sweden, one near New York, NY, and one near Tampa, FL. 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 have also retained a number of expert advisors and consultants who help navigate us through different aspects of our business.

Item 1A. Risk Factors.

An investment in our shares of 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 shares of common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business and Industry

We may become delinquent in our payments to Eisai. In consideration for extension of certain deadlines and payment obligations, we entered into several amendments to an Exclusive License Agreement with Eisai.

On August 2, 2024, the Company and Eisai entered into a sixth amendment to the Exclusive License Agreement with an effective date of August 2, 2024. The terms of the amended Exclusive License Agreement were further updated in order to align the definition of a successful phase 2 completion and amend the related to Eisai's right of termination for development. 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. If all milestones have been achieved which would reflect regulatory and commercial success, 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. In addition to the milestone payments described above, we have agreed to pay Eisai royalties based on annual incremental sales of 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 in such country and expiring on the later of (i) the expiration of the last valid claim of any and all Eisai patents, Company patents and joint patents covering such product in such country; or, (ii) 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. 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 on April 15, 2019, and as of the date of this Annual Report, Eisai has not indicated an intention to exercise its repurchase option. In light of our financial condition and dependence on financing for our operations, we may be unable to meet the payment requirements under the 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.

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, the conflicts in Israel and the Gaza Strip and the broader Middle East, terrorism or other geopolitical events. Sanctions imposed by the U.S. 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 Nasdaq continued 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 26, 2025, we employed a total of 6 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 stenoparib. 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 stenoparib 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 stenoparib 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., our President and Chief Development Officer, Dr. Jeremy R. Graff, PhD and Mr. Thomas H. Jensen, our Chief Executive Officer. We do not maintain "key person" insurance for Dr. Knudsen, Dr. Graff or Mr. 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, cancer drug development 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 candidate 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 stenoparib 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 authorization 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 Annual 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 stenoparib, 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.

Risks Related to Our Financial Position and Need for Additional 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 candidate, including conducting clinical trials on our therapeutic candidate, 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 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.

Since our inception of our predecessor, Allarity Therapeutics A/S, we have incurred losses and have an accumulated deficit of $119.0 million as of December 31, 2024. Our net losses were $24.5 million and $11.9 million for the years ended December 31, 2024, and 2023, respectively. We expect to incur substantial operating losses for the foreseeable future and may never achieve profitability. Our current therapeutic candidate has not been approved for marketing in the U.S., 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 stenoparib, including, but not limited to, advancing our DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer;
- initiate preclinical studies and clinical trials for any additional indications for stenoparib;
- 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 stenoparib;
- ultimately establish a sales, marketing, distribution and other commercial infrastructure to commercialize our 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 our therapeutic candidate with significant market potential or license our therapeutic candidate to an industry partner. This will require us to be successful in a range of challenging activities, including completing clinical trials of our therapeutic candidate, publishing our data and findings on our therapeutic candidate with peer reviewed publications, developing commercial scale manufacturing processes, obtaining marketing approval, manufacturing, marketing and selling our current therapeutic candidate for which we may obtain marketing approval, and satisfying any post-marketing requirements.

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 our therapeutic candidate. 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 therapeutic candidate, our expenses could increase, and profitability could be further delayed.

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 program for stenoparib or its 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 stenoparib, we may not be able to enter into a partnership or out-license for stenoparib 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 stenoparib 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.

As of December 31, 2024, we had cash, cash equivalents and marketable securities of $19.5. In addition, in the first quarter of 2025, we issued and sold an aggregate of 9,719,173 shares of our common stock under our at-the-market offering program for aggregate net proceeds of $9.7 million, after deducting commissions and offering expenses payable by us. We believe that our existing cash, cash equivalents and marketable securities, including the net proceeds from sales of common stock under our at-the-market offering program during the first quarter of 2025, will enable us to fund our operating expenses and capital expenditure requirements at least into the second half of 2026. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. As a result, we could deplete our capital resources sooner than we currently expect and could be forced to seek additional funding sooner than planned.

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 stenoparib 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 stenoparib;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending against intellectual property related claims;
- 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 associated with maintaining and expanding our cybersecurity systems; and
- the costs of operating as a public company.

Failure to achieve and maintain effective internal controls could have a material adverse effect on our business.

Effective internal controls are necessary for us to provide reliable financial reports. If we cannot provide reliable financial reports, our operating results could be harmed. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results, or cause us to fail to meet our reporting obligations. Failure to achieve and maintain an effective internal control environment could cause investors to lose confidence in our reported financial information, which could have a material adverse effect on our stock price. Failure to comply with Section 404 of the Sarbanes-Oxley Act could also potentially subject us to actions or investigations by the SEC or other regulatory authorities.

Risks Related to the Discovery and Development of Stenoparib

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 our therapeutic candidate is substantial. It is impossible to predict when or if our therapeutic candidate will prove effective or safe or effective in humans or will receive regulatory approval. To obtain the requisite regulatory approvals to market and sell our therapeutic candidate, we must demonstrate through extensive preclinical studies and clinical trials that our therapeutic candidate is 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 candidate 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 our therapeutic candidate, the development timeline and regulatory approval and commercialization prospects for our therapeutic candidate, 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 candidate, 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 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 candidate, 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 candidate, 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 candidate 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 candidate, 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 candidate could be negatively impacted, and our ability to generate revenues from our therapeutic candidate 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 candidate, 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 candidate 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 candidate.

If we fail to comply with our obligations in the agreements under which we have licensed the intellectual property rights from third parties for stenoparib or otherwise experience disruptions to our business relationships with our licensors, we could lose rights to advance the development of 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 stenoparib.

Prior to the acquisition of our therapeutic candidate, 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 candidate 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, the therapeutic candidate.

We are dependent on our ability to advance the development of our therapeutic candidate. 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.

If we do not obtain the regulatory approval for and successfully commercialize our therapeutic candidate 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 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 candidate in one or more disease indications.

The success of stenoparib will depend on several factors, including the following:

- our ability to successfully complete clinical trials to obtain regulatory approval for our therapeutic candidate without significant delay;
- advancing our DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer;
- 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 U.S. 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 stenoparib 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 stenoparib, 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 candidate 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 our existing therapeutic candidate or any therapeutic candidates we may seek to develop in the future will never obtain regulatory approval.

Stenoparib 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 candidate or the FDA or comparable foreign regulatory authorities may not approve a DRP® companion diagnostic that is required to select patients responsive to our therapeutic candidate;
- 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 candidate may not be sufficient to support the submission of an NDA, or other submission or to obtain regulatory approval in the U.S. 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 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 candidate 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 candidate, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve our therapeutic candidate 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 candidate.

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 our therapeutic candidate will be successful in clinical trials or receive regulatory approval. Further, our therapeutic candidate may not receive regulatory approval even if it is successful in clinical trials. If we do not receive regulatory approval for our therapeutic candidate, we may be unable to continue our operations. Even if we successfully obtain regulatory approvals to market our therapeutic candidate, 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 market for patients that we are targeting for our therapeutic candidate is 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 drug, if approved.

We plan to seek regulatory approval to commercialize our therapeutic candidate both in the U.S. 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 candidate, and we cannot predict success in these jurisdictions.

Our business strategy of using our proprietary DRP® companion diagnostics platform to advance stenoparib may not be successful, and important issues relating to safety and efficacy remain to be resolved for stenoparib. Our strategy also involves risks and uncertainties that differ from other biotechnology companies that focus solely on new therapeutic candidates.

Our therapeutic candidate portfolio includes small molecules that others have tried to develop into an approved commercialized drug. Our strategy to use our proprietary DRP® companion diagnostics platform to identify and subsequently clinically advance our therapeutic candidate.

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 our therapeutic candidate. We use our proprietary DRP® companion diagnostics platform to advance our therapeutic candidate 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 our therapeutic candidate 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. 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, 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.

Smerud Medical Research International and Chosa ApS are responsible for the development of our LiPlaCis® in conjunction with our 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 stenoparib. 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;
- 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 candidate, 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 candidate may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development program;
- the number of patients required for clinical trials of our therapeutic candidate 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 candidate may be greater than we anticipate;
- the supply or quality of our therapeutic candidate or other materials necessary to conduct clinical trials of our therapeutic candidate may be insufficient or inadequate;
- regulators may revise the requirements for approving our therapeutic candidate, 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 candidate beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our therapeutic candidate 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 stenoparib 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 stenoparib, 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 stenoparib, the commercial prospects of stenoparib will be harmed, and our ability to generate revenues from stenoparib will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down stenoparib's 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 stenoparib.

Stenoparib 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 stenoparib 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 stenoparib 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 stenoparib 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 stenoparib to understand the side effect profiles for our clinical trials and upon any commercialization of stenoparib. Inadequate training in recognizing or managing the potential side effects of stenoparib could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if stenoparib receives marketing approval, and we or others later identify undesirable side effects caused by stenoparib, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of stenoparib;
- we may be required to recall stenoparib or change the way such stenoparib is administered to patients;

- additional restrictions may be imposed on the marketing or distribution of stenoparib or the manufacturing processes for stenoparib 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;
- stenoparib 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.

We are leveraging our proprietary DRP® companion 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 stenoparib 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 stenoparib 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 stenoparib or help us identify additional potential therapeutic candidates.

As with any drug development endeavor, 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 stenoparib 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 stenoparib. 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 U.S. 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 U.S. and may not obtain marketing approvals for stenoparib in Europe and other jurisdictions.

In addition to regulations in the U.S., should we or our collaborators pursue marketing approvals for stenoparib 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 stenoparib. Whether or not we, or our collaborators, obtain applicable FDA regulatory clearance and marketing approval for stenoparib, 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.

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 stenoparib.

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 U.S. 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 Stenoparib

Even if we are successful in completing all preclinical studies and clinical trials, we may not be successful in commercializing stenoparib.

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 stenoparib. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize stenoparib, and our ability to generate revenue will be materially impaired.

Stenoparib and the activities associated with its 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 U.S. and by the European Medicines Agency (the "EMA") and similar regulatory authorities outside of the U.S. 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 stenoparib in the U.S. 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. Stenoparib 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 stenoparib receives marketing approval, the accompanying label may limit the approved use of stenoparib in this way, which could limit sales of stenoparib.

The process of obtaining marketing approvals, both in the U.S. 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 stenoparib 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 stenoparib 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 stenoparib 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 stenoparib 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 stenoparib, we may be unable to obtain approval of or market stenoparib.

We may rely on orphan drug status to commercialize stenoparib, 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 stenoparib. In the U.S., 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 U.S. 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 U.S. 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. It is unclear how the new Trump administration will impact the scope of the orphan drug exclusivity.

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

We may seek a breakthrough therapy designation for stenoparib. 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 stenoparib 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 stenoparib qualifies as a breakthrough therapy, the FDA may later decide that the drug no longer meets 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 stenoparib. 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 stenoparib 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 U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside of the U.S., 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 U.S. 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 U.S. 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 stenoparib, and we do not obtain or face delays in obtaining FDA approval of a DRP® diagnostic device, we will not be able to commercialize stenoparib 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 stenoparib, and we do not obtain or there are delays in obtaining FDA approval of a diagnostic device, we may not be able to commercialize stenoparib 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 stenoparib. We intend to file a PMA for stenoparib if, and when, we decide to pursue the submission of an NDA for stenoparib.

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 stenoparib receives marketing approval, the accompanying label may limit the approved use of stenoparib in this way, which could limit sales of stenoparib.

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 U.S., 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 stenoparib 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 stenoparib.

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, stenoparib may not be accepted by physicians or the medical community in general.

There can be no assurance that stenoparib will be accepted by physicians, hospitals and other health care facilities. Stenoparib 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;
- timing of market approval and commercial launch of stenoparib;
- the clinical indication(s) for which stenoparib is approved;
- drug label and package insert requirements;
- advantages and disadvantages of stenoparib 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 U.S. 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 stenoparib's 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 U.S. 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 U.S., new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the U.S. 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.

Recent efforts by the Trump Administration to reduce government spending include reductions in the FDA's workforce. This may impact the FDA's ability to approve current or future products and could delay regulatory approval of our current or future product candidates. This could delay commercialization of our products.

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 stenoparib and may affect the price we may set.

In the United States and other foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changes the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare and Medicaid Innovation at the Centers for Medicare and Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011 has, among other things, led to aggregate reductions of Medicare payments to providers, which, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional action is taken by Congress. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price. These laws and any laws enacted in the future may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D continue to penalize price increases that outpace inflation; and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on the pharmaceutical industry cannot yet be fully determined but, is likely to be significant.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for ABP-450, if approved, or additional pricing pressures.

Individual states in the United States have also become increasingly active in passing legislation and implementing 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. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on our product pricing.

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

Governments outside of the U.S. 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 stenoparib 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 stenoparib. 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 stenoparib 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 stenoparib. As a result, our results of operations and the commercial prospects for stenoparib 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 stenoparib 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 stenoparib. 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 stenoparib 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 stenoparib in sufficient quality and quantity, which would delay or prevent us from developing and commercializing stenoparib.

In order to conduct clinical trials of stenoparib and commercialize stenoparib, we, or our manufacturers, will need to manufacture stenoparib in large quantities. We, or our manufacturers, may be unable to successfully increase the manufacturing capacity for stenoparib 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 stenoparib in sufficient quality and quantity, the development, testing, and clinical trials of stenoparib may be delayed or infeasible, and regulatory approval or commercial launch of stenoparib 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 stenoparib, or to do so on commercially reasonable terms, we may not be able to develop and commercialize stenoparib 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 stenoparib.

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 stenoparib. 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 Intellectual Property

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

In the U.S., 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-U.S. jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, when stenoarpib receives 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 stenoparib, 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 U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect stenoparib.

Changes in either the patent laws or interpretation of patent laws in the U.S., 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 U.S. 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 U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent.

After March 2013, under the Leahy-Smith Act, the U.S. 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 U.S., 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 U.S. 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 stenoparib and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. 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 stenoparib nears 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 stenoparib or force us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign stenoparib, 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 stenoparib, 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 stenoparib. 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 U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. 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 U.S. 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 U.S. 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 Ownership of our Securities and Our Status as a Public Company

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 stenoparib 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 any public health crisis 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 stenoparib;
- adverse results from, delays in or termination of clinical trials;
- unanticipated serious safety concerns related to the use of stenoparib;
- lower than expected market acceptance of stenoparib 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 Annual 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 stenoparib, if it receives 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 stenoparib;
- changes in the development status of stenoparib;
- 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 stenoparib;
- unanticipated safety concerns related to the use of stenoparib;
- 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 and exchange of any outstanding 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.

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.

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.

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 no shares are outstanding as of March 31, 2025. The 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 shares of common stock, and therefore, reduce the value of our shares of 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 Securities Exchange Act of 1934, as amended (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 Annual 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 U.S. 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 U.S. require significant expenditures and will place significant demands on our management and other personnel, including costs resulting from our reporting obligations under 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 stenoparib 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 stenoparib 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 stenoparib 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.

The development and use of artificial intelligence, or AI, presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data and could give rise to legal and/or regulatory actions, damage our reputation or otherwise materially harm our business.

Artificial intelligence, or AI, is increasingly being used in the biopharmaceutical, pharmaceutical, technology, and consumer health industries. We may develop and incorporate AI technology in certain of our products and services. Issues relating to the use of new and evolving technologies such as AI, machine learning, generative AI, and large language models, may cause us to experience perceived or actual brand or reputational harm, technical harm, competitive harm, legal liability, cybersecurity risks, privacy risks, compliance risks, security risks, ethical issues, and new or enhanced governmental or regulatory scrutiny, and we may incur additional costs to resolve such issues. Litigation or government regulation related to the use of AI may also adversely impact our ability to develop and offer products that use AI, as well as increase the cost and complexity of doing so. In addition, uncertainties regarding developing legal and regulatory requirements and standards may require significant resources to modify and maintain business practices to comply with U.S. and non-U.S. laws concerning the use of AI, the nature of which cannot be determined at this time. In addition, the European Union recently passed the Artificial Intelligence Act, whose regulations will be developed over the coming year and, in the U.S., the recent Executive Order concerning artificial intelligence may result in extensive new federal rule-making. Further, market demand and acceptance of AI technologies are uncertain, and we may be unsuccessful in our product development efforts.

We plan to develop policies governing the use of AI to help reasonably ensure that such AI is used in a trustworthy manner by our employees, contractors, and authorized agents and that our assets, including intellectual property, competitive information, personal information we may collect or process, and customer information, are protected. Any failure by our personnel, contractors, or other agents to adhere to our established policies could violate confidentiality obligations or applicable laws and regulations, jeopardize our intellectual property rights, cause or contribute to unlawful discrimination, or result in the misuse of personally identifiable information or the injection of malware into our systems, any of which could have a material adverse effect on our business, results of operations, and financial condition.

Our share buyback program that was approved by the Board in March 2025 could affect our stock price and increase its volatility, and may reduce the market liquidity for our stock. The share buyback program may also materially impact the Company's liquidity.

Repurchases pursuant to the share buyback program entered into in March 2025, or any other share buyback program we adopt in the future, could affect our stock price and increase its volatility and may reduce the market liquidity for our stock. The existence of a share buyback program could also cause our stock price to be higher than it would be in the absence of such a program. Additionally, these repurchases will diminish our cash and may subject us to additional taxes, which could impact our ability to pursue possible future strategic opportunities and acquisitions and would result in lower overall returns on our cash balances. There can be no assurance that any future share repurchases will, in fact, occur, or, if they occur, that they will enhance stockholder value. Although share buyback programs are intended to enhance long-term stockholder value, short-term stock price fluctuations could reduce the effectiveness of these repurchases.

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, 2024, 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 located at 24 School St, 2nd Fl, Boston, MA 02108. We lease at-will, month-to-month the virtual office space, where we are not bound by any lease. Additionally, we lease a space in a technology park consisting of approximately 4,283 square feet in Hoersholm, Denmark. The facility lease in continuing on a month-to-month basis. We believe that our facilities are adequate to meet our current needs and the additional space can be obtained on commercially reasonable terms as needed.

Item 3. Legal Proceedings.

For information regarding our material legal proceedings, see "*Note 16. Commitments and Contingencies*" in the accompanying "*Notes to Consolidated Financial Statements*" in this Annual Report, which information is incorporated herein by reference.

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 the Nasdaq Capital 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 Annual Report, we had 3 stockholders of record for our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners, but whose share are held in street name by brokers and nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

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 our 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 Annual 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 Annual 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 the "Company," "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 clinical-stage, precision medicine pharmaceutical company focused on developing novel anti-cancer therapeutics for patients with high unmet medical need. We were founded on the innovation of our novel Drug Response Predictor (DRP®) platform. The DRP® technology is designed to define the gene expression signatures in cancer cells that predict the cancer cell's sensitivity to a specific cancer therapeutic. Once defined, the DRP® gene expression signature can then be assessed in cancer tissue biopsies from patients to identify those cancers that share this signature of drug sensitivity, and by extension, to identify those patients who may then be most likely to receive benefit from that specific anti-cancer therapeutic. We have developed and published DRP® signatures for dozens of anti-cancer therapeutics. Ideally, by using DRP to identify the patients most likely to benefit clinically from a given therapeutic, clinical development of that therapeutic can be focused on a smaller, more responsive patient population, which would allow for smaller, cheaper and quicker trials while also enhancing the probability of clinical and regulatory success for that therapeutic. Historically, we have generated DRP signatures for numerous anti-cancer therapeutics and had in-licensed numerous assets for DRP-guided development, including Liposomal CisPlatin (LiPlaCis), Irofulven and dovitinib as well as the novel PARP/tankyrase inhibitor, stenoparib.

In the second half of 2023, we seated two new independent directors to our board of directors, Laura E. Benjamin, PhD and Joseph W. Vazzano, CPA. Along with the chairman of the board, Gerald W. McLaughlin, Dr. Benjamin and Mr. Vazzano took the decision to replace the prior CEO, Mr. James Cullem, with Thomas H. Jensen as interim CEO. Mr. Jensen is a co-founder of Allarity and has extensive experience not only with the core DRP® platform technology but also with capital fund raising. Mr. Jensen was tasked with streamlining the organization and its finances. In June 2024, Mr. Jensen was permanently installed as the CEO. In the second half of 2024, we added a new Chief Financial Officer, Mr. Alexander Epshinsky, who comes to us after serving in accounting and controller roles in a series of small cap biotech companies. To help Mr. Jensen re-focus our clinical development program, we also added a new President and Chief Development Officer, Jeremy R. Graff, PhD, who was brought in with deep experience in cancer drug development including nearly 17 years at Eli Lilly and Company and 10 more years in various C-suite roles in biotech.

We are now singularly focused on the development of stenoparib and the parallel development of the stenoparib-DRP® as a companion diagnostic. All other assets including dovitinib, Irofulven and LiPlaCis, were terminated and are no longer part of our portfolio. Stenoparib was in-licensed with exclusive world-wide rights from the Japanese Pharmaceutical company, Eisai Pharmaceuticals. Stenoparib is a novel, dual inhibitor of poly-ADP-ribose polymerase (PARP1/2) as well as tankyrases, enzymes critically important in the WNT cancer cell survival pathway. Stenoparib is currently being explored in a phase 2 clinical trial in patients with advanced, recurrent ovarian cancer who have been pre-selected for enrollment using the stenoparib-DRP®. Emerging clinical data from this ongoing trial in heavily pre-treated, advanced ovarian cancer patients show promising clinical benefit including a patient with a complete, confirmed response (i.e., absence of active disease by RECISTv1.1 criteria) as well as two patients with ongoing stable disease still on therapy more than 14 months. These compelling data in heavily pre-treated ovarian cancer patients have now prompted us to design a new clinical protocol, guided by key gynecologic oncology experts, to deepen and enrich the understanding of the clinical benefit from stenoparib treatment while also advancing the stenoparib- DRP® as a companion diagnostic used to select patients for stenoparib treatment.

Recent Developments

Authorized Share Increase

On March 20, 2023 we filed a Second Certificate of Amendment of Certificate of Incorporation with the Secretary of State of the State of Delaware to increase the number of authorized shares from 30,500,000 to 750,500,000 and to increase the number of common stock from 30,000,000 to 750,000,000. The amendment was approved by the holders of the majority of our outstanding common stock and Series C Preferred Stock.

On September 9, 2024, we filed the Sixth Certificate of Amendment with the Secretary of State of the State of Delaware to decrease the number of authorized shares from 750,500,000 to 250,500,000, and to decrease the number of our common stock from 750,000,000 to 250,000,000. The amendment was approved by our stockholders at the 2024 annual meeting held on September 3, 2024.

Reverse Stock Splits

On June 28 and March 24, 2023, April 9, 2024, and September 11, 2024, we effected a 1-for-40 reverse stock split, 1-for-35 reverse stock split, 1-for-20 reverse stock split, and 1-for-30 reverse stock split, respectively, of our shares of common stock (collectively, the "Reverse Stock Splits"). All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Splits for all periods presented. Proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all stock options, restricted stock, preferred stock and warrants outstanding on September 12, 2024, which resulted in a proportional decrease in the number of shares of our common stock reserved for issuance upon exercise or vesting of such stock options, restricted stock and warrants, and, in the case of stock options and warrants, a proportional increase in the exercise price of all such stock options and warrants. No fractional shares were issued in connection with the Reverse Stock Splits. If, as a result of the Reverse Stock Splits, a stockholder would otherwise have been entitled to a fractional share, each fractional share was rounded up to the next whole number.

Novartis Termination Notice

On January 26, 2024, we received a termination notice from Novartis Pharma AG, a company organized under the laws of Switzerland ("Novartis") due to a material breach of that certain license agreement dated April 6, 2018, as amended to date (the "License Agreement"). Accordingly, under the terms of the License Agreement, we ceased all development and commercialization activities with respect to all licensed products, all rights and licenses granted by Novartis to us reverted to Novartis; and all liabilities due to Novartis became immediately due and payable inclusive of interest which is continuing to accrue at 5% per annum. There were no payments made to Novartis in 2024. As of December 31, 2024, the liability is recorded as a current liability on our condensed consolidated balance sheets as follows: $3.6 million in accounts payable and $1.6 million in convertible promissory notes and accrued interest.

SEC Investigation

On July 19, 2024, we received a "Wells Notice" from the Staff of the SEC relating to our previously disclosed SEC investigation. The Wells Notice relates to our disclosures regarding meetings with the United States Food and Drug Administration (the "FDA") regarding our NDA for Dovitinib or Dovitinib-DRP, which was submitted to the FDA in 2021. We understand that all conduct relating to the SEC Wells Notice occurred during or prior to fiscal year 2022. We also understand that three of our former officers received Wells Notices from the SEC relating to the same conduct. A Wells Notice is neither a formal charge of wrongdoing nor a final determination that the recipient has violated any law. The Wells Notice informed us that the SEC Staff has made a preliminary determination to recommend that the SEC file an enforcement action against us that would allege certain violations of the federal securities laws. On March 13, 2025, we issued a press release that we have reached a final settlement with the SEC relating to our previously disclosed SEC investigation, and as part of the settlement, we have agreed to pay a one-time civil penalty of $2.5 million.

Class Action

On September 13, 2024, a purported class action captioned *Osman Mukeljic v. Allarity Therapeutics, Inc., et al*, 1:24-cv-06952, was filed in the United States District Court for the Southern District of New York against us and certain of our current and former officers. The complaint alleged, among other things, that defendants made false and misleading statements and/or failed to disclose information related to Dovitinib NDA's continued regulatory prospects and purported misconduct in connection with the Dovitinib NDA and/or the Dovitinib-DRP PMA. The complaint asserted violations of Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder against all defendants as well as violations of Section 20(a) of the Exchange Act against the individual defendants. On February 26, 2025, we issued a press release announcing the dismissal of this class action lawsuit.

Chief Executive Officer

On December 8, 2023, James G. Cullem was terminated as our Chief Executive Officer and effective January 27, 2024, Mr. Cullem resigned as a director of Allarity.

On December 8, 2023, Thomas H. Jensen was appointed by our board of directors as Interim Chief Executive Officer to replace Mr. Cullem. Prior to his appointment as Chief Executive Officer, Mr. Jensen was paid consulting fees for his services to us. Effective June 1, 2024, we entered into a Management Services Agreement ("MSA") with Ljungaskog Consulting AB, a Swedish limited liability company owned and managed by Mr. Jensen, which superseded and replaced the existing consulting agreement.

Funding and Capital Resources

Since our inception through December 31, 2024, our operations have been financed primarily by the sale of preferred stock, convertible promissory notes, and the sale and issuance of our common shares.

Since inception, we have had significant operating losses. Our net loss was $24.5 million and $11.9 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had $19.5 million in cash, and an accumulated deficit of $119.0 million. Our primary use of cash is to fund operating expenses, which consist of research and development as well as regulatory expenses related to advancing our therapeutic candidate, stenoparib, in addition to 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.

We expect that our current cash is sufficient to fund operations through at least the next 12 months from the date of this Annual Report. We have based this estimate on assumptions that may prove wrong, and we could use our capital resources sooner than we currently expect. We will need to secure additional funding to carry out potential future pre-clinical, clinical, and commercialization activities. Until we can generate substantial revenue from product sales, if that occurs, we plan to finance our activities through equity sales, debt financing, or other capital sources, including collaborations or strategic transactions. However, we may face challenges in raising additional funds or securing favorable terms for such agreements. If we fail to secure necessary capital or agreements in a timely manner, we may need to significantly delay, reduce, or halt the development and commercialization of one or more programs which would adversely affect our business prospects and our ability to continue operations.

Given the inherent risks in product development, we cannot accurately predict the timing or magnitude of increased expenses or when we might achieve profitability. Even if we successfully generate product sales, profitability is not guaranteed. If we fail to achieve or sustain profitability, we may be compelled to reduce or terminate operations at planned levels.

In the year ended December 31, 2024, we received $37.3 million in proceeds from ATM sales net of issuance costs, $1.3 million in proceeds from 3i promissory notes, and $2.9 million in proceeds from the issuance of Convertible Redeemable Series A Preferred Stock; and we repaid $1.3 million of 3i promissory notes, and redeemed $3.5 million of Convertible Redeemable Series A Preferred Stock.

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.

April 2023 Offering

In April 2023, we issued 119 shares of our common stock and 119 common stock purchase warrants, each exercisable for one share of common stock, at a combined public offering price of $18,000.00, and 297 pre-funded warrants, each exercisable for one share of common stock, and 297 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 $18,000.00 less the $0.001 for the pre-funded warrants, for aggregate net proceeds of approximately $6.8 million, after deducting placement agents fees and offering expenses paid by us of approximately $0.7 million, 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 were immediately separable and were issued separately in the offering. All the pre-funded warrants from the April Offering were exercised in exchange for 297 common shares.

July 2023 Offering

In July 2023, we issued 596 shares of our common stock pre-funded warrants to purchase up to 3,478 shares of common stock (the “July Pre-Funded Warrants”), and common warrants to purchase up to 4,075 shares of common stock (the “2023 July Common Warrants”) at an effective combined purchase price of $2,700.00 per share and related common stock purchase warrants for aggregate net proceeds of approximately $10 million, after deducting placement agent fees and offering expenses paid by us of approximately $0.9 million on July 10, 2023 (the “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 $2,700.00 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. All July Pre-Funded Warrants were exercised prior in exchange for 3,478 common shares.

3i Convertible Secured Promissory Notes (2023)

On November 22, 2022, we entered into a Secured Note Purchase Agreement (the “Secured Note Purchase Agreement”) with 3i, LP ("3i"), for a bridge loan to extend our cash runway beyond December 31, 2022, in order to provide us with more time to complete the process of amending our Certificate of Incorporation to increase our authorized share capital and proposed reverse stock split to facilitate additional capital investments (the “Bridge Loan”). Under the Secured Note Purchase Agreement, we had 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 represented the payment of $1,666,640 due to 3i 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 our filing a registration statement with SEC in connection with a registered offering. Each 3i Promissory Note was due to mature on January 1, 2024, carried an interest rate of 5% per annum, and was secured by all of our assets pursuant to the Security Agreement. For the twelve months ended December 31, 2023, interest expense totaled $43,000 comprised of $33,000 for contractual interest and $10,000 for the amortization of the debt discount.

The bridge loan was paid in full and cancelled on April 21, 2023.

On April 19, 2023, 3i provided us with a loan for $350,000, which was evidenced by a secured promissory note dated April 19, 2023 (the “April Note”), which required a mandatory conversion of the principal into 486 shares of Series A Preferred Stock (the “Note Conversion Shares”) subject to and upon the closing of the April Offering which occurred on April 21, 2023 (“April Offering Closing”). Upon the April Offering Closing, the Note Conversion Shares were issued to 3i and the April Note was cancelled.

On April 20, 2023, we 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 our outstanding indebtedness under the Notes and the Alternative Conversion Amount (as defined therein) due by us 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 $3.3 million in cash from a portion of the proceeds from the April Offering.

On June 29, 2023, we 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 was secured by all of our assets pursuant to that certain security agreement dated June 29, 2023 (the “Security Agreement”). As contemplated by the June 2023 Purchase Agreement, we 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, we redeemed the 3i June Promissory Note for $351,000 in cash.

3i Convertible Senior Promissory Notes (2024)

During the year ended December 31, 2024, we entered into a Securities Purchase Agreement ("SPA") with 3i, pursuant to which three senior convertible promissory notes (the "2024 Notes") were issued as follows:

- On January 18, 2024, in an aggregate principal amount of $440,000 due on January 18, 2025, and with a set conversion price of $268.50 per share, for an aggregate purchase price of $400,000, representing an approximate 10% original issue discount (the “First Note”).

- On February 13, 2024, in an aggregate principal amount of $440,000 due on February 13, 2025, and with a set conversion price of $243.00 per share, for an aggregate purchase price of $400,000, representing an approximately 10% original issue discount (the “Second Note”).

- On March 14, 2024, in an aggregate principal amount of $660,000 due on March 14, 2025, and with a set conversion price of $210.00 per share, for an aggregate purchase price of $600,000, representing an approximately 10% original issue discount (the “Third Note”).

We agreed to pay interest to 3i on the aggregate unconverted and then outstanding principal amount of the 2024 Notes at the rate of 8% per annum with interest payments commencing one month after initial receipt of net proceeds.

The 2024 Notes and accrued interest were redeemed in full and cancelled on May 6, 2024.

Additional Issuances of Common Stock Upon Exercise of Certain Warrants

On April 20, 2023, we entered into a certain Modification and Exchange Agreement (the “Exchange Agreement”) with 3i pursuant to which the parties agreed to, among other things, exchange a warrant to purchase common stock issued on December 20, 2021 to 3i for a new warrant (the “Exchange Warrant”), which reflects an exercise price of $18,000.00 and represents a right to acquire 526 shares of common stock.

On December 5, 2023, we received exercise notices from holders of certain warrants pursuant to which we authorized (i) the issuance of 938 shares of common stock pursuant to exercise of common stock purchase warrants at $600.00 per share for $0.6 million in cash, and (ii) the issuance of 833 shares of common stock pursuant to partial exercise of Exchange Warrant on a cashless exercise basis.

Amendments to the Certificate of Designation of Series A Preferred Stock

On January 14, 2024, pursuant to the terms of the First Note, we modified the conversion price of the 3i Exchange Warrants from $600.00 to $268.50, thereby increasing the number of Exchange Warrants outstanding from 7,346 at December 31, 2023 to 16,411 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 $600.00 to $268.50. We filed the Fifth Certificate of Amendment to Amended and Restated COD (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 $268.50. As of January 14, 2024, we used the Black-Scholes option pricing model to determine the fair value of the 1,417 Series A Preferred Stock outstanding at $2.0 million versus their carrying value of $1.7 million. Accordingly, we had recorded a deemed dividend of $0.2 million on January 14, 2024. At a stated value of $1.1 million for each share of Series A Preferred Stock, the revised price of $268.50 per share results in the 1,417 shares being convertible into 5,699 shares of common stock as of January 14, 2024.

On February 13, 2024, pursuant to the terms of the Second Note, we modified the conversion price of the 3i Exchange Warrants from $268.50 to $243.00 and thereby increased the number of Exchange Warrants outstanding from 16,411 on January 18, 2024, to 18,137 on February 13, 2024. We filed the Sixth Certificate of Amendment to Amended and Restated COD (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 $243.00. As of February 14, 2024, we used the Black-Scholes option pricing model to determine the fair value of the then 1,296 Series A Preferred Stock outstanding and concluded there was a gain on extinguishment of $0.1 million. At a stated value of $1.1 million for each share of Series A Preferred Stock, the revised price of $243.00 per share results in the 1,296 shares being convertible into 16,453 shares of common stock.

On March 14, 2024, pursuant to the terms of the Third Note, we modified the conversion price of the 3i Exchange Warrants from $243.00 to $210.00 and thereby increased the number of Exchange Warrants outstanding from 18,137 on February 13, 2024, to 27,648 on March 14, 2024. We filed the Seventh Certificate of Amendment to Amended and Restated COD (the "Seventh Amendment") with the Secretary of State of the State of Delaware to reflect the new conversion price of the Series A Preferred Stock of $210.00. As of March 14, 2024, we used the Black-Scholes option pricing model to determine the fair value of the then 1,296 Series A Preferred Stock outstanding and concluded there was a gain on extinguishment of $0.1 million. At a stated value of $1.1 million for each share of Series A Preferred Stock, the revised price of $210.00 per share results in the 1,215 shares being convertible into 17,843 shares of common stock.

During the period April 1, 2024, through May 2, 2024, we had further amended the conversion prices of the Series A Convertible Preferred Stock, the Exchange Warrants and the 2024 Notes to equal the then current last sale price of shares of our common stock of $34.50 as of May 1, 2024.

3i exercised its option to convert 1,417 shares of Series A Preferred Stock for 14,376,690 shares of common stock at fair value of $1.8 million. As of December 31, 2024, there were no issued and outstanding shares of Series A Preferred Stock.

ATM Facility

On March 19, 2024, we entered into an At-The-Market Issuance Sales Agreement, as amended (the "Sales Agreement") with Ascendiant Capital Markets, LLC ("Ascendiant") under which we may offer and sell, from time to time at our sole discretion, shares of our common stock, par value $0.0001 per share, having an aggregate gross sales price of up to $50 million, to or through Ascendiant. The offer and sales of the shares are made pursuant to a previously filed shelf registration statement on Form S-3 (File No. 333-275282), originally filed with the Securities and Exchange Commission (the "SEC") on November 2, 2023 and declared effective on November 29, 2023, and the related prospectus supplement dated September 9, 2024 and filed with the SEC on such date. We agreed to pay Ascendiant a commission of 3.0% of the gross proceeds from the sales of shares sold through Ascendiant under the Sales Agreement. We agreed to reimburse Ascendiant for certain expenses incurred in connection with the Sales Agreement. Both we and Ascendiant may each terminate the Sales Agreement at any time upon specified prior written notice. For the year ended December 31, 2024, we sold an aggregate of 6,953,259 shares of our common stock pursuant to the Sales Agreement, resulting in net proceeds of approximately $38.8 million after deducting underwriting discounts. As of March 26, 2025, no more shares of our common stock remained available for the sale under the ATM program.

August 2024 Series A Convertible Redeemable Preferred Stock

On August 19, 2024 (the "Closing Date") we entered into a Securities Purchase Agreement (the "August 2024 SPA") with certain purchasers (the "August 2024 Purchasers"), pursuant to which we issued and sold, in a private placement (the "August 2024 Offering"), 35,000 shares of our Series A Convertible Redeemable Preferred Stock, par value $0.0001 per share (the "August 2024 Preferred Stock"), for net proceeds of approximately $2.9 million, after the deduction of discounts, fees and offering expenses.

On the Closing Date, we filed a certificate of designation (the "August 2024 COD") with the Secretary of the State of Delaware designating the rights, preferences and limitations of the August 2024 Preferred Stock. Under the August 2024 COD, for purposes of determining the presence of a quorum at any meeting of the stockholders of Allarity at which the August 2024 Preferred Stock are entitled to vote and the voting power of the August 2024 Preferred Stock, each holder of the August 2024 Preferred Stock shall be entitled to a number of votes equal to shares of our common stock into which such August 2024 Preferred Stock are then convertible, disregarding, for such purposes, any limitations on conversion. The August 2024 Preferred Stock shall be entitled to vote on each matter submitted to a vote of the stockholders generally and shall vote together with the common stock and any other class or series of capital stock entitled to vote thereon as a single class and on an as converted to the common stock basis.

The holders of the August 2024 Preferred Stock are entitled to dividends, on an as-if converted basis, equal to dividends actually paid, if any, on the common stock. The August 2024 Preferred Stock is convertible, at the option of the holders and, in certain circumstances, by us, into common stock, as determined by dividing the net purchase price of $90 per share by the conversion price of $5.10, at the option of the holders.

On the Closing Date, we entered into a Registration Rights Agreement (the "August 2024 RRA") with the August 2024 Purchasers, pursuant to which we agreed to file a registration statement with the SEC, to register for resale the common stock issuable upon the conversion of the August 2024 Preferred Stock. The registration statement was filed with the SEC on August 30, 2024.

In connection with the August 2024 Offering, we paid $0.2 million to Ascendiant Capital Markets, LLC, our placement agent. All of the August 2024 Preferred Stock was redeemed in September 2024. As a result of the redemption of the August 2024 Preferred Stock, we presented a deemed dividend of $0.6 million during the twelve months ended December 31, 2024.

The Private Placement (PIPE Financing) and Amendments to the Certificate of Designation of Series A Preferred Stock

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.

On November 22, 2022, we 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 our stockholders eligible to vote on such matters), except as required by law (including without limitation, the DGCL) or as otherwise expressly provided in our 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, we 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 us 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, we 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, we 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. We 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, we filed an Amended and Restated Certificate of Designations of our Series A Convertible Preferred Stock (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, we determined that the Series A Preferred Stock met the definition of equity and reclassified it from mezzanine equity.

On May 30, 2023, we 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 our 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, we and 3i 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, we 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, we 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, we 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, we 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, we 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, we 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. We 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.

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 and Sale of Series C Preferred Stock

On February 24, 2023, we 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, we 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 our 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 we 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 us 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, we entered into a registration rights agreement with 3i, L.P. (the "RRA") pursuant to which we are 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. We had 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, we 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.

Risks and Uncertainties

We are 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 our research and development efforts are successful, it is uncertain when, if ever, we will realize significant revenue from product sales.

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. 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.

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, 2024 and 2023, 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. 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, 2024 and 2023, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Acquired in-process research and development (IPR&D)

Acquired IPR&D represents the fair value assigned to research and development assets that we 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 our 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 our 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 our 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. During the year ended December 31, 2024, we recorded impairment losses of $9.7 million on our intangible assets and as of December 31, 2024, the intangible assets have been fully impaired. During the year ended December 31, 2023, no impairment losses were recognized.

Research contract costs and accruals

We have 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. We record accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, we analyze 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 our estimates. Our historical accrual estimates have not been materially different from the actual costs.

Convertible debt instruments

We follow 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, we account 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 we issue warrants we evaluate 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"), we classify a warrant as equity so long as it is "indexed to our equity" and several specific conditions for equity classification are met. A warrant is not considered indexed to our equity, in general, when it contains certain types of exercise contingencies or adjustments to exercise price. If a warrant is not indexed to our 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, 2024, and 2023, we had warrants outstanding for stock-based compensation that were classified as equity, and outstanding investor warrants that were classified as derivative liabilities and classified as "Warrant liability" in the Consolidated Balance Sheets.

Derivative financial instruments

We do not use derivative instruments to hedge exposures to interest rate, market, or foreign currency risks. We evaluate 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.

Stock-based compensation

We account for stock-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 our consolidated statements of operations and comprehensive loss.

We record the expense for option awards using either a graded or straight-line vesting method. We account for forfeitures as they occur. For stock-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.

We review stock award modifications when there is an exchange of original award for a new award. We calculate 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. We immediately recognize 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. We apply the Black-Scholes model as it believes it is the most appropriate fair value method for all equity awards.

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 $119.0 million as of December 31, 2024. Our net losses were $24.5 million and $11.9 million for the years ended December 31, 2024 and 2023, respectively.

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 stenoparib through clinical trials;
- pursue regulatory approval of stenoparib;
- operate as a public company;
- continue our preclinical programs and clinical development efforts;
- continue research activities for stenoparib; 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 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 stenoparib 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 stenoparib.

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 stenoparib 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, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023:

	Year ended December 31,		Increase/ (Decrease)
	2024	2023	
	(In thousands)		
Operating expenses:			
Research and development	$ 6,096	$ 7,103	$ (1,007)
Impairment of intangible assets	9,703	—	9,703
General and administrative	11,442	10,026	1,416
Total operating costs and expenses	27,241	17,129	10,112
Loss from operations	**(27,241)**	**(17,129)**	**(10,112)**
Other income (expense)			—
Interest income	533	22	511
Interest expenses	(653)	(498)	(155)
Foreign exchange gains (losses)	(212)	133	(345)
Fair value of inducement warrants	—	(4,189)	4,189
Loss on modification of warrants	—	(591)	591
Change in fair value adjustment of warrant derivative liabilities	2,677	10,434	(7,757)
Total other income	2,345	5,311	(2,966)
Loss before income tax expense (benefit)	(24,896)	(11,818)	(13,078)
Income tax expense (benefit)	(381)	83	(464)
Net loss	$ **(24,515)**	$ **(11,901)**	$ **(12,614)**

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, 2024 and 2023, is provided below.

	Year ended December 31,		Increase/ (Decrease)
	2024	2023	
	(In thousands)		
Research study expenses	$ 2,906	$ 2,887	$ 19
Tax credit	(798)	(800)	2
Milestone payments	150	150	—
Manufacturing & supplies	1,715	2,906	(1,191)
Contractors	855	996	(141)
Staffing	1,197	873	324
Other	71	91	(20)
	$ 6,096	$ 7,103	$ (1,007)

The decrease of $1.0 million in research and development cost was primarily due to decreases of $1.2 million in manufacturing and supplies, and $0.1 million in contractor costs, partially offset by an increase of $0.3 million in staffing costs.

Impairment of Intangible Assets

As a result of continued downward pressure on our common stock and updated clinical development plan, we performed an impairment assessment on the individual intangible assets utilizing a discounted cash flow model with a weighted average cost of capital of 26%, and recognized a full impairment charge of $9.7 million during the year ended December 31, 2024. There was no impairment charge in 2023.

General and Administrative Expenses

General and administrative expenses increased by $1.4 million for the year ended December 31, 2024, compared to the year ended December 31, 2023. The increase was primarily due to an increase of $3.5 million in audit and legal expenses, which includes a $2.5 million SEC settlement charge, $0.3 million in franchise tax expense, $0.3 million in personnel costs, partially offset by a decrease of $1.1 million in insurance expense, $1.1 million in financing costs, and $0.5 million in consulting and professional services.

Other Income (Expense)

Other income of $2.3 million recognized in the year ended December 31, 2024, consisted primarily of a $2.7 million fair value adjustment of warrant derivative liabilities, and $0.5 million in interest income, partially offset by $0.7 million in interest expense and $0.2 million in foreign exchange loss.

Other income of $5.3 million recognized in the year ended December 31, 2023, consisted primarily of a $10.4 million fair value adjustment of warrant derivative liabilities and $0.2 million in foreign exchange gain, partially offset by $4.2 million fair value of inducement warrants, $0.6 million loss on modification to warrants, and $0.5 million in interest expense.

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, 2024, and 2023, we recognized $0.4 million in income tax recovery and $0.1 million in income tax expense, respectively.

Liquidity, Capital Resources and Plan of Operations

Cash Flows for the Years Ended December 31, 2024 and 2023

The following table summarizes our cash flows for the years indicated:

	Year Ended December 31,	
(In thousands)	2024	2023
Total cash provided by (used in):		
Operating activities	$ (17,352)	$ (12,745)
Investing activities	(298)	—
Financing activities	36,792	10,995
Effect of foreign exchange rates on cash	225	(113)
Net increase (decrease) in cash	$ 19,367	$ (1,863)

Operating Activities

Net cash used in operating activities was approximately $17.4 million for the year ended December 31, 2024, primarily comprised of our $24.5 million net loss and $2.7 million reduction in fair value of warrant derivative liability, $0.4 million reduction in deferred income tax, and $0.1 million unrealized foreign exchange gain, partially offset by $9.7 million intangible asset impairment, $0.3 million in common stock issued for services, $0.2 million non-cash interest expense, $0.1 million stock-based compensation and $0.1 million change in operating assets and liabilities.

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 $0.6 million loss on modification of warrants, and non-cash interest of $0.5 million, offset by a $10.4 million fair value adjustment to derivative liabilities, stock-based compensation of $0.1 million and unrealized gain on foreign currency of $0.2 million.

Investing Activities

Net cash used in investing activities was approximately $0.3 million for the year ended December 31, 2024, due to $0.3 million in purchases of lab equipment. There was no investing activity for the year ended December 31, 2023.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2024 was $36.8 million, primarily related to $38.8 million in proceeds from ATM sales of common stock net of issuance costs, $2.9 million in net proceeds from the issuance of Series A Convertible Redeemable Preferred Stock, and $1.3 million in proceeds from 3i debt promissory notes, partially offset by the $3.5 million redemption of Series A Convertible Redeemable Preferred Stock and repayment of $1.3 million of 3i debt promissory notes.

Net cash provided by financing activities for the year ended December 31, 2023 was $11.0 million, primarily related to $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, partially offset by the repayment of $3.7 million in debt and $6.7 million for the redemption of Series A Preferred Stock.

Recently Issued Accounting Pronouncements

See the section titled in Note 2 to the Company's consolidated financial statements for the year ended December 31, 2024, appearing elsewhere herein.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are 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.

None.

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 Annual 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 Exchange Act of 1934, as amended (the "Exchange Act"). 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, 2024.

Management's Report on Internal Control over Financial Reporting

Our management 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, 2024, our management assessed the effectiveness of our 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.

Based on the results of its evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2024.

Because we are a non-accelerated filer and smaller reporting company, Wolf & Company, P.C., our independent registered public accounting firm, is not required to attest to or issue a report on the effectiveness of our internal control over financial reporting.

Change in Internal Control over Financial Reporting

There have been no changes in our internal controls over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, during the fourth quarter of 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdiction that Prevents Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The Company has an insider trading policy governing the purchase, sale and other dispositions of the Company's securities that applies to all Company personnel, including directors, officers, employees, and other covered persons. The Company also follows procedures for the repurchase of its securities. The Company believes that its insider trading policy and repurchase procedures are reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to the Company. A copy of the Company's insider trading policy is filed as Exhibit 19 to this Annual Report.

The remaining information required by this Item will be included in the Company's definitive proxy statement to be filed with the SEC within 120 days after December 31, 2024, in connection with the solicitation of proxies for the Company's 2025 annual meeting of stockholders (the "2025 Proxy Statement"), and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item will be included in the 2025 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 will be included in the 2025 Proxy Statement, and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions and Director Independence.

The information required by this Item will be included in the 2025 Proxy Statement, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item will be included in the 2025 Proxy Statement, and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

The following documents are filed as part of this Annual Report:

(1) Financial Statements

The following financial statements of Allarity, and the Report of Independent Registered Public Accounting Firm, is included at the end of this Annual 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)
3.20(pp)	Form of Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Redeemable Preferred Stock
3.21(qq)	Sixth Certificate of Amendment to Certificate of Incorporation of Allarity Therapeutics, Inc.
3.22(qq)	Seventh Certificate of Amendment to Certificate of Incorporation of Allarity Therapeutics, Inc.
3.23(rr)	Certificate of Correction to the Seventh Certificate of Amendment to the Certificate of Incorporation 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 (Dovitinib)
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
10.64(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
10.68(ss)	Consulting Agreement (James G. Cullem)
10.69(ss)	Confidential Settlement Agreement and General Release (James G. Cullem)
10.70(tt)	First Comprehensive Amendment to At-The-Market Issuance Sales Agreement, dated May 17, 2024
10.71(uu)	Management Services Agreement, effective as of June 1, 2024
10.72(pp)	Form of Securities Purchase Agreement between the Company and the investors thereto, dated August 19, 2024
10.73(pp)	Form of Registration Rights Agreement by and among the Company and the investors named therein, dated August 19, 2024
10.74	Fifth Amendment to Exclusive License Agreement with Eisai, Inc.
10.75(pp)	Sixth Amendment to Exclusive License Agreement with Eisai, Inc.
10.76(vv)	Second Amendment to At-The-Market Issuance Sales Agreement, dated September 9, 2024
10.77(vv)	Employment Agreement, dated as of September 12, 2024, by and between Allarity Therapeutics, Inc., and Alexander Epshinsky.
10.78(ww)	Employment Agreement, dated as of September 30, 2024, by and between Allarity Therapeutics, Inc., and Jeremy R. Graff.
16(n)	Letter from Marcum, LLP dated August 23, 2022, regarding Change in Independent Registered Public Accounting Firm
19	Policy on Insider Trading
21(xx)	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(xx)	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) Incorporated 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 from Form 8-K filed on September 27, 2023.
(ii) Incorporated by reference from Form S-1 filed on October 30, 2023.
(jj) Incorporated by reference from Form 8-K filed with the SEC on January 19, 2024.
(kk) Incorporated by reference from Form 8-K filed with the SEC on January 25, 2024.
(ll) Incorporated by reference from 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 from Form 8-K filed with the SEC on March 1, 2024.
(pp) Incorporated by reference from Form 8-K filed with the SEC on August 21, 2024.
(qq) Incorporated by reference from Form 8-K filed with the SEC on September 9, 2024.
(rr) Incorporated by reference from Form 8-K filed with the SEC on September 10, 2024.
(ss) Incorporated by reference from Form 8-K filed with the SEC on May 14, 2024.
(tt) Incorporated by reference from Form 8-K filed with the SEC on May 21, 2024.
(uu) Incorporated by reference from Form 8-K filed with the SEC on June 6, 2024.
(vv) Incorporated by reference from Form 8-K filed with the SEC on September 13, 2024.
(ww) Incorporated by reference from Form 8-K filed with the SEC on October 4, 2024.
(xx) Incorporated by reference from Form 10-K filed with the SEC on March 8, 2024.

* Furnished herewith.
† Certain portions of this exhibit were omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.
# 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 H. Jensen
Name: Thomas H. 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 H. Jensen Thomas H. Jensen	Chief Executive Officer and Director (*Principal Executive Officer*)	March 31, 2025
/s/ Alexander Epshinsky Alexander Epshinsky	Chief Financial Officer (*Principal Financial Officer*)	March 31, 2025
/s/ Gerald W. McLaughlin Gerald W. McLaughlin	Chairman of the Board	March 31, 2025
/s/ Joseph W. Vazzano Joseph W. Vazzano	Director	March 31, 2025
/s/ Laura E. Benjamin Laura E. Benjamin	Director	March 31, 2025

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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, 2024 and 2023, 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, 2024 and 2023, 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.

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 31, 2025

ALLARITY THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
As of December 31, 2024 and 2023
(in thousands, except for share and per share data*)

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash	$ 19,533	$ 166
Receivables from ATM sales	1,416	—
Other current assets	115	209
Prepaid expenses	507	781
Tax credit receivable	770	815
Total current assets	22,341	1,971
Non-current assets:		
Property, plant and equipment, net	309	20
Intangible assets	—	9,871
Total assets	$ 22,650	$ 11,862
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 4,182	$ 8,416
Accrued expenses and other current liabilities	5,232	1,309
Warrant derivative liability	1	3,083
Income taxes payable	74	59
Convertible promissory note and accrued interest	1,350	1,300
Total current liabilities	10,839	14,167
Non-current liabilities:		
Deferred tax	—	446
Total liabilities	10,839	14,613
Commitments and contingencies (Note 16)		
Stockholders' equity (deficit)		
Series A Preferred stock, $0.0001 par value, 500,000 authorized, 20,000 designated Series A shares, 0 and 1,417 shares issued and outstanding at December 31, 2024 and 2023, respectively (liquidation preference of $17.54 at December 31, 2023)	—	1,742
Common Stock, $0.0001 par value, 250,000,000 and 750,000,000 shares authorized, at December 31, 2024 and 2023, respectively; 7,302,797 and 9,812 shares issued and outstanding at December 31, 2024 and 2023, respectively	1	—
Additional paid-in capital	131,130	90,369
Accumulated other comprehensive loss	(354)	(411)
Accumulated deficit	(118,966)	(94,451)
Total stockholders' equity (deficit)	11,811	(2,751)
Total liabilities and stockholders' equity (deficit)	$ 22,650	$ 11,862

* All common share data has been retroactively adjusted to effect reverse stock splits in 2023 and 2024 (see Note 1).

See accompanying notes to the consolidated financial statements.

ALLARITY THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
For the years ended December 31, 2024 and 2023
(in thousands, except for share and per share data*)

	2024	2023
Operating expenses:		
Research and development	$ 6,096	$ 7,103
Impairment of intangible assets	9,703	—
General and administrative	11,442	10,026
Total operating expenses	27,241	17,129
Loss from operations	(27,241)	(17,129)
Other income (expense)		
Interest income	533	22
Interest expenses	(653)	(498)
Foreign exchange gains (losses)	(212)	133
Fair value of inducement warrants	—	(4,189)
Loss on modification of warrants	—	(591)
Change in fair value adjustment of warrant derivative liabilities	2,677	10,434
Total other income	2,345	5,311
Loss before income tax expense (benefit)	(24,896)	(11,818)
Income tax expense (benefit)	(381)	83
Net loss	(24,515)	(11,901)
Deemed dividends on Series A Preferred Stock	(299)	(8,392)
Deemed dividend on Series A Convertible Preferred Stock	(562)	—
Gain on extinguishment of Series A Convertible Preferred Stock	222	—
Deemed dividend of on Series C Preferred Stock	—	(123)
Net loss attributable to common stockholders	$ (25,154)	$ (20,416)
Net loss per common share, basic and diluted	$ (15.65)	$ (6,031.31)
Weighted average common shares outstanding, basic and diluted	1,606,989	3,385
Other comprehensive loss		
Net loss	$ (24,515)	$ (11,901)
Change in cumulative translation adjustment	57	310
Total comprehensive loss	$ (24,458)	$ (11,591)

* All common share data has been retroactively adjusted to effect reverse stock splits in 2023 and 2024 (see Note 1).

See accompanying notes to the 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, 2024 and 2023
(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	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Number	Value	Number	Value	Number	Value	Number	Value	Number	Value	Capital	Loss	Deficit	(Deficit)
Balance, December 31, 2022	**13,586**	**$ 2,001**	**190,786**	**$ 2**	**—**	**$ —**	**—**	**—**	**19**	**$ —**	**$ 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	—	—	—	—	—	—	—	—	1	—	—	—	—	—
Conversion of Series A Preferred Stock into common stock, net	(9,347)	(1,377)	—	—	—	—	(2,705)	(2,522)	403	—	3,899	—	—	1,377
Redemption of Series B Preferred Stock	—	—	(190,786)	(2)	—	—	—	—	—	—	2	—	—	2
Issuance of common stock, net, April 2023 Financing	—	—	—	—	—	—	—	—	417	—	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	—	—	—	—	—	—	—	—	4,074	—	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 with July 2023 financing			—	—	—	—	(4,630)	(4,474)	—	—	(526)	—	—	(5,000)
September 2023 warrants exercised on inducement, net	—	—	—	—	—	—	—	—	4,065	—	2,962	—	—	2,962
Reclassification of derivative liabilities related to September 2023 warrants exercised	—	—	—	—	—	—	—	—	—	—	1,056	—	—	1,056
Cashless exercise of Exchange Warrants	—	—	—	—	—	—	—	—	833	—	1,031	—	—	1,031
Deemed dividend on September 2023 modification of Series A Preferred shares	—	—	—	—	—	—	—	373	—	—	(373)	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	71	—	—	71
Currency translation adjustment	—	—	—	—	—	—	—	—	—	—	—	310	—	310
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(11,901)	(11,901)
Balance, December 31, 2023	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**1,417**	**$ 1,742**	**9,812**	**$ —**	**$ 90,369**	**$ (411)**	**$ (94,451)**	**$ (2,751)**

* All common share data has been retroactively adjusted to effect reverse stock splits in 2023 and 2024 (see Note 1).

See accompanying notes to the 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, 2024 and 2023
(in thousands, except for share data*)

	Series A Convertible Redeemable Preferred Stock		Series A Convertible Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Number	Value	Number	Value	Number	Value				
Balance, December 31, 2023	—	$ —	1,417	$ **1,742**	**9,812**	$ —	$ **90,369**	$ **(411)**	$ **(94,451)**	$ **(2,751)**
Conversion of preferred stock into common stock, net	—	—	(1,417)	(1,819)	15,976	—	1,819	—	—	—
Extinguishment of preferred stock	—	—	—	(222)	—	—	222	—	—	—
Deemed dividend on preferred stock	—	—	—	299	—	—	(299)	—	—	—
Common stock issued for services	—	—	—	—	147,878	—	336	—	—	336
Issuance of common stock, net of offering costs under open market sales agreement (ATM)	—	—	—	—	6,953,259	4	38,766	—	—	38,770
Reverse split (1-for-30) rounding adjustment	—	—	—	—	97,216	(3)	3	—	—	—
Stock-based compensation expense (recoveries)	—	—	—	—	—	—	71	—	—	71
Cashless exercise of 3i Exchange Warrants	—	—	—	—	78,656	—	405	—	—	405
Issuance of convertible redeemable preferred stock, net of offering costs	35,000	2,938	—	—		—	—	—	—	2,938
Redemption of convertible redeemable preferred stock	(35,000)	(3,500)	—	—	—	—	—	—	—	(3,500)
Deemed dividend on redeemable preferred stock	—	562	—	—	—	—	(562)	—	—	—
Currency translation adjustment	—	—	—	—	—	—	—	57	—	57
Net loss	—	—	—	—	—	—	—	—	(24,515)	(24,515)
Balance, December 31, 2024	—	$ —	—	$ —	**7,302,797**	$ **1**	$ **131,130**	$ **(354)**	$ **(118,966)**	$ **11,811**

* All common share data has been retroactively adjusted to effect reverse stock splits in 2023 and 2024 (see Note 1).

See accompanying notes to the consolidated financial statements.

ALLARITY THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the years ended December 31, 2024 and 2023
(in thousands)

	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (24,515)	$ (11,901)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	9	37
Intangible asset impairment	9,703	—
Common stock issued for services	336	—
Stock-based compensation expense (recovery)	71	(71)
Unrealized foreign exchange gain	(126)	(179)
Non-cash interest expense	230	464
Non-cash finance expense	—	1,110
Fair value of inducement warrants	—	4,189
Loss on modification of warrants	—	591
Change in fair value of warrant derivative liabilities	(2,677)	(10,434)
Deferred income taxes	(446)	97
Changes in operating assets and liabilities:		
Other current assets	94	1,350
Unearned revenue	207	—
Tax credit receivable	45	(26)
Prepaid expenses	274	(190)
Accounts payable	(4,108)	2,165
Accrued liabilities	3,536	43
Income taxes payable	15	18
Operating lease liability	—	(8)
Net cash used in operating activities	(17,352)	(12,745)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(298)	—
Net cash used in investing activities	(298)	—
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from Series C Convertible Preferred Stock issuance, net	—	1,160
Proceeds from 3i promissory notes	1,340	1,050
Repayment of 3i debt	(1,340)	(3,699)
Proceeds from ATM sales of common stock, net of issuance costs	37,354	—
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)
Proceeds from issuance of Convertible Redeemable Series A Preferred Stock	2,938	—
Redemption of Convertible Redeemable Series A Preferred Stock	(3,500)	—
Net cash provided by financing activities	36,792	10,995
Net increase (decrease) in cash	19,142	(1,750)
Effect of exchange rate changes on cash	225	(113)
Cash, beginning of year	166	2,029
Cash, end of year	$ **19,533**	$ **166**

See accompanying notes to the consolidated financial statements.

ALLARITY THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (cont.)
For the years ended December 31, 2024 and 2023
(in thousands)

	2024	2023
Supplemental disclosure of cash flow information		
Cash paid for income taxes	$ —	$ 6
Cash paid for interest	$ 423	$ 34
Supplemental disclosure of non-cash investing and financing activities:		
Stock issued in conjunction with consulting agreement	$ 90	$ —
Issuance of common shares on conversion of 3i Exchange Warrants	$ 405	$ —
Conversion of Series A Redeemable Preferred Stock to common stock	$ 1,819	$ 3,899
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	$ 299	$ 8,392
Gain on extinguishment of Series A Preferred Stock	$ 222	$ —
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 Convertible Redeemable Series A Preferred Stock	$ 562	$ —

See accompanying notes to the consolidated financial statements.

ALLARITY THERAPEUTICS, INC.
NOTES TO FINANCIAL STATEMENTS
For the years ended December 31, 2024 and 2023
(in thousands, except for share and per share data and where otherwise noted)

1. Organization and Description of Business

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.

Liquidity

The Company has incurred significant losses and has an accumulated deficit of $119.0 million. Since inception, the Company's operations have been funded primarily through proceeds received from its collaboration arrangements, sale of equity and debt securities, and the proceeds from the exercise of warrants. The Company has incurred losses from operations and negative cash flows from operating activities since inception and expects to continue to incur substantial losses for the next several years as it continues to fully develop and prepare regulatory filings and obtain regulatory approvals for its existing and new product candidates. The Company's estimates its current cash of $19.5 million, based on the Company's current operating plan, is sufficient to enable the Company to fund its activities through at least the next 12 months from the date of this report on Form 10-K.

The Company is subject to industry risks and the expenses associated with any company performing research and development. There is no guarantee that our research and development projects will succeed, that developed products will secure necessary regulatory approvals, or that any approved products will be commercially successful. Furthermore, our industry is characterized by rapid technological advancements, and we heavily rely on the expertise of our employees and consultants. If we fail to achieve profitability or sustain it over time, we may be unable to maintain our operations at current levels and could be forced to scale back our activities.

Reverse Stock Splits

On March 24, 2023, June 28, 2023, April 9, 2024, and September 11, 2024, the Company effected a 1-for-40 reverse stock split, 1-for-35 reverse stock split, 1-for-20 reverse stock split, and 1-for-30 reverse stock split, respectively, of the shares of common stock of the Company (collectively, the "Reverse Stock Splits"). All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Splits for all periods presented, unless otherwise indicated. Proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all stock options, restricted stock, preferred stock and warrants outstanding on September 12, 2024, which resulted in a proportional decrease in the number of shares of the Company's common stock reserved for issuance upon exercise or vesting of such stock options, restricted stock and warrants, and, in the case of stock options and warrants, a proportional increase in the exercise price of all such stock options and warrants. No fractional shares were issued in connection with the Reverse Stock Splits. If, as a result of the Reverse Stock Splits, a stockholder would otherwise have been entitled to a fractional share, each fractional share was rounded up to the next whole number.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

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").

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.

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.

Risks and Uncertainties

The Company is subject to risks common to early-stage companies in the biopharmaceutical industry including, but not limited to, uncertainties related to clinical effectiveness of products, commercialization of products, regulatory approvals, dependence on key products, key personnel and third-party service providers such as contract research organizations ("CROs"), protection of intellectual property rights, the need and ability to obtain additional financing and the ability to make milestone, royalty or other payments due under any license, collaboration or supply agreements.

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 at the balance sheet date and the results of operations are translated using the average exchange rate for the year. 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 loss in the consolidated statements of operations and comprehensive loss as incurred. The Company recorded a foreign exchange translation gain of $0.1 million and $0.3 million, included in accumulated other comprehensive loss for the years ended December 31, 2024 and 2023, respectively.

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.

Cash

The company considers cash equivalents as highly liquid investments with original maturities of three months or less at the date of purchase. The Company had no cash equivalents or restricted cash on December 31, 2024 and 2023.

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 (in years)
Laboratory equipment	5
Furniture and office equipment	3

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, 2024 and 2023, 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.

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.

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. For the years ended December 31, 2024 and 2023, the Company has recorded impairment losses of $9.7 million and $0 respectively on its intangible assets. As of December 31, 2024, the IPR&D intangible assets have been fully amortized and have a $0 balance.

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 preferred shares, convertible debt, warrant liabilities, and warrant derivative liabilities. The warrant liabilities 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.

- 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.

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 operates as a single operating and reporting segment, reflecting our sole focus in developing a treatment for ovarian cancer. Our Chief Executive Officer serves as the Chief Operating Decision Maker (CODM), responsible for assessing the Company's performance and making resource allocation decisions. The CODM evaluates financial information on a consolidated basis, focusing on key metrics such as research and development expense, general and administrative expenses, and other income/expenses. The CODM allocates resources based on the Company's available cash resources, forecasted cash flow, and expenditures on a consolidated basis, as well as an assessment of the probability of success of its research and development activities. Resource allocation decisions are informed by budgeted and forecasted expense information, along with actual expenses incurred to date. The measure of segment assets is reported on the balance sheet as total assets. Disaggregated profit or loss information at the program or functional level is not regularly provided to or relied upon by the CODM, as our integrated operating model emphasizes shared resources and centralized decision-making. The Company operates in two geographic areas: Denmark and the United States.

Research and development expenses

Research and development ("R&D") costs are expensed as incurred. R&D expenses primarily consist of costs associated with preclinical studies and clinical trials as well as salaries, stock-based compensation and benefits, facilities costs and laboratory supplies, 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.

General and administrative expenses

General and administrative ("G&A") expenses consist primarily of employee-related expenses, such as salaries, stock-based compensation, and benefits for employees engaged in G&A activities. G&A also consists of marketing, advertising, legal and accounting fees, consulting services, and other operating costs relating to corporate matters and daily operations.

R&D 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 each of the years ended December 31, 2024 and 2023, research and development expenses include refundable tax credits of $0.8 million.

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.

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.

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.

Stock-based compensation

The Company accounts for stock-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 stock-based awards, 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 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 restricted stock units is based on the fair value of the Company's common stock on the date of the grant.

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.

Since the Company has limited option exercise history, it has generally elected to estimate the expected life of an award based upon the "simplified method" with the continued use of this method extended until such time the Company has sufficient exercise history. The Company has no foreseeable plans to pay dividends on its common stock, 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 expected share price volatility for the Company's common shares is estimated by taking the average historical price volatility for industry peers.

The Company classifies stock-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.

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, 2024 and 2023, the Company's other comprehensive loss was comprised of currency translation adjustments.

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.

Net 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, restricted stock units, 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, 2024 and 2023, the Company had a net loss attributable to common stockholders, and as such, all outstanding stock options, unvested restricted stock units, convertible notes, shares of redeemable convertible preferred stock, and warrants were excluded from the calculation of diluted loss per share.

	Year Ended December 31,	
	2024	**2023**
Warrants	8,557	15,893
Options	—	9
Unvested restricted stock units	174,038	—
Series A Convertible Preferred stock	—	2,551
Total	182,595	18,453

Recently Adopted Accounting Standards

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which requires that an entity report segment information in accordance with Topic 280, Segment Reporting. The amendment in the ASU is intended to improve reportable segment disclosure requirements primarily through enhanced disclosures about significant segment expenses. The Company adopted ASU 2023-07 for the year ended December 31, 2024 retrospectively to all periods presented in the consolidated financial statements. The adoption of this ASU had no impact on reportable segments identified and had no effect on the Company's consolidated financial position, results of operations, or cash flows.

Accounting Standards Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which expands disclosures in an entity's income tax rate reconciliation table and disclosures regarding cash taxes paid both in the U.S. and foreign jurisdictions. The update will be effective for annual periods beginning after December 15, 2024. The Company is currently evaluating the impact that this guidance will have on its financial statement disclosures.

In November 2024, the FASB issued ASU No. 2024-03, Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires new financial statement disclosures in tabular format, in the notes to financial statements, of specified information about certain costs and expenses. The amendments in this update do not change or remove current expense disclosure requirements. The amendments in this update are effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of the new standard on its financial statement disclosures.

3. Other Current Assets

The Company's other current assets are comprised of the following:

	December 31,	
	2024	**2023**
Deposits	$ 72	$ 56
Salary deposit	—	22
Value added tax ("VAT") receivable	43	131
Total	$ 115	$ 209

4. Intangible assets

Intangible assets, impairment charges and adjustments are summarized as follows:

	December 31,	
	2024	**2023**
Opening balance	$ 9,871	$ 9,549
Impairment recognized during the period	(9,703)	—
Foreign translation adjustment	(168)	322
Ending balance	$ —	$ 9,871

As of the year ended December 31, 2024, as a result of continued downward pressure on the Company's common stock and updated clinical development plan, the Company performed an impairment assessment on the individual intangible assets utilizing a discounted cash flow model with a weighted average cost of capital of 26%, and recognized a full impairment charge of $9.7 million during the year ended December 31, 2024. There was no impairment charge in 2023.

5. Accrued liabilities

The Company's accrued liabilities are comprised of the following:

	December 31,	
	2024	2023
Development cost liability	$ 152	$ 114
Accrued interest on milestone liabilities	281	101
Payroll accruals	458	398
Accrued Board member fees	—	60
Accrued consulting fees	—	150
Accrued audit and legal	1,567	425
Accrued SEC settlement	2,500	—
Other	274	61
	$ 5,232	$ 1,309

6. Convertible promissory note due to Novartis

On April 12, 2022, Allarity Denmark re-issued a Convertible Promissory Note (the "Novartis 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 $1.0 million. The Novartis Promissory Note was re-issued pursuant to an amendment of the 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 Novartis Promissory Note were unchanged and remain in full force and effect. The Novartis 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.

The roll forward of the Novartis Promissory Note as of December 31, 2024 and 2023 is as follows:

	December 31,	
	2024	2023
Convertible promissory note, opening balance	$ 1,300	$ 1,083
Less debt discount, opening	—	(232)
Plus, accretion of debt discount, interest expense	—	38
Convertible promissory note, net of discount	1,300	889
Interest accretion, opening	—	245
Interest accrual, expense	50	166
Convertible promissory note, ending balance	$ 1,350	$ 1,300

On January 26, 2024, the Company received a termination notice from Novartis due to a material breach of the Original Agreement. Accordingly, under the terms of the Original Agreement, the Company ceased all development and commercialization activities with respect to all licensed products, all rights and licenses granted by Novartis to the Company reverted to Novartis; and all liabilities due to Novartis became immediately due and payable inclusive of interest which is continuing to accrue at 5% per annum. As of December 31, 2024, the liability is recorded as a current liability on the Company's condensed consolidated balance sheets as follows: $3.6 million in accounts payable and $1.6 million in convertible promissory notes and accrued interest.

During the years ended December 31, 2024 and 2023, the Company recorded $0.2 million and $0.2 million, respectively, to interest expense.

7. Promissory Notes due to 3i, LP ("3i")

3i Convertible Senior Promissory Notes (2024) (collectively the "2024 Notes")

On January 18, 2024, the Company entered into a Securities Purchase Agreement (the "SPA"), as amended, with 3i, pursuant to which three senior convertible promissory notes were issued as follows:

i. On January 18, 2024, in an aggregate principal amount of $440,000 due on January 18, 2025, and with a set conversion price of $268.50 per share, for an aggregate purchase price of $400,000, representing an approximate 10% original issue discount (the “First Note”).

ii. On February 13, 2024, in an aggregate principal amount of $440,0000 due on February 13, 2025, and with a set conversion price of $243.00 per share, for an aggregate purchase price of $400,000, representing an approximately 10% original issue discount (the “Second Note”).

iii. On March 14, 2024, in an aggregate principal amount of $660,000 due on March 14, 2025, and with a set conversion price of $210.00 per share, for an aggregate purchase price of $600,000, representing an approximately 10% original issue discount (the “Third Note”).

The Company agreed to pay interest to 3i on the aggregate unconverted and then outstanding principal amount of the 2024 Notes at the rate of 8% per annum with interest payments commencing one month after the initial receipt of net proceeds.

The 2024 Notes and accrued interest were redeemed in full and cancelled on May 6, 2024.

3i Convertible Secured Promissory Notes (2023)

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 “2023 Notes”). Effective November 28, 2022, the Company issued: (1) a Note in the principal amount of $1.7 million as payment of $1.7 million 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 $0.4 million in exchange for cash. Effective December 30, 2022, the Company issued an additional Note in the principal amount of $0.7 million in exchange for cash. Each Note was due to mature on January 1, 2024, carried an interest rate of 5% per annum, and was secured by all of the Company’s assets pursuant to a security agreement (the “Security Agreement”).

On April 19, 2023, 3i provided the Company with a loan for $0.4 million, 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 $3.3 million 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 $0.4 million (the “June Note”). Such note matured on July 31, 2023, and carried an interest rate of 5% per annum, and was 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 $0.4 million in cash.

The roll forward of the April Note and the June Note for the twelve months ended December 31, 2023 is as follows:

	December 31, 2023
Secured promissory notes	$ 2,644
Less debt discount, opening	—
Plus, accretion of debt discount, interest expense	—
Carrying value of the Notes	2,644
Interest accretion, opening	10
Interest accrual, expense	33
	$ 2,687
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	$ —

The April Note and June Note were repaid in full in 2023.

8. Preferred Stock

Series A Preferred Stock and Common Stock Purchase Warrants

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 had 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, the Company 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 $450.00 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 $18,000.00 (the "New Exercise Price") and represents a right to acquire 526 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 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, $18,000.00 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 $18,000.00 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.

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 $2,700.00. 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 $600.00 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 $600.00.

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 $600.00 to $268.50, thereby increasing the number of Exchange Warrants outstanding from 7,346 at December 31, 2023 to 16,411 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 $600.00 to $268.50. 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 $268.50. At a stated value of $1,080 for each share of Series A Preferred Stock, the revised price of $268.50 per share results in the 1,417 shares being convertible into 5,699 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 $268.50 to $243.00 and thereby increased the number of Exchange Warrants outstanding from 16,411 on January 18, 2024, to 18,137 on February 13, 2024. The Company also agreed to amend the conversion price of the Series A Preferred Stock to equal $243.00 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 $243.00. At a stated value of $1,080 for each share of Series A Preferred Stock, the revised price of $243.00 per share results in the 1,296 shares being convertible into 5,760 common shares.

On March 14, 2024, pursuant to the terms of the Third Note, the Company modified the conversion price of the 3i Exchange Warrants from $4,860.00 to $4,200.00 and thereby increased the number of Exchange Warrants outstanding from 907 on February 13, 2024, to 1,383 on March 14, 2024. The Company filed the Seventh Certificate of Amendment to Amended and Restated COD (the "Seventh Amendment") with the Secretary of State of the State of Delaware to reflect the new conversion price of the Series A Preferred Stock of $4,200.00. As of March 14, 2024, the Company used the Black-Scholes option pricing model to determine the fair value of the then 1,296 Series A Preferred Stock outstanding and concluded there was a gain on extinguishment of $0.1 million. At a stated value of $1,080 for each share of Series A Preferred Stock, the revised price of $4,200.00 per share results in the 1,215 shares being convertible into 893 shares of common stock.

During the period April 1, 2024, through May 2, 2024, the Company amended the conversion prices of the Series A Convertible Preferred Stock, the Exchange Warrants and the 2024 Notes to equal the current last sale price of its shares of Common Stock of $34.50 as of May 1, 2024.

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 526 shares of common stock, exercisable at $18,000.00 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 15,755 shares of common stock, exercisable at $600.00 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 3,501 shares of Common Stock and $2,700.00 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 5,225 shares and $1,809.30 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 15,755 shares of common stock and $600.00 per share, respectively. On December 5, 2023, 3i exercised 8,410 Exchange Warrants on a cashless basis in exchange for 833 common shares.

Accounting

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 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.

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, valued with a Monte Carlo Simulation model and recorded as a derivative liability.

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 $8.4 million 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. $3.3 million on the elimination of Series A redemption rights as of April 21, 2023,
ii. $4.0 million on the Exchange of 50,000 Series C Preferred Stock for 5,577 Series A Preferred Stock;
iii. $0.2 million on the July 10, 2023, modification of Series A Preferred Stock;
iv. $0.5 million on the redemption of Series A Preferred Stock; and
v. $0.4 million on the September 14, 2023 modification of Series A Preferred Stock.

As a result of fair value adjustments during the twelve months ended December 31, 2024, the Company recognized a deemed dividend of $0.3 million on the Series A Preferred Stock. Inputs used in the Black-Scholes valuation models utilized to fair value the modification to the Series A Preferred Stock during the year ended December 31, 2024, are as follows:

	January 14 - March 14, 2024	**April 5 - May 2, 2024**
Initial exercise price	0.677 -0.2727	0.233 -0.0404
Stock price on valuation date	0.300 -0.2424	0.155 -0.0404
Risk-free rate	5.10% - 4.82%	5.47% - 5.49%
Term (in years)	0.25 - 0.08	0.08 - 0.01
Rounded annual volatility	145% - 130%	110%

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%

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%

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).

Series A Preferred Stock Conversions

During the year ended December 31, 2023, 3i exercised its option to convert 12,052 shares of Series A Preferred stock for 404 shares of common stock at the fair value of $3.9 million. 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 $5.0 million, and (ii) the 3i June Promissory Note (as defined below) for $0.4 million in cash. As a result of the payment, the 3i June Promissory Note was paid in full on July 10, 2023.

During the year ended December 31, 2024, 3i exercised its option to convert 202 shares of Series A Preferred Stock for 904 shares of common stock at the fair value of $0.3 million. 3i exercised its option to convert 1,215 shares of Series A Preferred Stock for 15,072 shares of common stock at the fair value of $1.5 million. As of December 31, 2024, there were no shares of Series A Preferred Stock issued and outstanding.

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").

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	$ —

August 2024 Series A Convertible Redeemable Preferred Stock

On August 19, 2024 (the "August Closing Date"), the Company entered into a Securities Purchase Agreement (the "August 2024 SPA") with certain purchasers (the "August 2024 Purchasers"), pursuant to which the Company issued and sold, in a private placement (the "August 2024 Offering"), 35,000 shares of the Company's Convertible Redeemable Series A Preferred Stock, par value $0.0001 per share (the "August 2024 Preferred Stock"), for net proceeds of approximately $2.9 million, after the deduction of discounts, fees and offering expenses. In connection with the August 2024 Offering, the Company paid $0.2 million to Ascendiant Capital Markets, LLC, the Company's placement agent.

On the August Closing Date, the Company filed a certificate of designation (the "August 2024 COD") with the Secretary of the State of Delaware designating the rights, preferences and limitations of the August 2024 Preferred Stock. Under the August 2024 COD, for purposes of determining the presence of a quorum at any meeting of the stockholders of the Company at which the August 2024 Preferred Stock were entitled to vote and the voting power of the August 2024 Preferred Stock, each holder of the August 2024 Preferred Stock was entitled to a number of votes equal to shares of the Company's common stock into which such August 2024 Preferred Stock are then convertible, disregarding, for such purposes, any limitations on conversion. The August 2024 Preferred Stock were entitled to vote on each matter submitted to a vote of the stockholders generally and shall vote together with the common stock and any other class or series of capital stock entitled to vote thereon as a single class and on an as converted to the common stock basis.

The holders of the August 2024 Preferred Stock were entitled to dividends, on an as-if converted basis, equal to dividends actually paid, if any, on the common stock. The August 2024 Preferred Stock was convertible, at the option of the holders and, in certain circumstances, by the Company, into common stock, as determined by dividing the net purchase price of $90 per share by the conversion price of $5.10, at the option of the holders.

On the August Closing Date, the Company and the August 2024 Purchasers also entered into a Registration Rights Agreement (the "August 2024 RRA"), pursuant to which the Company agreed to file a registration statement with the SEC, to register for resale the common stock issuable upon the conversion of the August 2024 Preferred Stock. The registration statement was filed with the SEC on August 30, 2024.

All of the August 2024 Preferred Stock was redeemed in September 2024. As a result of the redemption of the August 2024 Preferred Stock, the Company recognized a deemed dividend of $0.6 million.

9. 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, 2024 and 2023, is presented in the following tables:

	Common Share Purchase Warrants	3i Exchange Warrants
Balance as of December 31, 2022	$ —	$ 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
Change in fair value adjustment of derivative and warrant liabilities	(2,262)	(415)
Cashless conversion of 3i Exchange Warrants	—	(405)
Balance as of December 31, 2024	$ 1	$ —
Fair value per Common warrant / 3i Warrant / Series A Preferred share issuable at year end	$ 0.09	$ —

On December 31, 2024, the Company used the Black-Scholes Merton model to estimate the fair value of the Common Share Purchase Warrants derivative liability at approximately $1,000, using the following inputs:

	April 2023 Warrants	July 2023 Warrants	September 2023 Inducement Warrants
Initial exercise price	$ 600.00	$ 600.00	$ 600.00
Stock price on valuation date	$ 1.17	$ 1.17	$ 1.17
Risk-free rate	4.38%	4.38%	4.38%
Term (in years)	3.52	3.52	4.2
Rounded annual volatility	123.7%	123.7%	123.7%

See Note 10 for the inputs used for the Black-Scholes Merton model to estimate the fair value of the Common Share Purchase Warrants derivative liability in 2023.

3i Exchange Warrants – Valuation Inputs

On December 5, 2023, 3i converted 8,410 Exchange Warrants on a cashless basis for 833 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 15,755 Exchange Warrants immediately before 3i's conversion to be approximately $1.9 million as of December 5, 2023. Accordingly, we recorded a $2.0 million reduction in the fair value of the 15,755 Exchange Warrants as a credit to change in fair value of warrants in our consolidated statement of comprehensive loss and $1.0 million, being the fair value of the 8,410 converted Exchange Warrants, was recorded as a credit to additional paid in capital.

On December 31, 2023 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 $0.8 million and $0.4 million, respectively.

The 3i Exchange Warrants were valued at December 31, 2023 and December 5, 2023 using the following inputs:

	December 31, 2023	December 5, 2023
Exercise price	$ 600.00	$ 600.00
Stock price on valuation date	$ 330.00	$ 348.00
Risk-free rate	4.71%	4.92%
Expected life of the Warrant to convert (in years)	0.97	1.04
Rounded annual volatility	127%	123%
Timing of liquidity event	Q1 - 2024	March 31, 2024
Expected probability of event	10%	10%

10. Stockholders' Equity

Common Stock

On September 3, 2024, the stockholders of the Company voted at the Company's 2024 annual meeting of stockholders to approve an amendment to the Company's Fifth Amended and Restated Certificate of Incorporation, to decrease the number of authorized shares of common stock by 500,000,000 shares of common stock, bringing the total number of authorized shares of common stock to 250,000,000 shares with a par value of $0.0001, of which 7,302,797 shares of common stock are outstanding as of December 31, 2024. As of December 31, 2023, 750,000,000 shares were authorized and 9,812 shares of common stock were outstanding.

2023 Shelf

On November 2, 2023, the Company filed a shelf registration statement (File No. 333-275282) on Form S-3, which was declared effective on November 29, 2023 (the "Shelf"). Approximately $10.0 million of securities remain available for sale under the Shelf as of December 31, 2024.

ATM Facility

On March 19, 2024, the Company entered into an At-The-Market Issuance Sales Agreement, as amended (the "Sales Agreement") with Ascendiant Capital Markets, LLC ("Ascendiant") pursuant to which, the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, par value $0.0001 per share, having an aggregate gross sales price of up to $50 million, to or through Ascendiant. The offer and sale of the shares will be made pursuant to a previously filed shelf registration statement on Form S-3 (File No. 333-275282), originally filed with the SEC on November 2, 2023 and declared effective by the SEC on November 29, 2023, and the related prospectus supplement dated September 9, 2024 and filed with the SEC on such date pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the "Securities Act"). On May 2, 2024, the Company's public float increased above $75.0 million and, as a result, the Company is not subject to the limitations contained in General Instruction I.B.6 of Form S-3.

Under the Sales Agreement, Ascendiant may sell shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act. Ascendiant will use commercially reasonable efforts to sell the shares from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company agreed to pay Ascendiant a commission of 3.0% of the gross proceeds from the sales of shares sold through Ascendiant under the Sales Agreement and has provided Ascendiant with customary indemnification and contribution rights. The Company also agreed to reimburse Ascendiant for certain expenses incurred in connection with the Sales Agreement. The Company and Ascendiant may each terminate the Sales Agreement at any time upon specified prior written notice.

For the year ended December 31, 2024, the Company sold an aggregate of 6,953,259 shares of its common stock pursuant to the Sales Agreement, resulting in net proceeds of approximately $38.8 million, after deducting underwriting discounts. There were no sales of common stock pursuant to the Sales Agreement in 2023. As of December 31, 2024, $10.0 million remained available for the sale of the Company's common stock under the ATM program.

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 outstanding were automatically redeemed in 2023, 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.

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 (the "Series C Shares") 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 had 620 votes and was 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 Series C Shares beneficially owned by 3i for 5,577 shares of Series A Preferred Stock.

Common Share Purchase Warrant, Pre-Funded Warrant and 3i Warrant Derivative Liabilities

In April 2023, the Company issued 119 shares of our common stock and 119 common stock purchase warrants, each exercisable for one share of common stock, at a combined public offering price of $18,000.00, and 297 pre-funded warrants, each exercisable for one share of common stock, and 297 common stock purchase warrants, each exercisable for one share of common stock only (the common stock purchase warrants sold in the public offering hereinafter referred to as the "April 2023 Common Warrants") at a combined public offering price of $18,000.00 less the $0.001 for the pre-funded warrants, for aggregate net proceeds of approximately $6.8 million, after 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 297 common shares.

In July 2023, the Company issued 596 shares of our common stock pre-funded warrants to purchase up to 3,478 shares of common stock (the "July Pre-Funded Warrants"), and common warrants to purchase up to 4,075 shares of common stock (the "July 2023 Common Warrants") at an effective combined purchase price of $2,700.00 per share and related common stock purchase warrants for aggregate net proceeds of approximately $10 million, after deducting placement agent fees and offering expenses payable by the Company of approximately $0.9 million 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 July 2023 Common Warrant was equal to $2,700.00 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 3,478 common shares.

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 2023 Offering (the "April 2023 Warrants") and (ii) in the July Offering (the "July 2023 Warrants" and together with the April 2023 Warrants, the "Existing 2023 Warrants"). Pursuant to the Inducement Letter, the September Investors agreed to exercise for cash their respective Existing 2023 Warrants to purchase an aggregate of up to 4,065 shares of the Company's common stock (the "Existing Warrant Shares"), at a reduced exercise price of $600.00 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 2023 Warrant Shares issued (the "Inducement Warrants"), pursuant to each Existing Warrant exercise, exercisable for 5 years and six months from the issue date, at an exercise price of $600.00, 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 $3.0 million, net of costs in exchange for the exercise of 4,065 Existing Warrants.

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 $20,400.00 per share and expire on the 5-year anniversary of the date of issuance, April 21, 2023, unless otherwise agreed upon by the Company 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, the Company agreed that for a period of 90 days from the close of the April Offering, that the Company 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 its 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 the Company's 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 warrants 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 $2,700.00 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 $0.2 million as a fair value modification cost in other income (expenses).

Management considered the April 2023 Common Warrants, July 2023 Common Warrants, and Inducement Warrant Shares, 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 $4.2 million, $6.8 million, and $4.1 million, respectively, using the Black-Scholes option pricing model and as a reduction of additional paid in capital. Additionally, the total July financing cost of $0.9 million has been proportionately allocated to financing costs and additional paid in capital in the amounts of the amount of $0.6 million and $0.3 million, respectively; and the total April financing cost of $0.7 million has been proportionately allocated to the finance expense and additional paid in capital in the amounts of $0.4 million and $0.3 million, respectively. The September financing cost of $0.2 million has been allocated to a finance expense in general and administration costs.

On September 14, 2023, the exercise prices of the April 2023 Common Warrants and July 2023 Common Warrants were reduced to $600.00 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 April 2023 Common Warrants and July 2023 Common Warrants as of September 14, 2023, using the Black-Scholes option pricing model and recorded the incremental value of $0.4 million as a fair value modification cost in other income (expenses).

Inputs used in the above noted Black-Scholes valuation models for the April 2023 Common Warrants, July 2023 Common Warrants and Inducement Warrants are as follows:

	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%

On November 8, December 1, and December 5, 2023, a total of 622, 444, and 2,290 July 2023 Common Warrants were exercised, respectively, and we used the Black-Scholes option pricing model to fair value the July 2023 Common Warrants at $0.1 million, $0.1 million, and $0.2 million, respectively. On December 5, 2023, a total of 139 April 2023 Common Warrants were exercised, and we used the Black-Scholes option pricing model to fair value the April 2023 Common Warrants at $22 thousand.

Inputs used in the above noted Black-Scholes valuation models for the exercise of the April 2023 Common Warrants and July 2023 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%

11. Stock-based Compensation

2021 Equity Incentive Plan

The Company has in effect the Allarity Therapeutics, Inc. 2021 Incentive Plan (as amended, the "2021 Incentive Plan"). The 2021 Incentive Plan was approved by shareholders in connection with the Recapitalization Share Exchange and became effective on December 20, 2021. The 2021 Incentive 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. Under the 2021 Incentive Plan, the compensation committee of the Company's board of directors is authorized to grant stock-based awards to employees, directors, consultants, independent contractors and advisors. The 2021 Incentive Plan authorizes the issuance of up to 353,163 shares of authorized but unissued common stock and expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of the grant.

Total shares available for the issuance of stock-based awards under the Company's 2021 Incentive Plan as of December 31, 2024 was 353,163. 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. In January 2025, the Board approved an increase of 5% of the outstanding shares of common stock, or 364,778 shares, increasing the total shares authorized to 717,941.

Restricted Stock Units

The following table summarizes restricted stock unit activity for the year ended December 31, 2024:

	Number of Units	Weighted Average Grant Fair Value
Unvested balance at December 31, 2023	—	—
Granted	174,038	2.36
Unvested balance at December 31, 2024	174,038	2.36

For the years ended December 31, 2024 and 2023, stock-based compensation expenses associated with the restricted stock units for employees were approximately $68 thousand and $0, respectively.

At December 31, 2024, the Company had unrecognized stock-based compensation expense related to restricted stock units of $0.3 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.7 years. This expense is recognized over the vesting period of the award.

Stock Options

The following table summarizes the stock option activity for the years ended December 31, 2024 and 2023:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2022	10	$ 5,504,400	4.2	$ —
Forfeited	(1)	8,397,600	—	
Outstanding as of December 31, 2023	9	$ 4,725,600	3.2	$ —
Forfeited	(9)	$ 4,725,600	—	
Outstanding as of December 31, 2024	—	$ —	—	$ —

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the stock options and the fair value of common stock for those options that had exercise prices lower than the fair value of common stock. Upon exercise of stock options, the Company will issue new shares of its common stock.

For the years ended December 31, 2024 and 2023, stock-based compensation expenses (recoveries) associated with the options awards for employees and non-employees were approximately $3 thousand and ($71) thousand, respectively. As of December 31, 2024, there was no unrecognized compensation cost for options issued since all outstanding options were forfeited in December 2024.

Stock-Based Compensation

The following table summarizes stock-based compensation for the years ended December 31, 2024 and 2023 (in thousands):

	Year ended December 31,	
($ in thousands)	2024	2023
Research and development	46	(24)
General and administrative	25	(47)
Total stock-based compensation expense (forfeiture)	71	(71)

)

12. License and Development Agreements

License Agreement with Eisai Inc. for Stenoparib

The Company holds 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 (the "Eisai License Agreement"). Pursuant to the Eisai License Agreement, the Company is solely responsible for the development of stenoparib during the term of the Eisai License Agreement. Eisai License Agreement also provides for a joint development committee consisting of six members, three appointed by the Company and three appointed by Eisai. One of the Company's 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 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 Company agreed to pay Eisai in periodic payments as follows: (i) $100,000, which has been paid; (ii) $50,000 within 10 days of execution of the fourth amendment, which has been paid; (iii) $100,000 upon completion of a capital raise, which has been paid; and (iv) $850,000 on or before March 1, 2024.

On February 26, 2024, in exchange for an additional $0.2 million, paid as of May 1, 2024, the Company and Eisai entered into a fifth amendment to the Exclusive License Agreement to postpone the payment of $850,000. The Company agreed to make a one-time payment to Eisai of $850,000 upon completion of a ten-million dollar capital raising campaign, no later than September 1, 2024. The Company paid Eisai $850,000 on August 20, 2024 and no payments are currently outstanding.

On August 2, 2024, the Company and Eisai entered into a sixth amendment to the Exclusive License Agreement with an effective date of August 2, 2024. The terms of the amended exclusive license were further amended in order to (1) amend the definition of a successful completion and (2) amend the terms related to Eisai's right of termination for development.

Development Milestone Payments

The Company has agreed to make milestone payments to Eisai in connection with the development of stenoparib by the Company or its affiliates, or by a third-party program acquirer that assumes control of the stenoparib development program from the Company 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, the Company may be obligated to pay Eisai up to a maximum of $94 million. In addition, the Company has agreed to pay Eisai a one-time sales milestone payment in the amount of $50 million the first time the Company's annual sales of licensed product is $1 billion or more.

Royalty Payments

In addition to the milestone payments described above, the Company has 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.

The Company is 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 in such country and expiring on the later of (i) the expiration of the last valid claim of any and all Eisai patents, Company patents and joint patents covering such product in such country; or, (ii) 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 the Company 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 the Company that is not cured within 90 days (30 days for a payment default) or if the Company files for bankruptcy.

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 the Company's licensed rights to develop stenoparib for a purchase price equal to the fair market value of the Company's rights, giving effect to the stage of development of stenoparib that the Company has completed under the agreement. The Company commenced a Phase 2 clinical trial April 15, 2019, and as of the date of the Financial Statements, Eisai has not indicated an intention to exercise its repurchase option.

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 $5.0 million inclusive of interest which is continuing to accrue at 5% per annum. As of December 31, 2024, the liability is recorded as a current liability on our Consolidated Balance Sheets as follows: $3.6 million in accounts payable and $1.4 million convertible promissory note and accrued interest.

Development costs and Out-License Agreement with Smerud

Pursuant to the terms of the amendment on March 28, 2022 to the out-license agreement with Smerud Medical Research International (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.

In 2024, the Company signed service agreements with external biotech clients for both DRP® analysis and gene expression services. Leveraging its gene expression and diagnostic capabilities, its laboratory will provide the services to the external clients. The Company received down payments in 2024 totaling approximately $0.2 million, is actively preparing the laboratory and required samples, and expects to start recognizing revenue in 2025.

13. Income Tax

The reconciliation of the statutory rate to the effective tax rate is as follows:

	2024	2023
Tax computed on the loss before tax at a tax rate of 21.0% for the years ended December 31, 2024 and 2023	$ (5,228)	$ (2,482)
Foreign rate differential	(164)	(73)
Tax value of derivative warrants	(562)	(1,187)
Special tax deduction on research and development expenses	(645)	(559)
Loss offset to research and development incentive	798	798
Other adjustments	106	17
Adjustment of tax concerning previous years	320	45
Change in valuation allowance	4,994	3,524
	$ (381)	$ 83

The components of net loss before income taxes were as follows:

	Year ended December 31,	
	2024	2023
Denmark	$ (16,376)	$ (6,234)
United States	(8,520)	(5,584)
	$ (24,896)	$ (11,818)

The components of the provision for income taxes from operations were as follows:

	Year ended December 31,	
	2024	2023
Current:		
Denmark	$ —	$ —
United States	—	—
Total	—	—
Deferred:		
Denmark	(381)	83
United States	—	—
Total	(381)	83
	$ (381)	$ 83

Deferred tax comprises:	2024	2023
Property, plant and equipment	$ (24)	$ (25)
Intangible assets	719	(1,405)
Stock compensation	800	790
Other accruals	15	16
Capitalized R&E costs	243	—
Net operating losses	19,325	16,952
Total deferred tax	21,078	16,328
Valuation allowance	(21,078)	(16,774)
Net deferred tax liabilities	$ —	$ (446)

Tax on profit/loss for the year:	2024	2023
Change in deferred tax	$ (381)	$ 83
Tax (benefit) expense	$ (381)	$ 83

Tax losses carried forward of approximately $89.4 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, 2024, 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, 2019, 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 year ended December 31, 2023, Thomas H. Jensen, a director of the Company, was paid $0.1 million in fees as a consultant. Effective December 12, 2023, the Company announced the appointment of Thomas H. Jensen as CEO.

15. 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, 2024, Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Warrant liability	$ —	$ —	$ (1)	$ (1)
Derivative warrant liability	—	—	—	—
	$ —	$ —	$ (1)	$ (1)

	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)

Methods used to estimate the fair values of our financial instruments, not disclosed elsewhere in these consolidated financial statements, are as follows:

When available, the Company's marketable securities are valued using quoted prices for identical instruments in active markets. If the Company is unable to value its marketable securities using quoted prices for identical instruments in active markets, the Company values its investments using broker reports that utilize quoted market prices for comparable instruments. Accordingly, its investment is considered a Level 1 financial asset. The Company has 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.

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, 2024, or 2023.

During the year ended December 31, 2023 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 $0.8 million. 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, 2024 and 2023, 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.

16. Commitments and Contingencies

Indemnification

In accordance with its certificate of incorporation, bylaws, and indemnification agreements, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity.

SEC Investigation

On July 19, 2024, the Company received a "Wells Notice" from the Staff of the SEC relating to the Company's previously disclosed SEC investigation. The Wells Notice related to the Company's disclosures regarding meetings with the United States Food and Drug Administration (the "FDA") regarding the Company's NDA for Dovitinib or Dovitinib-DRP, which was submitted to the FDA in 2021. The Company understands that all conduct relating to the SEC Wells Notice occurred during or prior to fiscal year 2022. The Company also understands that three of its former officers received Wells Notices from the SEC relating to the same conduct. A Wells Notice is neither a formal charge of wrongdoing nor a final determination that the recipient has violated any law. The Wells Notice informed the Company that the SEC Staff has made a preliminary determination to recommend that the SEC file an enforcement action against the Company that would allege certain violations of the federal securities laws.

Nasdaq Delisting Notifications

On June 18, 2024, the Company received a letter from the Nasdaq Listing Qualifications Staff (the "Staff") of Nasdaq indicating that the Company has not complied with the Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule") which is the requirement that for 30 consecutive business days the bid

price for the Company's common stock close above the $1 per share minimum bid price requirement for continued inclusion on Nasdaq. On July 30, 2024, the Company attended a hearing before a Nasdaq Hearings Panel (the "Panel"), and by decision date August 15, 2024, the Panel granted the Company's request for an extension through September 6, 2024 to obtain shareholder approval for a reverse split at a ratio that will allow the Company to demonstrate compliance with the Bid Price Rule. This approval was granted by Allarity's shareholders at the Company's Annual Meeting of Stockholders on September 3, 2024. On October 9, 2024, the Company was formally notified by the Staff that the Company has evidenced compliance with the Bid Price Requirement for continued listing on the Nasdaq, as set forth in Nasdaq Listing Rule 5550(a)(2).

Class Action

On September 13, 2024, a purported class action captioned Osman Mukeljic v. Allarity Therapeutics, Inc., et al, 1:24-cv-06952, was filed in the United States District Court for the Southern District of New York against the Company and certain of its current and former officers. The complaint alleged, among other things, that defendants made false and misleading statements and/or failed to disclose information related to Dovitinib NDA's continued regulatory prospects and purported misconduct in connection with the Dovitinib NDA and/or the Dovitinib-DRP PMA. The complaint asserted violations of Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder against all defendants as well as violations of Section 20(a) of the Securities Exchange Act of 1934, as amended, against the individual defendants.

17. Subsequent Events

Class Action

On February 26, 2025, the Company issued a press release announcing the dismissal of the aforementioned class action lawsuit.

SEC Investigation

On March 13, 2025, the Company issued a press release that the Company has reached a final settlement with the SEC relating to the Company's previously disclosed SEC investigation, and as part of the settlement, the Company has agreed to pay a one-time civil penalty of $2.5 million.

ATM Facility

During the period January 1, 2025 through March 25, 2025, the Company had sold 9,719,173 shares of it's common stock for net proceeds of 9.7 million. As of March 26, 2025, there were no more shares of the Company's common stock available for sale under the ATM program.

Share Buyback

On March 3, 2025, the Company's board of directors authorized a share repurchase program, allowing for the repurchase of up to $5 million of the Company's common stock through February 28, 2026. The Company expects the purchases to be made from time to time through open market transactions or other methods as permitted by securities laws and regulations, including Rule 10b-18 under the Securities Exchange Act of 1934, as amended.

FIFTH AMENDMENT TO EXCLUSIVE LICENSE AGREEMENT

This Fifth Amendment ("Fifth Amendment") to Exclusive License Agreement effective as of February 26, 2024 ("Fifth Amendment Effective Date") is by and between: **Eisai Inc**., with its principal office at 200 Metro Blvd., Nutley, NJ 07110, United States of America ("Eisai") and **Allarity Therapeutics, Inc.**, with its principal office at 24 School Street, 2nd Floor, Boston MA 02108, together with its wholly-owned subsidiaries ("Allarity") (formerly Oncology Venture A/S), with reference to the following:

WITNESSETH:

WHEREAS, on July 6, 2017, the Parties entered into an Exclusive License Agreement, (the "Original Agreement") relating to the cancer drug E7449 (now Stenoparib (2X-121)), a PARP inhibitor; and

WHEREAS, on December 11, 2020, the Parties executed a First Amendment to said Exclusive License Agreement, expanding the Field; and

WHEREAS, on August 3, 2021, the Parties executed a Second Amendment to said Exclusive License Agreement, extending the due date for the Extension Payment and related clinical trial enrollment deadlines; and

WHEREAS, on July 12, 2022, the Parties executed a Third Amendment to said Exclusive License Agreement, extending the due date for the Extension Payment and related clinical trial enrollment deadlines;

WHEREAS, on May 16, 2023, the Parties executed a Fourth Amendment to said Exclusive License Agreement, extending the due date for the Extension Payment and related clinical trial enrollment deadlines; and

WHEREAS, the Parties now desire to amend certain provisions of the Original Agreement (as amended) in order to further postpone the due date of the Extension Payment (as defined below).

NOW, THEREFORE, in consideration of the foregoing premises, and the mutual promises and covenants of Parties set forth herein, the Parties have agreed as follows:

1. Definitions

Capitalized terms used in this Fifth Amendment and not defined herein shall have the meanings assigned thereto in the Original Agreement.

2. Amendments and Agreements

A. Section 7.6 of the Original Agreement (as amended), "Extension Payment", is hereby amended and restated in its entirety as follows:

Section 7.6 Extension Payment. Allarity and Eisai desire to extend the timeframe for Allarity' s Successful Completion of the first Phase 2 Clinical Trial of the Product beyond December 31, 2022. In consideration of this extended timeframe, and Allarity not achieving the minimum patient enrollment, by July 1, 2022, set out in the Second Amendment, Allarity agrees to pay a one-time payment to Eisai of One Million Two Hundred and Fifty Thousand U.S. Dollars ($1,250,000) (the "Extension Payment") as follows:

(i) Two hundred and fifty thousand dollars ($250,000) (which has already been paid); and

(ii) One hundred and fifty thousand dollars ($150,000) on or before May 1, 2024; and

(iii) Eight Hundred and Fifty Thousand Dollars ($850,000) upon completion of a ten-million-dollar capital raising campaign, expected to take place before the end of May 2024, but in no event later than September 1, 2024.

3. Effect

This Fifth Amendment shall be effective from the Fifth Amendment Effective Date.

4. No Other Amendments

This Fifth Amendment shall be deemed to be part of and incorporated into the Original Agreement. Except as expressly set forth in this Fifth Amendment, all of the terms and conditions of the Original Agreement shall remain unchanged and are ratified, confirmed in all respects, and remain in full force and effect.

5. Counterparts

This Fifth Amendment may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. An executed signature page of this Fifth Amendment delivered by facsimile transmission or by electronic mail in "portable document format" shall be as effective as an original executed signature page.

IN WITNESS WHEREOF, the Parties hereto have executed this Fifth Amendment through their duly authorized representatives and made effective as of the Fifth Amendment Effective Date.

Allarity Therapeutics, Inc.
Eisai Inc.

Allarity Therapeutics Inc.

By: /s/ Thomas H. Jensen

Name: Thomas H. Jensen
Title: Chief Executive Officer
Date: 15 March 2024

Eisai Inc.

By: /s/ Takashi Owa

Name: Takashi Owa
Title: Chief Scientific Officer
Deep Human Biology Learning
Date: 18 March 2024

[Signature Page to Fifth Amendment to Exclusive License Agreement between Allarity and Eisai]

Allarity Therapeutics, Inc.

Policy on Insider Trading

This Insider Trading Policy describes the standards of Allarity Therapeutics, Inc., a Delaware corporation and its subsidiaries (the "**Company**") on trading, and causing the trading of, the Company's securities or securities of certain other publicly traded companies while in possession of confidential information. This Policy is divided into two parts: the first part prohibits trading in certain circumstances and applies to all directors, officers and employees and their respective immediate family members of the Company and the second part imposes special additional trading restrictions and applies to all (i) directors of the Company, (ii) executive officers of the Company (together with the directors, "**Company Insiders**") and (iii) the employees listed on
Appendix A (collectively, "**Covered Persons**") and (iv) certain other employees that the Company may designate from time to time as "Covered Persons" because of their position, responsibilities or their actual or potential access to material information.

One of the principal purposes of the federal securities laws is to prohibit so-called "insider trading." Simply stated, insider trading occurs when a person uses material nonpublic information obtained through involvement with the Company to make decisions to purchase, sell, give away or otherwise trade the Company's securities or to provide that information to others outside the Company. The prohibitions against insider trading apply to trades, tips and recommendations by virtually any person, including all persons associated with the Company, if the information involved is "material" and "nonpublic." These terms are defined in this Policy under Part I, Section 3 below. The prohibitions would apply to any director, officer or employee who buys or sells Company stock on the basis of material nonpublic information that he or she obtained about the Company, its customers, suppliers, or other companies with which the Company has contractual relationships or may be negotiating transactions.

PART I

1. Applicability

This Policy applies to all trading or other transactions in the Company's securities, including common stock, options and any other securities that the Company may issue, such as preferred stock, notes, bonds and convertible securities, as well as to derivative securities relating to any of the Company's securities, whether or not issued by the Company.

This Policy applies to all employees of the Company, all officers of the Company and all members of the Company's board of directors and their respective family members. This Policy also applies to all officers, directors and employees of the Company's subsidiaries and any of their immediate family.

2. General Policy: No Trading or Causing Trading While in Possession of Material Nonpublic Information

(a) No director, officer or employee or any of their immediate family members or officers, directors and employees of the Company's subsidiaries, or any of their immediate family, may purchase or sell, or offer to purchase or sell, any Company security, whether or not issued by the Company, while in possession of material nonpublic information about the Company. (The terms
"material" and "nonpublic" are defined in Part I, Section 3(a) and (b) below.)

(b) No director, officer or employee or any of their immediate family members or officers, directors and employees of the Company's subsidiaries, or any of their immediate family, who knows of any material nonpublic information about the Company may communicate that information to ("**tip**") any other person, including family members and friends, or otherwise disclose such information without the Company's authorization.

(c) No director, officer or employee or any of their immediate family members or officers, directors and employees of the Company's subsidiaries, or any of their immediate family, may purchase or sell any security of any other company, whether or not issued by the Company, while in possession of material nonpublic information about that company that was obtained in the course of his or her involvement with the Company. No director, officer or employee or any of their immediate family members or officers, directors and employees of the Company's subsidiaries, or any of their immediate family, who knows of any such material nonpublic information may communicate that information to, or tip, any other person, including family members and friends, or otherwise disclose such information without the Company's authorization.

(d) For compliance purposes, you should never trade, tip or recommend securities (or otherwise cause the purchase or sale of securities) while in possession of information that you have reason to believe is material and nonpublic unless you first consult with, and obtain the advance approval of, the Compliance Officer (which is defined in Part I, Section 3(c) below).

(e) Covered Persons must "pre-clear" all trading in securities of the Company in accordance with the procedures set forth in Part II, Section 3 below.

3. Definitions

(a) Material. Insider trading restrictions come into play only if the information you possess is "material." Materiality, however, involves a relatively low threshold. Information is generally regarded as "material" if it has market significance, that is, if its public dissemination is likely to affect the market price of securities, or if it otherwise is information that a reasonable investor would want to know before making an investment decision.

Information dealing with the following subjects is reasonably likely to be found material in particular situations:

(i) significant changes in the Company's prospects;

(ii) significant write-downs in assets or increases in reserves;

(iii) developments regarding significant litigation or government agency investigations;

(iv) liquidity problems;

(v) changes in earnings estimates or unusual gains or losses in major operations;

(vi) major changes in the Company's management or the board of directors;

(vii) changes in dividends;

(viii) extraordinary borrowings;

(ix) major changes in accounting methods or policies;

(x) award or loss of a significant contract;

(xi) cybersecurity risks and incidents, including vulnerabilities and breaches;

(xii) changes in debt ratings;

(xiii) proposals, plans or agreements, even if preliminary in nature, involving mergers, acquisitions, divestitures, recapitalizations, strategic alliances, licensing arrangements, or purchases or sales of substantial assets;

(xiv) offerings of Company securities;

(xv) significant research or product development;

(xvi) results of clinical trials and pre-clinical studies; and

(xvii) approval or disapproval of regulatory authorities concerning a therapeutic candidate or companion diagnostic.

Material information is not limited to historical facts but may also include projections and forecasts. With respect to a future event, such as a merger, acquisition or introduction of a new product, the point at which negotiations or product development are determined to be material is determined by balancing the probability that the event will occur against the magnitude of the effect the event would have on a company's operations or stock price should it occur. Thus, information concerning an event that would have a large effect on stock price, such as a merger, may be material even if the possibility that the event will occur is relatively small. When in doubt about whether particular nonpublic information is material, you should presume it is material. **If you are unsure whether information is material, you should either consult the Compliance Officer before making any decision to disclose such information (other than to persons who need to know it) or to trade in or recommend securities to which that information relates or assume that the information is material.**

(b) Nonpublic. Insider trading prohibitions come into play only when you possess information that is material and "nonpublic." The fact that information has been disclosed to a few members of the public does not make it public for insider trading purposes. To be "public" the information must have been disseminated in a manner designed to reach investors generally, and the investors must be given the opportunity to absorb the information. Even after public disclosure of information about the Company, you must wait until the close of business on the second trading day after the information was publicly disclosed before you can treat the information as public.

Nonpublic information may include:

(i) information available to a select group of analysts or brokers or institutional investors;

(ii) undisclosed facts that are the subject of rumors, even if the rumors are widely circulated; and

(iii) information that has been entrusted to the Company on a confidential basis until a public announcement of the information has been made and enough time has elapsed for the market to respond to a public announcement of the information (normally two trading days).

As with questions of materiality, if you are not sure whether information is considered public, you should either consult with the Compliance Officer or assume that the information is nonpublic and treat it as confidential.

(c) Compliance Officer. The Company has appointed the Chief Financial Officer as the Compliance Officer for this Policy. The duties of the Compliance Officer include, but are not limited to, the following:

(i) assisting with implementation and enforcement of this Policy;

(ii) circulating this Policy to all employees and ensuring that this Policy is amended as necessary to remain up-to-date with insider trading laws;

(iii) pre-clearing all trading in securities of the Company by Covered Persons in accordance with the procedures set forth in Part II, Section 3 below; and

(iv) providing approval of any Rule 10b5-1 plans under Part II, Section 1(c) below and any prohibited transactions under Part II, Section 4 below.

(v) providing a reporting system with an effective whistleblower protection mechanism.

4. Exceptions

The trading restrictions of this Policy do not apply to the following:

(a) Options. Exercising stock options granted under the Company's 2021 Equity Incentive Plan for cash or the delivery of previously owned Company stock. However, the sale of any shares issued on the exercise of Company-granted stock options and any cashless exercise of Company granted stock options are subject to trading restrictions under this Policy.

5. Violations of Insider Trading Laws

Penalties for trading on or communicating material nonpublic information can be severe, both for individuals involved in such unlawful conduct and their employers and supervisors, and may include jail terms, criminal fines, civil penalties and civil enforcement injunctions. Given the severity of the potential penalties, compliance with this Policy is absolutely mandatory.

(a) **Legal Penalties.** A person who violates insider trading laws by engaging in transactions in a company's securities when he or she has material nonpublic information can be sentenced to a substantial jail term and required to pay a criminal penalty of several times the amount of profits gained or losses avoided.

In addition, a person who tips others may also be liable for transactions by the tippees to whom he or she has disclosed material nonpublic information. Tippers can be subject to the same penalties and sanctions as the tippees, and the SEC has imposed large penalties even when the tipper did not profit from the transaction.

The SEC can also seek substantial civil penalties from any person who, at the time of an insider trading violation, "directly or indirectly controlled the person who committed such violation," which would apply to the Company and/or management and supervisory personnel. These control persons may be held liable for up to the greater of $1 million or three times the amount of the profits gained or losses avoided. Even for violations that result in a small or no profit, the SEC can seek penalties from a company and/or its management and supervisory personnel as control persons.

(b) **Company-Imposed Penalties.** Employees who violate this Policy may be subject to disciplinary action by the Company, including dismissal for cause. Any exceptions to the Policy, if permitted, may only be granted by the Compliance Officer and must be provided before any activity contrary to the above requirements takes place.

6. Inquiries

If you have any questions regarding any of the provisions of this Policy, please contact the Compliance Officer.

PART II

1. Blackout Periods

All Covered Persons are prohibited from trading in the Company's securities during blackout periods as defined below.

(a) **Quarterly Blackout Periods.** Trading in the Company's securities is prohibited during the period beginning at the close of the market on two weeks before the end of each fiscal quarter and ending at the close of business on the second trading day following the date the Company's financial results are publicly disclosed and Form 10-Q or Form 10-K is filed. During these periods, Covered Persons generally possess or are presumed to possess material nonpublic information about the Company's financial results.

(b) **Other Blackout Periods.** From time to time, other types of material nonpublic information regarding the Company (such as negotiation of mergers, acquisitions or dispositions, investigation and assessment of cybersecurity incidents or new product developments) may be pending and not be publicly disclosed. While such material nonpublic information is pending, the Company may impose special blackout periods during which Covered Persons are prohibited from trading in the Company's securities. If the Company imposes a special blackout period, it will notify the Covered Persons affected.

(c) **Exception.** These trading restrictions do not apply to transactions under a pre-existing written plan, contract, instruction, or arrangement under Rule 10b5-1 under the Securities Exchange Act of 1934 (an "**Approved 10b5-1 Plan**") that:

(i) has been reviewed and approved at least one month in advance of any trades thereunder by the Compliance Officer (or, if revised or amended, such revisions or amendments have been reviewed and approved by the Compliance Officer at least one month in advance of any subsequent trades);

(ii) was entered into in good faith by the Covered Person at a time when the Covered Person was not in possession of material nonpublic information about the Company; and

(iii) gives a third party the discretionary authority to execute such purchases and sales, outside the control of the Covered Person, so long as such third party does not possess any material nonpublic information about the Company; or explicitly specifies the security or securities to be purchased or sold, the number of shares, the prices and/or dates of transactions, or other formula(s) describing such transactions.

2. Trading Window

Covered Persons are permitted to trade in the Company's securities when no blackout period is in effect. Generally, this means that Covered Persons can trade during the period beginning on Day That Blackout Period Under Section 1(a) Ends and ending on Day That Next Blackout Period
Under Section 1(a) Begins. However, even during this trading window, a Covered Person who is in possession of any material nonpublic information should not trade in the Company's securities until the information has been made publicly available or is no longer material. In addition, the Company may close this trading window if a special blackout period under Part II, Section 1(b) above is imposed and will re-open the trading window once the special blackout period has ended.

3. Pre-Clearance of Securities Transactions

(a) Because Company Insiders are likely to obtain material nonpublic information on a regular basis, the Company requires all such persons to refrain from trading, even during a trading window under Part II, Section 2 above, without first pre-clearing all transactions in the Company's securities.

(b) Subject to the exemption in subsection (d) below, no Company Insider may, directly or indirectly, purchase or sell (or otherwise make any transfer, gift, pledge or loan of) any Company security at any time without first obtaining prior approval from the Compliance Officer. These procedures also apply to transactions by such person's spouse, other persons living in such person’s household and minor children and to transactions by entities over which such person exercises control.

(c) The Compliance Officer shall record the date each request is received and the date and time each request is approved or disapproved. Unless revoked, a grant of permission will normally remain valid until the close of trading two business days following the day on which it was granted. If the

transaction does not occur during the two-day period, pre-clearance of the transaction must be re-requested.

(d) Pre-clearance is not required for purchases and sales of securities under an Approved 10b5-1 Plan. With respect to any purchase or sale under an Approved 10b5-1 Plan, the third party effecting transactions on behalf of the Company Insider should be instructed to send duplicate confirmations of all such transactions to the Compliance Officer.

4. Prohibited Transactions

(a) Company Insiders are prohibited from trading in the Company's equity securities during a blackout period imposed under an "individual account" retirement or pension plan of the Company, during which at least 50% of the plan participants are unable to purchase, sell or otherwise acquire or transfer an interest in equity securities of the Company, due to a temporary suspension of trading by the Company or the plan fiduciary.

(b) Covered Persons, including any person's spouse, other persons living in such person's household and minor children and entities over which such person exercises control, are prohibited from engaging in the following transactions in the Company's securities unless advance approval is obtained from the Compliance Officer:

(i) Short-term trading. Company Insiders who purchase Company securities may not sell any

Company securities of the same class for at least six months after the purchase;

(ii) Short sales. Covered Persons may not sell the Company's securities short;

(iii) Options trading. Covered Persons may not buy or sell puts or calls or other derivative securities on the Company's securities;

(iv) Trading on margin or pledging. Covered Persons may not hold Company securities in a margin account or pledge Company securities as collateral for a loan; and

(v) Hedging. Covered Persons may not enter into hedging or monetization transactions or similar arrangements with respect to Company securities.

5. **Acknowledgment and Certification**

All Covered Persons are required to sign the attached acknowledgment and certification.

ACKNOWLEDGMENT AND CERTIFICATION

The undersigned does hereby acknowledge receipt of the Company's Insider Trading Policy. The undersigned has read and understands (or has had explained) such Policy and agrees to be governed by such Policy at all times in connection with the purchase and sale of securities and the confidentiality of nonpublic information.

_____
(Signature)

_____
(Please print name)

Date: _____

Exhibit 31.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Thomas H. Jensen, certify that:

1. I have reviewed this Annual Report on Form 10-K of Allarity Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2025

/s/ Thomas H. Jensen
Thomas H. Jensen
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS OF CHIEF FINANCIAL OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Alexander Epshinsky, certify that:

1. I have reviewed this Annual Report on Form 10-K of Allarity Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2025

/s/ Alexander Epshinsky
Alexander Epshinsky
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Allarity Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, in the capacities and on the date indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: March 31, 2025

/s/ Thomas H. Jensen
Thomas H. Jensen
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Allarity Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, in the capacities and on the date indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to her knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: March 31, 2025

/s/ Alexander Epshinsky
Alexander Epshinsky
Chief Financial Officer
(Principal Financial Officer)