ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "estimate," or "continue," and similar expressions or variations. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including but not limited to those discussed in the section titled "Risk Factors" and in other parts of this Annual Report on Form 10-K. A discussion and analysis of our financial condition, results of operations, and cash flows for the year ended December 31, 2023 compared to the year ended December 31, 2022 is included in Item 7 of Part II, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 28, 2024.

Overview

We are a late-stage clinical specialty pharmaceutical company with a sole mission to address the global nicotine dependence epidemic in combustible cigarette and e-cigarette usage through the development and commercialization of cytisinicline. There are an estimated 29 million adults in the United States alone who smoke combustible cigarettes and an estimated 11 million adults in the United States who utilize e-cigarettes. Tobacco use is currently the leading cause of preventable death and is responsible for more than eight million deaths worldwide and nearly half a million deaths in the United States annually. More than 87% of lung cancer deaths, 61% of all pulmonary disease deaths, and 32% of all deaths from coronary heart disease are attributable to smoking and exposure to secondhand smoke.

While nicotine e-cigarettes are thought to be less harmful than combustible cigarettes, they remain highly addictive and can deliver harmful chemicals which can cause lung injury or cardiovascular disease. In 2024, 1.6 million high school and middle school students reported using e-cigarettes. Research shows adolescents who have used e-cigarettes are seven times more likely to become smokers one year later compared to those who have never used e-cigarettes. Recently, the U.S. Food and Drug Administration, or FDA, granted Breakthrough Therapy Designation for cytisinicline for nicotine e-cigarette, or vaping, cessation. Breakthrough Therapy Designation is a process that expedites the development and review of new drugs and biologics that are intended to treat serious or life-threatening conditions and have preliminary clinical evidence indicating substantial improvement over existing therapies. Currently, there are no FDA approved drug therapies indicated specifically as an aid to nicotine e-cigarette cessation. We believe cytisinicline represents a unique opportunity to significantly impact global health by addressing the considerable unmet need among millions of smokers and e-cigarettes users.

Cytisinicline is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is believed to work in treating nicotine dependence for smoking and e-cigarette cessation by interacting with nicotine receptors in the brain by reducing the severity of withdrawal symptoms, and reducing the reward and satisfaction associated with nicotine products. Cytisinicline is an investigational product candidate being developed for treatment of nicotine dependence and has not been approved by the FDA for any indication in the United States.

We believe cytisinicline represents a unique opportunity to significantly impact global health by addressing the considerable unmet need among millions of smokers and e-cigarettes users. If approved by the FDA, it may become one of the first new prescription medicines in nearly two decades aimed at aiding individuals in overcoming nicotine dependence. We believe cytisinicline is differentiated from existing smoking cessation treatments given its combination of efficacy, well-tolerated safety profile, and a shorter therapy duration, as demonstrated in clinical trials.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. We have never been profitable and have incurred operating losses in each year since inception. Our net loss was $39.8 million for the year ended December 31, 2024. As of December 31, 2024, we had an accumulated deficit of $205.6 million, cash, cash equivalents and marketable securities balance of $34.4 million and a positive working capital balance of $29.8 million. During the year ended December 31, 2024, net cash used in operations was $29.8 million.

Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is subject to material uncertainty and dependent on our ability to obtain additional financing. For additional information, see the section titled "— Liquidity, Capital Resources and Going Concern."

License & Supply Agreements

Sopharma License and Supply Agreements

We are party to a license agreement, or the Sopharma License Agreement, and a supply agreement, or the Sopharma Supply Agreement, with Sopharma. Pursuant to the Sopharma License Agreement, we were granted access to all available manufacturing, efficacy and safety data related to cytisinicline, as well as a granted patent in several European countries related to new oral dosage forms of cytisinicline providing enhanced stability. Additional rights granted under the Sopharma License Agreement include the exclusive use of, and the right to sublicense, certain cytisinicline trademarks in all territories described in the Sopharma License Agreement. Under the Sopharma License Agreement, we agreed to pay a nonrefundable license fee. In addition, we agreed to make certain royalty payments equal to a mid-single digit percentage of all net sales of cytisinicline products in our territory during the term of the Sopharma License Agreement, including those sold by a third party pursuant to any sublicense which may be granted by us. To date, any amounts paid to Sopharma pursuant to the Sopharma License Agreement have been immaterial.

Share Purchase Agreement

In May 2015, we entered into a Share Purchase Agreement with Sopharma to acquire 75% of the outstanding shares of Extab Corporation for $2.0 million in cash and $2.0 million in a deferred payment, contingent on regulatory approval of cytisinicline by the FDA or the European Medicines Agency, or EMA. The fair value of the contingent consideration on the acquisition date was nil. The contingent consideration liability is measured at fair value in our financial statements,

As of December 31, 2024, the fair value of the contingent consideration was estimated to be $1.1 million as compared to $0.5 million as of December 31, 2023. (see Note 2 "Significant Accounting Policies, Sopharma Share Purchase Agreement Contingent Consideration" in the accompanying consolidated Financial Statements). We recognized a loss of $0.6 million for the year ended December 31, 2024.

University of Bristol License Agreement

In July 2016, we entered into a license agreement with the University of Bristol, or the University of Bristol License Agreement. Under the University of Bristol License Agreement, we received exclusive and nonexclusive licenses from the University of Bristol to certain patent and technology rights resulting from research activities into cytisinicline and its derivatives, including a number of patent applications related to novel approaches to cytisinicline binding at the nicotinic receptor level.

In consideration of rights granted by the University of Bristol, we paid a nominal license fee and agreed to pay amounts of up to $3.2 million, in the aggregate, tied to a financing milestone and to specific clinical development and commercialization milestones resulting from activities covered by the University of Bristol License Agreement. Additionally, if we successfully commercialize any product candidates subject to the University of Bristol License Agreement, we are responsible for royalty payments in the low-single digits and payments up to a percentage in the mid-teens of any sublicense income, subject to specified exceptions, based upon net sales of such licensed products.

On January 22, 2018, we and the University of Bristol entered into an amendment to the University of Bristol License Agreement. Pursuant to the amended University of Bristol License Agreement we received exclusive rights for all human medicinal uses of cytisinicline across all therapeutic categories from the University of Bristol from research activities into cytisinicline and its derivatives. In consideration of rights granted by the amended University of Bristol License Agreement, we paid an initial amount of $37,500 and agreed to pay additional amounts of up to $1.7 million, in the aggregate, tied to a financing milestone and to specific clinical development and commercialization milestones, in addition to amounts under the original University of Bristol License Agreement. Additionally, if we successfully commercialize any product candidate subject to the amended University of Bristol License Agreement or to the original University of Bristol License Agreement, we will be responsible for royalty payments in the low-single digits and payments up to a percentage in the mid-teens of any sublicense income, subject to specified exceptions, based upon net sales of such licensed products. Through December 31, 2024, we have paid the University of Bristol $125,000 pursuant to the University of Bristol License Agreement.

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of costs for clinical trials, manufacture of product, personnel costs, milestone payments to third parties, facilities, regulatory activities, non-clinical studies and allocations of other R&D-related costs. External expenses for clinical trials include fees paid to clinical research organizations, clinical trial site costs and patient treatment costs.

We manage our clinical trials through contract research organizations and independent medical investigators at our sites and at hospitals and expect this practice to continue. Due to our ability to utilize resources across several projects, we do not record or maintain information regarding the indirect operating costs incurred for our R&D programs on a program-specific basis. In addition, we believe that allocating costs on the basis of time incurred by our employees does not accurately reflect the actual costs of a project.

The process of conducting clinical trials and non-clinical studies necessary to obtain regulatory approval is costly and time consuming and we may never succeed in achieving marketing approval for cytisinicline. (See "Item 1A. Risk Factors—Risks Related to the Development of Our Product Candidate Cytisinicline.")

Successful development of cytisinicline is highly uncertain and may not result in an approved product. We cannot estimate completion dates for development activities or when we might receive material net cash inflows from our R&D projects, if ever. We anticipate we will make determinations as to which markets, and therefore, which regulatory approvals, to pursue and how much funding to direct toward achieving regulatory approval in each market on an ongoing basis in response to our ability to enter into new strategic alliances with respect to each program or potential product candidate, the scientific and clinical success of each future product candidate, and ongoing assessments as to each future product candidate's commercial potential. We will need to raise additional capital and may seek additional strategic alliances in the future in order to advance our various programs.

Our projects or intended R&D activities may be subject to change from time to time as we evaluate results from completed studies, our R&D priorities and available resources.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for our personnel in executive, finance and accounting, and other administrative functions, as well as consulting costs, including commercial, corporate communications, market research, business consulting, human resources and intellectual property. Other costs include professional fees for legal and auditing services, insurance and facility costs.

Results of Operations

Years Ended December 31, 2024 and 2023

Research and Development Expenses

Our research and development expenses for our cytisinicline clinical development program are as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Clinical development program:		
Cytisinicline	$ 22,817	$ 15,814
Total research and development expenses	**$ 22,817**	**$ 15,814**

Research and development expenses for the years ended December 31, 2024 and 2023 were $22.8 million and $15.8 million, respectively. The increase in 2024 as compared to 2023 was primarily due to the initiation, in May 2024, of our ORCA-OL open label safety trial. This increase was partially offset by a reduction in costs associated with our Phase 3 ORCA-3 trial and Phase 2 ORCA-V1 trial as both were completed in the second quarter of 2023.

General and Administrative Expenses

Our general and administrative expenses were as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Total general and administrative expenses	**$ 16,252**	**$ 11,436**

G&A expenses for the years ended December 31, 2024 and 2023 were $16.3 million and $11.4 million, respectively. The increase in 2024 as compared to 2023 was primarily due to higher employee expenses associated with stock based compensation expense and severance costs, commercial launch preparation costs, consulting costs, and legal expenses associated with patent activities and general corporate activities.

Interest Income

Total interest income for the years ended December 31, 2024 and 2023 was $2.4 million and $0.8 million, respectively. The increase in interest income for the year ended December 31, 2024 as compared to the same period in 2023was primarily due to higher average cash balances throughout 2024 and higher interest rates.

Interest Expense

Total interest expense for the years ended December 31, 2024 and 2023 was $2.2 million and $2.9 million, respectively. The decrease in interest expense for the year ended December 31, 2024 as compared to the same period in 2023 was due to a lower principal balance on our New Convertible Term Loan, relative to the Convertible Term Loan, that bears only a monthly interest as a result of the debt refinancing under the New Debt Agreement (see "Liquidity and Capital Resources" below).

Change in fair value of contingent consideration

We determine the fair value of the contingent consideration using a probability based discounted cash flow model whereby we forecast the timing of the cash flow of the related future payment based on cytisinicline's current clinical development phase and the remaining requirements for regulatory approval. Adjustments to the fair value of the contingent liabilities, other than payments, are recorded as a gain or loss in the Consolidated Statements of Loss and Comprehensive Loss (see Note 7 "Fair Value Measurements, Fair Value of Sopharma Share Purchase Agreement Contingent Consideration" in the accompanying consolidated Financial Statements).

For the years ended December 31, 2024 and 2023 we recognized losses of $0.6 million and $0.5 million, respectively.

Loss on extinguishment of 2023 SVB convertible term loan

The debt refinancing under the New Debt Agreement was recognized as an extinguishment of debt under Accounting Standards Update, or ASU, 470-50. The difference between the reacquisition price and carrying value was recognized on the Consolidated Statement of Loss as a loss on extinguishment of debt.

For the year ended December 31, 2024 we incurred a loss on extinguishment of debt of $0.3 million.

Liquidity, Capital Resources and Going Concern

We have incurred an accumulated deficit of $205.6 million through December 31, 2024 and we expect to incur substantial additional losses in the future as we operate our business and continue or expand our regulatory, manufacturing, commercialization and other R&D activities and other operations. We have not generated any revenue from product sales to date, and we may not generate product sales revenue in the near future, if ever. As of December 31, 2024, we had a cash, cash equivalents and marketable securities balance of $34.4 million and a positive working capital balance of $29.8 million. For the year ended December 31, 2024, net cash used in operations was $29.8 million.

We have historically financed our operations through equity and debt financings. While we believe that we will be able to settle our commitments and liabilities in the normal course of business as they fall due during the next 12 months, as a late-stage clinical specialty pharmaceutical company with no current sources of revenue, we are dependent on our ability to raise funds (through public or private securities offerings, debt financings, government funding or grants, or other sources, which may include licensing, collaborations or other strategic transactions or arrangements) to support the ongoing advancement of our clinical trials and corporate activities. We believe that our existing cash, cash equivalents and marketable securities will be sufficient for us to fund our current operating expenses and capital expenditures into the third quarter of 2025.

The financial results have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and liabilities and commitments in the normal course of business.

Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is subject to material uncertainty and dependent on our ability to obtain additional financing. We have historically financed our operations through equity offerings and/or debt financings. There can be no assurance that financing from these or other sources will be available to us in the future. Without additional funds, we may be forced to delay, scale back or eliminate some of our research and development activities or other operations and potentially delay product development in an effort to provide sufficient funds to continue our

operations. If any of these events occur, our ability to achieve our development and commercialization goals would be adversely affected.

Our current resources are insufficient to fund our planned operations for the next 12 months. We will continue to require substantial additional capital to continue our clinical development and commercialization activities. Accordingly, we will need to raise substantial additional capital from the sale of our securities, debt, partnering arrangements, non-dilutive fundraising or other financing transactions in order to continue to fund our operations and finance the remaining development and commercialization of our product candidate. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development, regulatory review and commercialization efforts. The uncertainty with respect to our operations and the market generally may also make it challenging to raise additional capital on favorable terms, if at all. In addition, current macroeconomic conditions have caused uncertainty in various sectors, including capital markets. Failure to raise capital as and when needed, on favorable terms or at all, will have a negative impact on our financial condition and our ability to develop our product candidate.

In addition, we expect to incur significant expenses and increasing operating losses for at least the next several years as we continue our clinical development of, seek regulatory approval for, and commercialize, cytisinicline and add personnel necessary to operate as a commercial-stage public company. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of clinical development programs and efforts to achieve regulatory approval and commercialization.

The consolidated financial statements do not include any adjustments to the amounts and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern. Such adjustments could be material.

We did not have during the periods presented, and we do not currently have, any commitments or obligations, including contingent obligations, other than the Sopharma Contingent Consideration, arising from arrangements with unconsolidated entities or persons that have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, cash requirements or capital resources.

Convertible Debt

On July 25, 2024, we entered into a contingent convertible debt agreement, or New Debt Agreement**,** with Silicon Valley Bank, or SVB, a division of First-Citizens Bank & Trust Company, or FCB, in its capacity as administrative agent and collateral agent, and FCB, as a lender, or Lender, pursuant to which the Lender provided term loans having an aggregate original principal amount of $10.0 million, with additional term loans of up to $10.0 million available upon the occurrence of certain events as provided for in the New Debt Agreement and further described below, or New Convertible Term Loan. Our obligations under the New Debt Agreement are secured by substantially all of our assets, other than intellectual property.

The New Convertible Term Loan matures on December 1, 2027, which maturity date may be extended to June 1, 2028 upon the occurrence of certain events as provided for in the New Debt Agreement. The first tranche of the New Convertible Term Loan, which was advanced on July 25, 2024, has an aggregate original principal amount of $10.0 million. The Lender will further make available to us, upon our request: (a) on or prior to October 31, 2025, a second tranche of the New Convertible Term Loan having an aggregate principal amount of $5.0 million in the event that we receive written notice that the FDA has accepted for filing our NDA with respect to cytisinicline for a smoking cessation indication, or the Additional Term Loan Event I, and (b) on or prior to December 31, 2025, a third tranche of the New Convertible Term Loan having an aggregate principal amount of $5.0 million, subject to the Lender's sole discretion. Interest is calculated on the outstanding principal amount of the New Convertible Term Loan at a floating rate per annum equal to the greater of (i) 7.0% and (ii) the prime rate minus 1.0%, which interest shall be payable in cash monthly in arrears and shall be payable on the earlier to occur of (x) the first day of the first month following any extension of credit by the Lender for our credit, (y) the date of any prepayment pursuant to the New Debt Agreement, or (z) the maturity date. The New Convertible Term Loan will be "interest-only" until December 31, 2025, subject to extension as provided for in the New Debt Agreement. The "interest-only" period may be extended to June 30, 2026, if (i) prior to December 31, 2025, we have received at least $40,000,000 in net cash proceeds from the issuance equity interests and (ii) the conditions of Additional Term Loan Event I have been satisfied.

Subject to certain terms and conditions, the conversion feature grants the Lender or, pursuant to an assignment, any designee thereof, or Conversion Right Holders (as defined in the New Debt Agreement), the right to convert part or all of the outstanding aggregate original principal amount of the New Convertible Term Loan, plus accrued and unpaid interest, into shares of our common stock at a conversion price equal to $7.00, subject to customary adjustment provisions. The Conversion Right Holders have the further right to convert part or all of the outstanding principal amount of the second and third tranches of the New Convertible Term Loan, plus accrued and unpaid interest, into shares of our common stock at a conversion price equal to the greater of (i) $4.854, subject to customary adjustment provisions, and (ii) the lower of (a) 150% of the average of the closing sale price of our common stock during

the 10 trading days preceding the effective date of such tranche and (b) 150% of the closing sale price of our common stock on the trading day immediately preceding the effective date of such tranche.

The conversion rights may be exercised at each Conversion Right Holder's option any time prior to repayment of the New Convertible Term Loan; provided, however, that the Conversion Right Holders will not be permitted to convert part or all of the outstanding aggregate original principal amount of the New Convertible Term Loan without the agreement of the relevant Conversion Right Holder and us if the sum of the amount of debt to be converted; and the aggregate amount of debt previously converted pursuant to any such voluntary conversion, divided by the aggregate of all debt that is then outstanding or that has been repaid other than by conversion exceeds 50%.

Additionally, the outstanding principal of the New Convertible Term Loan, plus accrued and unpaid interest, will automatically be converted into shares of our common stock at the applicable conversion price on such date if any, when the closing price per share of our common stock has been equal to or greater than (a) in the case of the outstanding aggregate original principal amount of the New Convertible Term Loan, plus accrued and unpaid interest, $24.00 or, (b) in the case of the outstanding principal amount of the second and third tranches of the New Convertible Term Loan, plus accrued and unpaid interest, three times the applicable conversion price, in each case for the thirty consecutive trading days prior to such date, and the Liquidity Conditions (as defined in the New Debt Agreement) have been satisfied.

The New Convertible Term Loan may be repaid at our election and upon notice to the Agent (as defined in the New Debt Agreement) by paying the Lender an amount equal to (i) a prepayment fee equal to (a) 3.0% of the aggregate outstanding principal balance if such prepayment occurs on or prior to the first anniversary of the New Convertible Term Loan, (b) 2.0% of the aggregate outstanding principal balance if such prepayment occurs after the first anniversary, but on or prior to the second anniversary, of the New Convertible Term Loan or (c) 1.0% of the aggregate outstanding principal balance if such prepayment occurs after the second anniversary of the New Convertible Term Loan and before the maturity date; (ii) 4.0% of the original aggregate principal amount of the New Convertible Term Loan and (iii) all other sums due and payable under the New Convertible Term Loan.

The New Debt Agreement contains customary affirmative and restrictive covenants, including covenants regarding the incurrence of additional indebtedness or liens, investments, transactions with affiliates, delivery of financial statements, payment of taxes, maintenance of insurance, dispositions of property, mergers or acquisitions, among other customary covenants. We are also restricted from paying dividends or making other distributions or payments on our capital stock, subject to limited exceptions. The New Debt Agreement also includes customary representations and warranties, events of default and termination provisions. The Lender may not engage in any short sales of, or other hedging transactions in, our common stock while any amounts are outstanding under the New Debt Agreement.

In connection with the New Debt Agreement, we entered into a Registration Rights Agreement, or RRA, with the Lender, pursuant to which we registered for resale shares of our common stock issuable to the Conversion Right Holders upon the conversion of outstanding debt under the New Debt Agreement. Our obligations under the RRA will terminate with respect to a holder of applicable registrable securities if, as of the date we would be required to provide written notice of such registration, (x) the aggregate number of registrable securities then issued and issuable to such holder and to such holder’s affiliates, together with all other shares then held beneficially and/or of record by such holder and its affiliates, does not exceed 7.0% of our then-total shares issued and outstanding (calculated including all such registrable securities and other shares), or (y) we and such holder mutually reasonably agree that all registrable securities then issued and issuable to such holder and its affiliates may then be sold by such holder without the requirement to be in compliance with Rule 144 promulgated under the Securities Act, or Rule 144, and otherwise without restriction or limitation pursuant to Rule 144.

Virtu At-the-Market Sales Agreement

On December 21, 2021, we entered into an At-the-Market Offering Sales Agreement, or ATM, with Virtu Americas, LLC, as sales agent. The ATM was terminated on February 29, 2024, and no further sales of our common stock will be made pursuant to the ATM.

Through the date of termination of the ATM, we offered and sold an aggregate of 200,000 shares of our common stock. These aggregate sales resulted in gross proceeds to us of approximately $1.5 million. During the year ended December 31, 2024, we did not sell any shares of our common stock pursuant to the ATM.

November 2022 Private Placement

In November 2022, we entered into subscription agreements with certain accredited investors pursuant to which we sold to the purchasers in a private placement transaction approximately 4,093,141 units at a purchase price of $4.625 per unit, with each unit

consisting of two shares of common stock and a common stock purchase warrant to purchase one share of common stock, or the Warrants.

The Warrants are exercisable at a price per share of common stock of $4.50, subject to adjustment. The Warrants are exercisable beginning on the six-month anniversary of the initial closing date of the private placement offering, or May 18, 2023, or the Initial Exercise Date, and will expire on the seven year anniversary of the initial closing date of the private placement offering, or November 18, 2029. The Warrants cannot be exercised by a Warrant holder if, after giving effect thereto, such Warrant holder would beneficially own more than 19.99% of our outstanding common stock. Additionally, subject to certain exceptions, if, after the Initial Exercise Date, (i) the volume weighted average price of our common stock for each of 30 consecutive trading days, or the Measurement Period, which Measurement Period commenced on November 18, 2022, exceeds 300% of the exercise price (subject to adjustments for stock splits, recapitalizations, stock dividends and similar transactions), (ii) the average daily trading volume for such Measurement Period exceeds $500,000 per trading day and (iii) certain other equity conditions are met, and subject to a beneficial ownership limitation, then we may call for cancellation of all or any portion of the Warrants then outstanding.

We received approximately $17.9 million in net proceeds from the private placement after deducting placement agent expenses and commissions and offering expenses.

May 2023 Registered Direct Offering

In May 2023, we entered into a securities purchase agreement with certain purchasers, pursuant to which we sold 3,000,000 shares of common stock at a price of $5.50 per share in a registered direct offering. The offering of the shares was made pursuant to our shelf registration statement on Form S-3, including the prospectus dated January 5, 2022 contained therein, and the prospectus supplement dated May 25, 2023.

We received approximately $15.3 million in net proceeds from the registered direct offering after deducting placement agent fees and offering expenses.

February 2024 Registered Direct Offering and Concurrent Private Placement

In February 2024, we entered into a securities purchase agreement with certain purchasers, pursuant to which we sold 13,086,151 shares of common stock at a price of $4.585 per share in a registered direct offering. The offering of the shares was made pursuant to our shelf registration statement on Form S-3, including the prospectus dated January 5, 2022 contained therein, and the prospectus supplement dated February 29, 2024.

In a concurrent private placement, we issued unregistered warrants to purchase up to 13,086,151 shares of common stock at an exercise price of $4.906 per share (provided, however, that the purchaser may elect to exercise the warrants for pre-funded warrants in lieu of shares of common stock at an exercise price of $4.906, minus $0.001, the exercise price of each pre-funded warrant). These warrants will be immediately exercisable for shares of common stock or pre-funded warrants in lieu thereof, and will expire on the earlier of (i) three and one-half years following the date of issuance and (ii) 30 days following our public disclosure of the acceptance of an NDA for cytisinicline by the FDA in a Day 74 Letter or equivalent correspondence. The shares of common stock issuable upon exercise of the warrants (or pre-funded warrants, as applicable) were subsequently registered pursuant to our registration statement on Form S-3, which was declared effective on May 6, 2024.

The registered direct offering raised total gross proceeds of approximately $60.0 million, and after deducting approximately $3.9 million in placement agent fees and offering expenses, we received net proceeds of approximately $56.1 million.

Jefferies Open Market Sale Agreement

On September 27, 2024, we entered into an Open Market Sale Agreement, or Sale Agreement, with Jefferies LLC, or Jefferies, as sales agent, to establish an at-the-market offering program through which we may sell shares of our common stock with an aggregate offering price of up to $50.0 million. During the year ended December 31, 2024, we did not sell any shares under the Sale Agreement. As of December 31, 2024, we had $50.0 million available under the Sale Agreement.

Cash Flows

Operating Activities

For the years ended December 31, 2024 and 2023, net cash used in operating activities was $29.8 million and $24.5 million, respectively. The increase in net cash used in operations in 2024 as compared to 2023 was due to higher R&D expenses associated with initiation, in May 2024, and ramp up of enrollment of our ORCA-OL trial and the timing of required upfront prepayments by our clinical vendors. This was partially offset by reduced costs associated with our Phase 3 ORCA-3 trial and Phase 2 ORCA-V1 trial as both were completed in the second quarter of 2023.

Financing Activities

For the years ended December 31, 2024 and 2023 net cash provided by financing activities was $48.5 million and $15.3 million, respectively. Net cash provided by financing activities for the year ended December 31, 2024 relates to proceeds received from our February 2024 registered direct offering, the New Convertible Term Loan associated with the refinancing transaction in July 2024, warrant exercises, and stock sales under our employee stock purchase plan. This was partially offset by repayment of our Convertible Term Loan associated with the refinancing transaction. Net cash provided by financing activities for the year ended December 31, 2023 relates to proceeds received from our May 2023 private placement, and warrant exercises.

Investing Activities

Net cash used in investing activities in 2024 was due to transactions involving marketable securities in the normal course of business. Investing activities in 2023 consisted of property and equipment purchases.

Critical Accounting Policies and Estimates

Use of Estimates

The preparation of consolidated financial statements in conformity with United States generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and notes thereto. Actual results could differ from these estimates. Estimates and assumptions principally relate to estimates of contingent considerations, the initial fair value and forfeiture rates of stock options issued to employees and consultants, the estimated compensation cost on performance restricted stock unit awards, clinical trial and manufacturing accruals, estimated useful lives of property, plant, equipment and intangible assets, estimates and assumptions in contingent liabilities.

Intangible Assets

Our intangible assets are subject to amortization and are amortized using the straight-line method over their estimated period of benefit. We evaluate the carrying amount of intangible assets periodically by taking into account events or circumstances that may warrant revised estimates of useful lives or that indicate the asset may be impaired.

Impairment of Long-Lived Assets

We review long-lived assets for impairment whenever events or changes in circumstances indicate that the asset's carrying amount may not be recoverable. We conduct our long-lived asset impairment analyses in accordance with ASC 360-10-15, "Impairment or Disposal of Long-Lived Assets." ASC 360-10-15 requires us to group assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities and evaluate the asset group against the sum of the undiscounted future cash flows. If the undiscounted cash flows do not indicate the carrying amount of the asset is recoverable, an impairment charge is measured as the amount by which the carrying amount of the asset group exceeds its fair value based on discounted cash flow analysis or appraisals.

Goodwill

Goodwill acquired in a business combination is assigned to the reporting unit that is expected to benefit from the combination as of the acquisition date. Goodwill is tested for impairment on an annual basis or, more frequently, if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit.

Sopharma Share Purchase Agreement Contingent Consideration

We may be required to pay future contingent consideration to Sopharma as part of the Share Purchase Agreement, which is contingent upon obtaining regulatory approval of cytisinicline by the FDA or the EMA. We determine the fair value of the contingent consideration using a probability based discounted cash flow approach whereby we forecast the timing of the cash flow of the related future payment based on cytisinicline's current clinical development phase and the remaining requirements for regulatory approval. We then discount the expected payment amount to calculate the present value and then apply a probability of success in obtaining regulatory approval as of the valuation date. We evaluate the underlying projection used in determining the fair value each period and make updates as necessary.

The significant assumptions we use to value the contingent consideration are the forecasted timing of the future payment, the risk-adjusted discount rate and the probability of success which are all considered significant unobservable inputs, and as such, the liability is classified as a Level 3 measurement. The risk-adjusted discount rate is adjusted for credit risk. An increase in the discount rate or decrease in the probability of success would result in a decrease in the fair value of the contingent consideration. Conversely, a decrease in the discount rate or increase in the probability of success would result in an increase in the fair value of the contingent consideration.

Government Grants

We account for government grants by recognizing the benefit of the grant as qualifying expenditures are incurred provided that there is reasonable assurance that we have complied with all conditions under the terms of the grant and that the amount requested for reimbursement will be received. The government grant reduces the research and development expenses to which it relates on our statement of profit and loss.

Research and Development Expenses

Research and development costs are expensed as incurred, net of related refundable investment tax credits, with the exception of non-refundable advance payments for goods or services to be used in future research and development, which are capitalized in accordance with ASC 730, “Research and Development” and included within Prepaid Expenses or Other Assets depending on when the assets will be utilized.

Clinical trial expenses are a component of research and development costs. These expenses include fees paid to contract research organizations and investigators and other service providers, which conduct certain product development activities on our behalf. We use an accrual basis of accounting, based upon estimates of the amount of service completed. In the event payments differ from the amount of service completed, prepaid expense or accrued liabilities amounts are adjusted on the balance sheet. These expenses are based on estimates of the work performed under service agreements, milestones achieved, patient enrollment and experience with similar contracts. We monitor each of these factors to the extent possible and adjust estimates accordingly.

Stock-Based Compensation

Under the fair value recognition provisions of the ASC 718, “Stock Compensation”, we use the modified prospective method with respect to options granted to employees and directors. The expense is amortized on a straight-line basis over the graded vesting period.

Restricted Stock Unit Awards

We grant restricted stock unit awards that generally vest and are expensed over a four-year period. We also granted restricted stock unit awards that vest in conjunction with certain performance conditions to certain executive officers and key employees. At each reporting date, we evaluate whether achievement of the performance conditions is probable. Compensation expense is recorded over the appropriate service period based upon our assessment of accomplishing each performance provision or the occurrence of other events that may have caused the awards to accelerate and vest.

Warrants

We account for warrants pursuant to the authoritative guidance on accounting for derivative financial instruments indexed to, and We account for warrants pursuant to the authoritative guidance on accounting for derivative financial instruments indexed to, and potentially settled in, a company’s own stock, on the understanding that in compliance with applicable securities laws, the warrants require the issuance of registered securities upon exercise and therefore do not sufficiently preclude an implied right to net cash settlement. We have warrants classified as equity and these are not reassessed for their fair value at the end of each reporting period. Warrants classified as equity are initially measured at their fair value and recognized as part of stockholders’ equity. Determining the appropriate fair-value model and calculating the fair value of registered warrants requires considerable judgment, including estimating stock price volatility and expected warrant life. The computation of expected volatility was based on the historical volatility of

comparable companies from a representative peer group selected based on industry and market capitalization. A small change in the estimates used may have a relatively large change in the estimated valuation. We use the Black-Scholes pricing model to value the warrants.

Recent Accounting Standards

In December 2023, the Financial Accounting Standards Board, or FASB, issued ASU 2023-09 "Income Taxes (Topic 740): Improvements to Income Tax Disclosures". This guidance is intended to enhance the transparency and decision usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the United States. and in foreign jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis, with the option to apply the standard retrospectively. Early adoption is permitted. We are evaluating this standard to determine if adoption will have a material impact on our consolidated financial statements.

Recent Adopted Accounting Policies

In November 2023, FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which is intended to provide enhanced segment disclosures. The standard will require disclosures about significant segment expenses and other segment items and identifying the Chief Operating Decision Maker and how they use the reported segment profitability measures to assess segment performance and allocate resources. These enhanced disclosures are required for all entities on an interim and annual basis, even if they have only a single reportable segment. The standard is effective for years beginning after December 15, 2023, and interim periods within annual periods beginning after December 15, 2024 and early adoption is permitted. The adoption of this standard did not have a significant impact on our financial position or results of operations.