

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this Annual Report. This Annual Report, including the following section, contains forward-looking statements. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see Item 1A "Risk Factors" in this Annual Report. See also "Special Note Regarding Forward-Looking Statements." We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Annual Report. We undertake no obligation to update forward-looking statements, which reflect events or circumstances occurring after the date of this Annual Report, except as required by law.

Our U.S. GAAP accounting policies are referred to in Note 2 of the Consolidated Financial Statements. All amounts are in United States dollars, unless otherwise indicated.

Overview

We are a late-stage clinical biopharmaceutical company developing novel product candidates to treat brain health disorders. Our mission is to be the global leader in the development and delivery of treatments for brain health disorders that unlock new opportunities to improve patient outcomes. We are developing a pipeline of innovative product candidates targeting neurotransmitter pathways that play key roles in brain health disorders. This specifically includes pharmaceutically optimized product candidates derived from the psychedelic and empathogen drug classes including MM120 and MM402, our lead product candidates.

Our lead product candidate, MM120, is a proprietary, pharmaceutically optimized form of lysergide D-tartrate that we are developing for the treatment of generalized anxiety disorder and major depressive disorder ("MDD"). In December 2023, we announced positive topline results from our Phase 2b clinical trial of MM120 for the treatment of GAD. The trial met its primary endpoint, with MM120 demonstrating statistically significant and clinically meaningful dose-dependent improvements on the Hamilton Anxiety Rating Scale ("HAM-A") compared to placebo at Week 4. In March 2024, we announced that the U.S. Food and Drug Administration ("FDA") granted breakthrough designation to our MM120 program for the treatment of GAD. We also announced in March 2024 that our Phase 2b clinical trial of MM120 in GAD met its key secondary endpoint, and 12-week topline data demonstrated clinically and statistically significant durability of activity observed through Week 12.

On June 20, 2024, we announced the completion of our End-of-Phase 2 meeting with the FDA, supporting the advancement of MM120 into pivotal trials for the treatment of adults with GAD. Our Phase 3 clinical program for MM120 orally disintegrating tablet ("ODT") is expected to consist of two clinical trials: the Voyage study (MM120-300) and the Panorama study (MM120-301). Both trials are comprised of two parts: Part A, which is a 12-week, randomized, double-blind, placebo-controlled, parallel-group trial assessing the efficacy and safety of MM120 ODT versus placebo; and Part B, which is a 40-week extension period during which participants will be eligible for open-label treatment with MM120 ODT, subject to certain conditions for treatment eligibility. Voyage is anticipated to enroll approximately 200 participants (randomized 1:1 to receive MM120 ODT 100 µg or placebo) and Panorama is anticipated to enroll approximately 250 participants (randomized 2:1:2 to receive MM120 ODT 100 µg, MM120 ODT 50 µg or placebo). We expect both trials will utilize an adaptive trial design with a blinded interim sample size re-estimation, allowing for an increase in sample size by up to 50% in each trial in the case of certain parameters. The primary endpoint for each trial is the change from baseline in HAM-A score at Week 12 between MM120 ODT 100 µg and placebo. On December 16, 2024, we announced the initiation of Voyage, with an anticipated topline readout (Part A results) in the first half of 2026. On January 30, 2025, we announced the initiation of Panorama, with an anticipated topline readout (Part A results) in the second half of 2026. Both trials are subject to ongoing regulatory review and discussions, which could result in changes to trial design, including of the Phase 3 clinical trials.

In addition to our Phase 3 clinical program for GAD, we are developing MM120 ODT for the treatment of MDD. In the first quarter of 2024, we held a pre-IND meeting with FDA to discuss the initiation of our Phase 3 clinical program for MM120 ODT in MDD and the trial design for our planned Emerge study (MM120-310), which like our pivotal trials in GAD, we anticipate will be comprised of two parts: Part A, which is a 12-week, randomized, double-blind, placebo-controlled, parallel group trial assessing the efficacy and safety of MM120 ODT versus placebo; and Part B, which is a 40-week extension period during which participants will be eligible for open-label treatment with MM120 ODT, subject to certain conditions for treatment eligibility. Emerge is anticipated to enroll at least 140 participants (randomized 1:1 to receive MM120 ODT 100 µg or placebo). The primary endpoint is the change from baseline in Montgomery Åsberg Depression Rating Scale ("MADRS") score at Week 6 between MM120 ODT 100 µg and placebo. We expect to initiate Emerge in the first half of 2025 with an anticipated topline readout (Part A results) in the second half of 2026. We expect to

conduct a second Phase 3 pivotal trial in MDD, with the trial design and timing to be informed by the progress from Emerge and additional regulatory discussions.

Our second lead product candidate, MM402, also referred to as R(-)-MDMA, is our proprietary form of the R-enantiomer of 3,4-methylenedioxymethamphetamine (“MDMA”), which we are developing for the treatment of autism spectrum disorder (“ASD”). MDMA is a synthetic molecule that is often referred to as an empathogen because it is reported to increase feelings of connectedness and compassion. Preclinical studies of R(-)-MDMA demonstrated its acute pro-social and empathogenic effects, while its diminished dopaminergic activity suggests that it has the potential to exhibit less stimulant activity, neurotoxicity, hyperthermia and abuse liability compared to racemic MDMA or the S(+)-enantiomer. In October 2024, we completed our first clinical trial of MM402, a single-ascending dose trial in adult healthy volunteers. The data from this Phase 1 clinical trial helped to characterize the tolerability, pharmacokinetics and pharmacodynamics of MM402. We expect to initiate further trials of MM402 for the treatment of ASD, with the exact timing and scope of such trials to be determined.

Beyond our clinical stage product candidates, we are exploring additional programs, including through external collaborations, which we seek to expand our drug development pipeline and broaden the potential applications of our lead product candidates. These research and development programs include non-clinical, pre-clinical and human clinical trials of current and new product candidates and research compounds with our collaborators.

Our business is premised on a growing body of research supporting the use of novel psychoactive compounds to treat a myriad of brain health disorders. For all product candidates, we intend to proceed through research and development, and with marketing of the product candidates that may ultimately be approved pursuant to the regulations of the FDA and the regulations in other jurisdictions. This entails, among other things, conducting clinical trials with research scientists, using internal and external clinical drug development teams, producing and supplying product candidates according to current Good Manufacturing Practices (“cGMP”), and conducting all trials and development in accordance with the regulations of the FDA, and other regulations in other jurisdictions.

We were incorporated under the laws of the Province of British Columbia in 2010. Our wholly-owned subsidiary, Mind Medicine, Inc. (“MindMed US”), was incorporated in Delaware in 2019. Prior to February 27, 2020, our operations were conducted through MindMed US.

Since inception, we have incurred losses while advancing the research and development of our products and processes. Our net losses were \$108.7 million for the year ended December 31, 2024, and \$95.7 million for the year ended December 31, 2023. As of December 31, 2024, we had an accumulated deficit of \$398.9 million and cash and cash equivalents of \$273.7 million.

Components of Operating Results

Operating Expenses

Research and Development

Research and development expenses account for a significant portion of our operating expenses. Research and development expenses consist primarily of direct and indirect costs incurred for the development of our product candidates.

External expenses include:

- payments to third parties in connection with the clinical development of our product candidates, including licensing fees and fees to contract research organizations and consultants;
- the cost of manufacturing products for use in our preclinical studies and clinical trials, including payments to contract manufacturing organizations and consultants;
- payments to third parties in connection with the preclinical development of our product candidates, including outsourced professional scientific development services, consulting research fees and sponsored research arrangements with third parties; and
- allocated operational expenses, which include direct or allocated expenses for information technologies and human resources.

We may also incur in-process research and development expenses as we acquire or in-license assets from other parties. Technology acquisitions are expensed or capitalized based upon the asset achieving technological feasibility in accordance with management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use. Acquired in-process research and development costs that have no alternative future use are immediately expensed.

Internal expenses include employee-related costs such as salaries, related benefits and non-cash stock-based compensation expense for employees engaged in research and development functions.

We expect our research and development expenses to increase for the foreseeable future as we continue the clinical development of our product candidates and other preclinical programs in GAD and MDD and other potential or future indications, including initiating additional and larger clinical trials.

We expense research and development costs in the periods in which they are incurred. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. We track external costs by program, clinical or preclinical. We do not track internal costs by program because these costs are deployed across multiple programs and, as such, are not separately classified.

General and Administrative

General and administrative expenses consist primarily of compensation costs, including stock-based compensation, for executive management and administrative employees, including finance and accounting, legal, human resources and other administrative functions, professional services fees, advisory and professional service fees in connection with financing transactions, insurance expenses, costs to support our commercialization efforts and allocated expenses.

We expect our general and administrative expenses to increase for the foreseeable future as we continue to advance our research and development programs, grow our business and, if any of our product candidates receive marketing approval, commence commercialization activities.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

The following tables summarize our results of operations for the periods presented (in thousands):

	For the Year Ended December 31, 2024	For the Year Ended December 31, 2023	\$ Change	% Change
Operating expenses:				
Research and development	\$ 65,297	\$ 52,124	\$ 13,173	25%
General and administrative	38,619	41,742	(3,123)	-7%
Total operating expenses	103,916	93,866	10,050	11%
Loss from operations	(103,916)	(93,866)	(10,050)	11%
Other income/(expense):				
Interest income	11,558	5,584	5,974	107%
Interest expense	(2,283)	(920)	(1,363)	148%
Foreign exchange (loss)/gain, net	(638)	157	(795)	*
Change in fair value of 2022 USD Financing Warrants	(15,941)	(6,636)	(9,305)	140%
Gain on extinguishment of contribution payable	2,541	—	2,541	100%
Other expense	—	(51)	51	-100%
Total other expense, net	(4,763)	(1,866)	(2,897)	155%
Net loss	(108,679)	(95,732)	(12,947)	14%
Other comprehensive loss:				
Gain/(loss) on foreign currency translation	476	(284)	760	-268%
Comprehensive loss	<u>\$ (108,203)</u>	<u>\$ (96,016)</u>	<u>\$ (12,187)</u>	13%

* Represents a change greater than 300%

Operating Expenses

Research and Development (in thousands):

	For the Year Ended December 31, 2024	For the Year Ended December 31, 2023	\$ Change	% Change
External Costs				
MM120 program	\$ 34,964	\$ 23,516	\$ 11,448	49%
MM402 program	3,975	1,904	2,071	109%
Preclinical and other programs	2,845	5,858	(3,013)	-51%
Total external costs	41,784	31,278	10,506	34%
Internal Costs	23,513	20,846	2,667	13%
Total research and development expenses	<u>\$ 65,297</u>	<u>\$ 52,124</u>	<u>\$ 13,173</u>	25%

Research and development expenses increased by \$13.2 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 \$11.4 million in expenses related to our MM120 program supporting the advancement into pivotal trials for the treatment of adults with GAD. The MM120 program completed a phase 2b trial in the first half of 2024, and has incurred increased expenses in relation to the initiation of phase 3 trials. Additionally, there was an increase of \$2.1 million in expenses related to our MM402 program driven by progress in phase 1 studies, and an increase of \$2.7 million in internal personnel costs as a result of increasing research and development capacities, partially offset by a decrease of \$3.0 million in expenses related to preclinical activities.

General and Administrative

General and administrative expenses decreased by \$3.1 million for the year ended December 31, 2024 compared to the year ended December 31, 2023. The decrease was primarily attributable to decreased professional services fees and expenses during the year ended December 31, 2024, partially offset by increased stock-based compensation expense and pre-commercialization activities during the year ended December 31, 2024.

Other Income (Expense)

Interest Income

Interest income increased by \$6.0 million for the year ended December 31, 2024 compared to the year ended December 31, 2023. This was primarily due to interest earned on our cash and cash equivalents as a result of increased balances held in cash and cash equivalents during the year ended December 31, 2024.

Interest Expense

Interest expense increased by \$1.4 million for the year ended December 31, 2024 compared to the year ended December 31, 2023. This was primarily due to interest expense related to our credit facility entered into on August 11, 2023.

Foreign Exchange (Loss)/Gain, Net

Foreign exchange loss increased by \$0.8 million for the year ended December 31, 2024 compared to the year ended December 31, 2023, the increase was primarily due to unfavorable changes in foreign exchange rates during the year ended December 31, 2024.

Change in fair value of 2022 USD Financing Warrants

Revaluation loss on the 2022 USD Financing Warrants liability was \$15.9 million and \$6.6 million for the years ended December 31, 2024 and 2023, respectively. Change in fair value of 2022 USD Financing Warrants consists of revaluation gains and losses attributed to the change in the fair value of our 2022 USD Financing Warrants that were issued as part of our public equity offering which closed on September 30, 2022.

Gain on extinguishment of contribution payable

Gain on extinguishment of contribution payable was \$2.5 million for the year ended December 31, 2024. In June 2024, we made a lump sum payment of \$0.3 million in full satisfaction of our remaining obligations of the contribution payable liability. As a result, both parties were subsequently released from any further commitments from the agreement. The difference between the fair value of the lump sum payment of \$0.3 million, and the carrying value of the contribution payable prior to the settlement of \$2.8 million, resulted in the gain on extinguishment of \$2.5 million.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have financed our operations primarily from the issuance of equity and our Loan Agreement (as defined below). Our primary capital needs are for funds to support our scientific research and development activities including staffing, manufacturing, preclinical studies, clinical trials, administrative costs and for working capital.

We have experienced operating losses and cash outflows from operations since inception and will require ongoing financing in order to continue our research and development activities. We have not earned any revenue or reached successful commercialization of our product candidates. Our future operations are dependent upon our ability to finance our cash requirements, which will allow us to continue our research and development activities and the commercialization of our product candidates, if approved. There can be no assurance that we will be successful in continuing to finance our operations.

Our cash and cash equivalents and our working capital at December 31, 2024 was \$273.7 million and \$242.8 million, respectively. We believe that our cash and cash equivalents as of December 31, 2024 will be sufficient to fund our operations into 2027. Based on our current operating plan and anticipated R&D milestones, we expect our cash runway to extend at least 12 months beyond the first Phase 3 topline data readout for MM120 ODT in GAD.

On August 11, 2023 (the "Closing Date"), we and certain of our subsidiaries party thereto, as co-borrowers (together with us, the "Borrowers") entered into a Loan and Security Agreement (the "Loan Agreement") with K2 HealthVentures LLC ("K2HV"), as administrative agent and Canadian collateral agent for lenders thereunder (K2HV, and any other lender from time to time, the "Lenders"), and Ankura Trust Company, LLC, as collateral trustee for the Lenders. The Loan Agreement provides for up to an aggregate principal amount of \$50.0 million in term loans ("Term Loans") consisting of a first tranche term loan of \$15.0 million funded on the Closing Date, subsequent tranches of term loans totaling \$20.0 million to be funded upon the achievement of certain time-based, clinical and regulatory milestones, and an additional tranche term loan of up to \$15.0 million upon our request, subject to review by the Lenders of certain information from us and discretionary approval by the Lenders. The second milestone-based tranche of \$10.0 million was funded in the second quarter of 2024.

On March 7, 2024, we entered into an underwriting agreement with Leerink Partners LLC and Cantor Fitzgerald & Co., as representatives of the underwriters named therein, in connection with the issuance and sale by us in an underwritten offering (the "March Offering") of 16,666,667 of our common shares at an offering price of \$6.00 per share, less underwriting discounts and commissions.

The net proceeds from the March Offering were approximately \$93.5 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

Also on March 7, 2024, we entered into a securities purchase agreement with certain investors, pursuant to which the Investors agreed to purchase, and we agreed to sell 12,500,000 of our common shares at a price of \$6.00 per share, in a private placement transaction (the "Private Placement").

The net proceeds from the Private Placement were approximately \$70.1 million, after deducting fees and expenses payable by us.

The March Offering and the Private Placement both closed on March 11, 2024.

On June 28, 2024, we entered into the Sales Agreement with the Agent to create an at-the-market equity program under which we from time to time may offer and sell the ATM Shares (as defined below), through or to the Agent. We filed a prospectus supplement on June 28, 2024 allowing for up to \$150.0 million of Common Shares (the "ATM Shares") to be sold under the Sales Agreement.

Subject to the terms and conditions of the Sales Agreement, the Agent will use its commercially reasonable efforts to sell the ATM Shares from time to time, based upon our instructions. The Agent will be entitled to a commission of up to 3.0% of the aggregate gross proceeds from each sale of the ATM Shares effectuated through or to the Agent.

We have no obligation to sell any of the ATM Shares and may at any time suspend offers under the Sales Agreement or terminate the Sales Agreement.

On August 9, 2024, we entered into an underwriting agreement with Leerink Partners LLC and Evercore Group L.L.C., as representatives of the several underwriters named therein, in connection with the an offering of (i) our common shares, and (ii) to certain investors, pre-funded warrants to purchase our common shares. The offering price for the common shares was \$7.00 per share, less underwriting discounts and commissions (the “August Offering”). The offering price for the pre-funded warrants was \$6.999 per pre-funded warrant, which represents the per share public offering price for the common shares less a \$0.001 per share exercise price for each such pre-funded warrant.

The net proceeds from the August Offering were approximately \$70.0 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. The August Offering closed on August 12, 2024.

Future Funding Requirements

To date, we have not generated any revenue. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates, and we do not know when, or if at all, that will occur. We will continue to require substantial additional capital to develop our product candidates and fund operations for the foreseeable future. Moreover, we expect our expenses to increase in connection with our ongoing activities, particularly as we continue the development of and seek regulatory approvals for our product candidates. Further, we are subject to all the risks incident in the development of new pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. Our expenses will increase if, and as, we:

- advance our product candidates through preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- seek to discover and develop additional product candidates;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize on our own or jointly; and
- expand our operational, financial and management systems and increase personnel, including personnel to support our development, manufacturing and commercialization efforts and our operations as a public company.

We believe that our cash and cash equivalents as of December 31, 2024 will be sufficient to fund our operations into 2027. Based on our current operating plan and anticipated R&D milestones, we expect our cash runway to extend at least 12 months beyond the first Phase 3 topline data readout for MM120 ODT in GAD. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. In order to complete the development of our product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we will require substantial additional funding. Until we can generate a sufficient amount of revenue from the commercialization of our product candidates, we may seek to raise any necessary additional capital through the sale of equity, debt financings or other capital sources, which could include income from collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties or from grants. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common shareholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, including restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our common shares, make certain investments or engage in merger, consolidation, licensing or asset sale transactions. If we raise funds through collaborations, strategic partnerships and other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We may be unable to raise additional funds or enter into such agreements or arrangements on favorable terms, or at all. If we are unable to raise additional funds when needed, we may be required to delay, reduce or eliminate our

product development or future commercialization efforts. We have based our projections of operating capital requirements on our current operating plan, which is based on several assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount and timing of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including building a commercial organization, product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and sufficient inventory to support commercial launch;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the cost and timing of hiring new employees to support our continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the ability to establish and maintain collaborations on favorable terms, if at all;
- the extent to which we acquire or in-license other product candidates and technologies; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our product candidates.

Cash Flows

	For the Year Ended December 31, 2024	For the Year Ended December 31, 2023
Net cash used in operating activities	\$ (79,129)	\$ (64,365)
Net cash provided by financing activities	253,196	21,848
Foreign exchange impact on cash	(30)	79
Net increase/(decrease) in cash and cash equivalents	<u>\$ 174,037</u>	<u>\$ (42,438)</u>

Cash flows used in operating activities

Cash used in operating activities for the year ended December 31, 2024 was \$79.1 million, which consisted of a net loss of \$108.7 million and a net change of \$3.3 million in our net operating assets and liabilities, partially offset by \$32.9 million in non-cash charges. The non-cash charges primarily consisted of share-based compensation of \$16.9 million, a change in fair value on the 2022 USD Financing Warrants liability of \$15.9 million, DDSU expense of \$0.8 million, amortization of debt issuance costs of \$0.7 million, unrealized foreign exchange of \$0.5 million, and amortization of intangible assets of \$0.5 million, partially offset by a gain on extinguishment of the contribution payable of \$2.5 million.

Cash used in operating activities for the year ended December 31, 2023 was \$64.4 million, which consisted of a net loss of \$95.7 million, partially offset by \$25.1 million in non-cash charges and a net change of \$6.2 million in our net operating assets and liabilities. The non-cash charges primarily consisted of a change in fair value on the 2022 USD Financing Warrants liability of \$6.6 million, share-based compensation of \$15.5 million, and amortization of intangible assets of \$3.2 million.

Cash flows from financing activities

Cash provided by financing activities for the year ended December 31, 2024 was \$253.2 million, which consisted of \$175.0 million of gross proceeds from the March Offering and Private Placement, \$75.0 million in proceeds from the August Offering, \$10.0 million proceeds from our credit facility, \$8.3 million of proceeds from the exercise of the 2022 USD Financing Warrants, \$1.0 million net proceeds from the 2022 ATM, net of issuance costs, and \$0.7 million in proceeds from the exercise of options, partially offset by \$11.1 million of issuance costs related to the March Offering and Private Placement, \$5.0 million of issuance costs related to the August Offering, \$0.5 million payment of deferred financing fees related to the 2024 ATM, \$0.1 million of our credit facility issuance costs and \$0.1 million of withholding taxes paid on vested RSUs.

Cash provided by financing activities for the year ended December 31, 2023 was \$21.8 million, which consisted of proceeds of \$15.0 million from our credit facility partially offset by \$0.8 million payment of our credit facility issuance costs, \$7.5 million of net proceeds from the 2022 ATM, net of issuance costs, and \$0.1 million of proceeds from the exercise of the 2022 USD Financing Warrants.

Contractual Obligations and Contingencies

We enter into research, development and license agreements in the ordinary course of business where we receive research services and rights to proprietary technologies. Milestone and royalty payments that may become due under various agreements are dependent on, among other factors, clinical trials, regulatory approvals and ultimately the successful development of a new drug, the outcome and timing of which is uncertain.

We periodically enter into research and license agreements with third parties that include indemnification provisions customary in the industry. These indemnities generally require us to compensate the other party for certain damages and costs incurred as a result of claims arising from research and development activities undertaken by us or on our behalf. In some cases, the maximum potential amount of future payments that could be required under these indemnification provisions could be unlimited. These indemnification provisions generally survive termination of the underlying agreement. The nature of the indemnification obligations prevents us from making a reasonable estimate of the maximum potential amount we could be required to pay. Historically, we have not made any indemnification payments under such agreements and no amount has been accrued in our financial statements with respect to these indemnification obligations.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Business Combinations

At the time of acquisition, we determine whether what is acquired meets the definition of a business, in which case if it does, the transaction is considered a business combination, and otherwise it is recorded as an asset acquisition.

For an asset acquisition, the net identifiable assets acquired and liabilities assumed are measured at the fair value of the consideration paid, based on their relative fair values at the acquisition date. Acquisition related costs are included in the consideration paid and capitalized. No goodwill is recorded and no deferred tax asset or liability arising from the assets acquired or liabilities assumed is recognized upon the acquisition of the assets.

Business combinations are accounted for using the acquisition method. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date. The excess of the fair value of the consideration transferred, over the fair value of our share of the identifiable net assets acquired is recorded as goodwill.

Goodwill is initially measured at cost, being the excess of the aggregate of the consideration transferred and the fair value of the net identifiable assets acquired and liabilities assumed.

Acquisition costs are expensed as incurred, unless they qualify to be treated as debt issue costs, or as cost of issuing equity securities. The measurement period is the period from the date of acquisition to the date we obtain complete information about facts and circumstances that existed as of the acquisition date – and is subject to a maximum of one year.

Fair Value Measurements

Certain of our assets and liabilities are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 – Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by us in determining fair value is greatest for instruments categorized in Level 3. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

Cash and cash equivalents, prepaid and other current assets, accounts payable, and accrued liabilities are all short-term in nature and, as such, their carrying values approximate fair values.

The 2022 USD Financing Warrants (as defined in Note 8 in the notes to our annual financial statements) are liability classified due to not meeting the criteria for equity treatment under the guidance in ASC 815-40. Accordingly, the 2022 USD Financing Warrants were recognized at fair value upon issuance and are remeasured to fair value at the end of each reporting period. Any change in fair value is recognized in general and administrative expense on the consolidated statements of operations. Issuance costs related to warrants were expensed within general and administrative expense on the consolidated statements of operations.

Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate research and development costs incurred during the period, which impacts the amount of accrued expenses and prepaid balances related to such costs as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel and service providers to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced. To date, our estimated accruals have not differed materially from actual costs incurred.

Research and development costs are expensed in the periods in which they are incurred. External costs consist primarily of payments to outside consultants, third-party CROs, CDMOs, clinical trial sites and central laboratories in connection with our discovery and preclinical activities, process development, manufacturing and clinical development activities. External costs also include laboratory supplies as well as allocated facilities, depreciation and other expenses. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service

that has been performed at each reporting date. We allocate external costs by program, clinical or preclinical. Internal costs consist primarily of employee-related costs including salaries, related benefits and stock-based compensation expense for employees engaged in research and development functions. We do not allocate internal costs by program because these costs are deployed across multiple programs and, as such, are not separately classified.

Share-Based Payments

When equity-settled share payments are awarded to management, employees and consultants, the fair value of the equity instruments at the date of grant is charged to the consolidated statements of operations and comprehensive loss over the vesting period. When the terms and conditions are modified before they vest, any increase in the fair value of the shares, measured immediately before and after the modification, is also charged to the consolidated statements of operations and comprehensive loss.

We recognize stock-based compensation expense for stock options on a straight-line basis over the requisite service period and account for forfeitures as they occur. Our stock-based compensation costs are based upon the grant date fair value of options estimated using the Black-Scholes option pricing model.

This model utilizes inputs which are highly subjective assumptions and generally require significant judgment. These assumptions include:

Fair Value of common shares—The fair value of our common shares is determined based upon the closing price of our common shares one day prior to grant.

Risk-free interest rate—The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of our stock options.

Expected volatility—Due to our limited operating history and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.

Expected term—The expected term represents the period that the stock-based awards are expected to be outstanding. We have opted to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option, which is generally between 5 to 10 years.

Dividend Yield—We have never paid dividends on our common shares and have no plans to pay dividends on our common shares. Therefore, we used an expected dividend yield of zero.

Recent Accounting Pronouncements

See Note 2—Summary of Significant Accounting Policies to our consolidated financial statements included elsewhere in this Annual Report for information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent we have made one yet, of their potential impact on our financial condition of results of operations.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies.

We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

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

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide the information required by this item.