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management to make judgments, assumptions and estimates that affect the amounts reported in its unaudited condensed consolidated financial statements and the accompanying notes. The accounting policies that reflect the Company's more significant estimates and judgments and that the Company believes are the most critical to aid in fully understanding and evaluating its reported financial results are the valuation of stock options, restricted stock units (RSUs), freestanding and hybrid instruments designated at fair value option (FVO), warrant liabilities, acquired in-process research and development (IPR&D), and useful lives assigned to long-lived assets; impairment assessment of non-financial assets; valuation adjustments for excess and obsolete inventory; allowance for doubtful accounts; deferred taxes and valuation allowances on deferred tax assets; evaluation and measurement of contingencies; and recognition of revenue, including estimates for product returns. Those estimates could change, and as a result, actual results could differ materially from those estimates. **11 Table of Contents A Cash**The Company's cash on deposit may exceed United States federally insured limits at certain times during the year. The Company maintains cash accounts with certain major financial institutions in the United States. The Company does not have cash equivalents as of September 30, 2024 and December 31, 2023. **Accounts Receivable**, netAccounts receivable is recorded net of allowances for discounts for prompt payment and credit losses. Upon adoption of ASU No. 2013-13 (ASC 326), the Company began utilizing a loss rate approach under the Current Expected Credit Losses (CECL) model to determine its lifetime expected credit losses on receivables from customers. This method calculates an estimate of credit losses based on historical experience, credit quality, age of the accounts receivable balances, and current and forecasted economic and business conditions that may affect a customer's ability to pay. In determining the loss rates, the Company evaluates information related to its historical losses, adjusted for existing conditions, and further adjusted for the period of time that can reasonably be forecasted. The facts and circumstances as of the balance sheet date are used to adjust the estimate for periods beyond those that can reasonably be forecasted. The past due status of accounts receivable is determined based on the contractual due dates for payments. Receivable is deemed past due when payment has not been received 30 days after the contractual due date. The credit loss allowance was immaterial as of September 30, 2024 and December 31, 2023. The corresponding expense for the credit loss allowance is reflected in general and administrative expenses. **Current Expected Credit Losses**The Company recognizes an allowance for credit losses for financial assets carried at amortized cost to present the net amount expected to be collected as of the balance sheet date. Such allowance is based on credit losses that are expected to arise over the contractual term of the asset, which includes consideration of historical credit loss information adjusted for current conditions and reasonable and supportable forecasts. Changes in the allowance for credit losses are recorded as provision (or reversal) of credit loss expense. Assets are written off when the Company determines that such are deemed uncollectible. Write-offs are recognized as a deduction from the allowance for credit losses. Expected recoveries of amounts previously written off, not to exceed the aggregate of the amount previously written off, are included in determining the necessary allowance at the balance sheet date. **Concentrations**Cash is the financial instrument that potentially subjects the Company to a concentration of credit risk as cash is deposited with a bank, and cash balances generally exceed Federal Deposit Insurance Corporation (FDIC) insurance limits. For the three and nine months ended September 30, 2024 and 2023, substantially all of the Company's revenue was derived from the sale of Mytesi. In looking at sales by the Company to specialty pharmacies whose net revenue percentage of total net revenue was equal to or greater than 10% for fiscal years 2024 and 2023, the Company earned Mytesi revenue primarily from two specialty pharmacies located in the United States. Revenue earned from each major customer as a percentage of total revenue is as follows: **Three Months Ended** **Nine Months Ended** **September 30, 2024** **Customer 1** 35 % **Customer 2** 27 % **Customer 3** 33 % **Customer 4** 27 % **Customer 5** 55 % **Customer 6** 51 % **Customer 7** 53 % **Customer 8** The Company is subject to credit risk from its accounts receivable related to its sales. The Company generally does not perform evaluations of customers' financial condition and generally does not require collateral. Accounts receivable balance of the significant customers as a percentage of total accounts receivable is as follows: **September 30, 2024** **Customer 1** 43 % **Customer 2** 42 % **Customer 3** 57 % **Customer 4** 12 % **Table of Contents** **The Company is subject to concentration risk from the single third-party contract manufacturer, Glenmark.** **Other Risks and Uncertainties**The Company's future operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations including, but not limited to, war, rapid technological change, obtaining second source suppliers and manufacturers, regulatory approval from the US Food and Drug Administration (FDA) or other regulatory authorities, the results of clinical trials and the achievement of milestones, market acceptance of the Company's product candidates, competition from other products and larger companies, protection of proprietary technology, strategic relationships and dependence on key individuals. **Other Global Events**Macroeconomic conditions worldwide are subject to constant change, influenced by several factors, including persistently high inflation, structural weaknesses in the labor market, low productivity growth, adverse weather conditions, and possible political unrest in certain regions. Despite these global economic challenges, no significant changes have occurred in the Company's operations. **Fair Value**The Company's financial instruments include accounts receivable, net, other receivable, accounts payable, accrued liabilities, operating lease liability, and debt. The recorded carrying amount of accounts receivable, other receivable, accounts payable, and accrued liabilities reflect their fair value due to their short-term nature. Other financial liabilities are initially recorded at fair value, and subsequently measured at fair value or amortized cost using the effective interest method. See Note 3 for the fair value measurements. **Fair Value Option**ASC 825-10, **Financial Instruments** (ASC 825-10), provides an FVO election that allows companies an irrevocable election to use fair value as the initial and subsequent accounting measurement attribute for certain financial assets and liabilities. ASC 825-10 permits entities to elect to measure eligible financial assets and liabilities at fair value on an ongoing basis. Unrealized gains and losses on items for which the FVO has been elected are reported in earnings. The decision to elect the FVO is determined on an instrument-by-instrument basis, must be applied to an entire instrument, and is irrevocable once elected. Assets and liabilities measured at fair value pursuant to ASC 825-10 are required to be reported separately from those instruments measured using another accounting method. In accordance with the options presented in ASC 825-10, the Company elected to present the aggregate of fair value and non-fair-value amounts in the same line item in the condensed consolidated balance sheets and parenthetically disclose the amount measured at fair value in the aggregate amount. The fair values of the Company's financial instruments reflect the amounts that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The fair value estimates presented in these financial statements are based on information available to the Company as of September 30, 2024 and December 31, 2023. **Inventory**Inventory is stated at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method. Cost is initially recorded at the invoiced amount of services or API provided by third-party processors, Probos and Corfasac, including the sum of qualified expenditures and charges for bringing the inventory to its existing condition and location. Inventory is categorized into raw materials, work-in-process, and finished goods. Raw materials consist of Crude Plant Latex (CPL), recognized as inventory upon harvest and valued at cost, including acquisition and harvest expenditures. Work-in-process inventory is recognized only when CPL has been transformed into API and is in transit to Patho, with costs comprising direct materials, labor, and applicable overheads. Finished goods represent completed Crofemeler tablets ready for sale, valued at cost, which includes direct materials, labor, and manufacturing overhead allocated during production. The Company calculates inventory valuation adjustments when conditions indicate that net realizable value is less than cost due to physical deterioration, usage, obsolescence, reductions in estimated future demand, or reductions in selling price. Inventory write-downs are measured as the difference between the cost of inventory and net realizable value. The Company does not have an allowance for inventory obsolescence as of September 30, 2024 and December 31, 2023. Inventory costs are removed from inventory and recorded in the cost of goods sold upon delivery of the tablets to customers. **Prelaunch Inventory**The Company's policy is to capitalize costs for prelaunch inventories within the drug development phase, which is evidence that the product's reasonably likely critical attributes for success are present and feasible, and the key causes of failures are absent based on management's assumptions. The costs that can be capitalized for pre-launch inventory are recorded as Prepaid expenses and other current assets. **Property and Equipment**Land is stated at cost, reflecting the fair value of the property at July 31, 2017, the date of the Napo merger. Equipment is stated at cost, net of accumulated depreciation. Equipment begins to be depreciated when it is placed into service. Depreciation is calculated using the straight-line method over estimated useful lives ranging between three to ten years. Expenditures for repairs and maintenance of assets are charged to expenses as incurred. Costs of major additions and betterments are capitalized and depreciated on a straight-line basis over their estimated useful lives. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts, and any resulting gain or loss is included in the unaudited condensed consolidated statements of operations. **Software Developed for Internal Use**The Company capitalizes the costs of developing software for internal use. These costs include both purchased software and internally developed software. Costs of developing software are expensed until technological feasibility has been established. Thereafter, all costs are capitalized and are carried at the lower of unamortized cost or net realizable value. Internally developed and purchased software costs are generally amortized over five years. The Company evaluated the carrying value of its internal use software costs as at December 31, 2023, in accordance with ASC 360-10, **Impairment of Long-lived Assets to be Held or Used**. Based on the evaluation, the Company determined that the internal use software costs' carrying value as of December 31, 2023, were no longer recoverable and recorded a corresponding impairment loss. The impairment loss was calculated as the difference between the registry's carrying value and its estimated fair value on December 31, 2023. The fair value was determined using a discounted cash flow (DCF) model, a Level 3 evaluation technique under ASC 820, **Fair Value Measurements** (ASC 820). The DCF model utilized entity-specific assumptions regarding future sales volume, pricing, and costs. These assumptions considered factors such as the continuity of existing customer relationships, potential shifts in economic conditions, and other relevant market influences. The net cash flows generated by the model were then discounted to present value using a rate reflective of the time value of money and the inherent use associated with the expected cash flows. The discount rate was based on the comparable debt instrument deemed appropriate by management. Given the changing market conditions, there is a reasonable possibility that the estimates used to determine the registry's fair value may require adjustments in the near future. Any such changes in assumptions could result in further impairment charges. The Company recognized an expense for the year ended December 31, 2023, and a corresponding reduction in the carrying value of the internal use software-registry as a result of the impairment. **Long-lived Assets**The Company regularly reviews the carrying value and estimated lives of all of its long-lived assets, including property and equipment and definite-lived intangible assets, to determine whether indicators of impairment exist that warrant adjustments to carrying values or estimated useful lives. The determinants used for this evaluation include management's estimate of the asset's ability to generate positive income from operations and positive cash flow in future periods, as well as the strategic significance of the assets to the Company's business objectives. If the Company determines that events or changes in circumstances indicate that the carrying amount of the asset group may not be recoverable, the Company evaluates the realizability of its long-lived assets (asset group) based on a comparison of projected undiscounted cash flows from use and eventual disposition with the carrying value of the related asset. Any write-downs (measured based on the difference between the fair value and the asset's carrying value) are treated as permanent reductions in the carrying amount of the assets (asset group). None of the Company's long-lived assets were deemed impaired as of September 30, 2024. **Indefinite-lived Intangible Assets**Acquired IPR&D are intangible assets acquired in the July 2017 Napo merger. Under ASC 80, **Business Combination**, IPR&D are initially recognized at fair value and classified as indefinite-lived assets until the successful completion or abandonment of the associated research and development efforts. During the development period, these assets will not be amortized as charges to earnings; instead, these assets will be tested for impairment on an annual basis or more frequently if impairment indicators are identified. An impairment loss is measured based on the excess of the carrying amount over the asset's fair value. The Company recorded no impairment for the three and nine months ended September 30, 2024 and 2023. **Leases**The Company accounts for its leases in accordance with ASC 842, **Leases** (ASC 842). At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. Because the interest rate implicit in lease contracts is typically not readily determinable, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. The Company elected to include both the lease and non-lease components as a single component and account for it as a lease. **Lease Modification**ASC 842 defines lease modification as a change to the terms and conditions of a contract that results in a change in the scope of or the consideration for a lease. A lease modification can result in either a separate new contract that is accounted for separately from the original contract or a single modified contract. The Company shall account for a modification to a contract as a separate contract when the modification grants the lessee an additional right of use not included in the original lease and the lease payments increase commensurate with the standalone price for the additional right of use, adjusted for the circumstances of the particular contract. When the Company concludes that a lease modification should be accounted for as a new contract that is separate and apart from the original lease, the new contract should be evaluated for whether it is a lease or contains an embedded lease. If the new contract is a lease or contains an embedded lease, the new lease should be accounted for as any other new lease. The new lease is recorded on the commencement date of the new lease, which is the date the lessee has access to the leased asset. If a lease modification is not accounted for as a separate contract, the Company should reassess whether the contract contains a lease. If the modified contract is a lease or contains an embedded lease, a lessee should reallocate contract consideration, reassess the lease classification, remeasure the lease liability, and adjust the right-of-use asset. **Research and Development Expense**Research and development expense consists of expenses incurred in performing research and development activities, including related salaries, clinical trials, and related drug and non-drug product costs, contract services, and other outside service expenses. Research and development expenses are charged to operating expenses during the period incurred. **Clinical Trial Accruals**Clinical trial costs are a component of research and development expenses. The Company accrues and expenses for clinical trial activities performed by third parties based upon actual work completed in accordance with agreements established with clinical research organizations and clinical sites. The Company determines the costs to be recorded based upon validation with the external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. **Revenue Recognition**The Company recognizes revenue in accordance with ASC 606, **Revenue from Contracts with Customers** (ASC 606). The Company's policy typically permits returns if the product is damaged, defective, or otherwise cannot be used when received by the customer if the product has expired. Returns are accepted for products that will expire within three months or that have expired up to one year after their expiration dates. Estimates for expected returns of expired products are based primarily on an ongoing analysis of our historical return patterns. **Table of Contents** The Company recognizes revenue in accordance with the core principle of ASC 606 or when there is a transfer of control of promised goods or services to customers in an amount that reflects the consideration that the Company expects to be entitled to in exchange for those goods or services. The Company recognizes the incremental costs of obtaining a contract as an expense when incurred if the amortization period of the asset that the Company otherwise would have recognized is one year or less. The Company does not adjust the amount of consideration for the effects of a significant financing component if, at contract inception, the expected period between the transfer of promised goods or services and customer payment is one year or less. The Company has elected to treat shipping and handling activities as fulfillment costs. Additionally, the Company elected to record revenue net of sales and other similar taxes. **Contracts - Distributor**The Company's Canalevia-CA1 and Neonorm products are primarily sold to distributor, who then sell the products to the end customers. Since 2021, the Company has entered into one distribution agreements with established distributor to distribute the Company's animal health products in the United States. The distribution agreement and the related purchase orders together meet the contract existence criteria under ASC 606. The Company sells directly to its customers without the use of an agent. **Performance obligations**For animal health products sold by the Company, the single performance obligation identified above is the Company's promise to transfer the Company's animal health products to distributors based on specified payment and shipping terms in the arrangement. Product warranties are assurance-type warranties that do not represent a performance obligation. For the Company's human health product, Mytesi, the single performance obligation identified above is the Company's promise to transfer Mytesi to specialty pharmacies based on specified payment and shipping terms as outlined in the Exclusive Distribution Agreement entered into by the Company and Cardinal Health as of January 16, 2019. **Transaction price**For contracts with Cardinal Health and other distributors, the transaction price is the amount of consideration that which the Company expects to collect in exchange for transferring the promised goods or services. The transaction price of Mytesi is the Wholesaler Acquisition Cost (WAC), and the transaction price of Canalevia-CA1 and Neonorm is the manufacturer's list price, net of discounts, returns, and price adjustments. Allocate transaction priceFor contracts with distributor, the entire transaction price is allocated to the single performance obligation contained in each contract. **Revenue recognition**For contracts with Cardinal Health, a single performance obligation is satisfied

at a point in time upon each contract's free on board (â€œFOBâ€) terms when control, including title and all risks, has transferred to the customer. Disaggregation of Product Revenue Human Sales of Mytesi are recognized as revenue at a point in time when the products are delivered to the specialty pharmacies. Net revenues from the sale of Mytesi were \$3.0 million and \$2.8 million for the three months ended September 30, 2024 and 2023, respectively. Net revenues from the sale of Mytesi were \$8.0 million and \$7.3 million for the nine months ended September 30, 2024 and 2023, respectively. A 16 Table of Contents A Animal The Company recognized Canalevia-CA1 products revenues of \$49,000 and \$24,000 for the three months ended September 30, 2024 and 2023, respectively, and Neornom revenues of \$4,000 and \$7,000 for the three months ended September 30, 2024 and 2023, respectively. The Company recognized Canalevia-CA1 products revenues of \$115,000 and \$91,000 for the nine months ended September 30, 2024 and 2023, respectively. Revenues are recognized at a point in time upon shipment when title and control are transferred to the buyer. Sales of Canalevia-CA1, Neornom Calf, and Foal to distributors are made under agreements that may provide distributor price adjustments and rights of return under certain circumstances. Contracts â€œ Specialty Pharmacies Effective October 1, 2020, the Company engaged a private company as an authorized specialty pharmacy provider of the Companyâ€™s Mytesi product. Under the Specialty Product Distribution Agreement, the Company shall supply the products directly to the private companyâ€™s specialty pharmacies in such amounts as may be ordered. There is no minimum purchase or inventory requirement. The specialty pharmacies were authorized distributors of record for all National Drug Codes of Mytesi. Effective April 20, 2021, the Company engaged another private company as an authorized specialty pharmacy provider of Mytesi. Under the Specialty Pharmacy Distribution and Services Agreement, the private company shall sell and dispense Mytesi directly ordered from the Company at the agreed price to patients within the territories identified in the agreement. The Company has entered into agreements with a total of five different specialty pharmacy chains that are authorized to provide Mytesi to patients. Performance obligations The single performance obligation is the Companyâ€™s promise to transfer Mytesi to specialty pharmacies, based on specified payment and shipping terms outlined in the agreements. Transaction price The transaction price is the amount of consideration the Company expects to collect in exchange for transferring the promised goods or services. The transaction price of Mytesi is the WAC, net of estimated discounts, returns, and price adjustments. Allocate transaction price The entire transaction price is allocated to the single performance obligation contained in each contract. Revenue recognition The single performance obligation is satisfied at a point in time, upon the FOB terms of each contract, when control, including title and all risks, has been transferred to the customer. Product Revenue Sales of Mytesi are recognized as revenue at a point in time when the products are delivered to the specialty pharmacies. Net revenues from the sale of Mytesi to the specialty pharmacies were \$3.0 million and \$2.8 million for the three months ended September 30, 2024 and 2023, respectively. Net revenues from the sale of Mytesi to the specialty pharmacies were \$8.0 million and \$7.3 million for the nine months ended September 30, 2024 and 2023, respectively. A 17 Table of Contents A Contracts â€œ License Agreement Effective March 18, 2024, the Company engaged in a securities purchased agreement, supplemented by a binding term sheet, with Gen Ilac Ve Saglik Urunleri Sanayi Ve Ticaret, A.S. (â€œGENâ€) (â€œLicenseeâ€). The Company grants GEN a right to access its intellectual properties for the Company's FDA-approved prescription drug Crofelemer and commercialize Crofelemer finished product in licensed Eastern Europe territories for a consideration including license fees, royalties and product sales. The agreement and binding term sheet collectively qualifies as a valid contract under ASC 606. Performance obligations The Company identified two promises, namely (1) the grant of license to manufacture and commercialize pharmaceutical products that utilize Crofelemer (the â€œLicensing Transactionâ€) and (2) the supply of Crofelemer Active Pharmaceutical Ingredient (â€œAPIâ€). Licensee cannot benefit from the license alone without the API as the latter comes from a plant exclusive to the Company. No other entities can produce the API. Consequently, the grant of license and the supply API are not distinct, and accounted as a single performance obligation. Transaction price Transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties. The transaction price in the contract with GEN includes both fixed and variable considerations. For the Licensing Transaction, the fixed consideration is measured as the difference between the proceeds from the related share issuance and the fair value of the shares issued. The variable consideration, in the form of royalty, is based on a percentage of the Licensee's revenue from the sale of pharmaceutical products utilizing Crofelemer. For the supply of Crofelemer API, the variable consideration is determined using the expected value of a wide range of possible amounts. Allocate transaction price The entire transaction price is allocated to the single performance obligation contained in the contract. Revenue recognition The single performance obligation is satisfied over-time, throughout the five-year license period, based on the expiration dates of the licensed patents. License Revenue For the three and nine months ended September 30, 2024, license fees recognized from the contract with GEN amounted to \$42,000 and \$85,000, respectively. As of September 30, 2024, the total deferred revenue associated with this contract amounted to \$765,000. Collaboration Revenue Revenue recognition for collaboration agreements requires significant judgment. The Companyâ€™s assessments and estimates are based on contractual terms, historical experience, and general industry practice. Revisions in these values or estimations increase or decrease collaboration revenue in the period of revision. On September 24, 2018, the Company entered into a Distribution, License, and Supply Agreement (â€œLicense Agreementâ€) with Knight Therapeutics (â€œKnightâ€). The License Agreement has a term of 15 years (with automatic renewals) and provides Knight with an exclusive right to commercialize current and future Jaguar human health products (including crofelemer, NP-300, and any product containing a proanthocyanidin or with an anti-secretory mechanism) in Canada and Israel. Knight forfeited its right of first negotiation for expansion to Latin America. Under the License Agreement, Knight is responsible for applying for and obtaining necessary regulatory approvals in the territory of Canada and Israel, as well as marketing, sales, and distribution of the licensed products. Knight will pay a transfer price for all licensed products, and upon achievement of certain regulatory and sales milestones, the Company may receive payments from Knight in an aggregate amount of up to approximately \$18.0 million, payable throughout the initial 15-year term of the agreement. The Company did not have any license revenues for the three and nine months ended September 30, 2024 and 2023. A 18 Table of Contents A Modifications to Liability-classified Instruments In accounting for debt modifications and exchange transactions, it is the Companyâ€™s policy first to determine whether it qualifies as a troubled debt restructuring (â€œTDRâ€) pursuant to the guidance provided in ASC 470-60, Debtâ€œ Troubled Debt Restructurings by Debtors (â€œASC 470-60â€). A debt modification or exchange transaction that is not within the scope of the ASC 470-60 is accounted for under ASC 470-50, Modification and Extinguishments (â€œASC 470-50â€), to determine if the transaction is a mere modification or an extinguishment. For the nine months ended September 30, 2024 and September 30, 2023, the Company has entered amendments to the terms of its royalty interests and purchase agreements. The cumulative impact of these amendments resulted to certain extinguishments and modifications (See Note 7). Modifications to Equity-classified Instruments In accounting for modifications of equity-classified warrants, the Companyâ€™s policy is to determine the impact by analogy to the share-based compensation guidance of ASC 718, Compensation-Stock Compensation (â€œASC 718â€). The model for a modified share-based payment award that is classified as equity and remains classified in equity after the modification is addressed in ASC 718-20-35-3, Compensation-Stock Compensationâ€œAwards Classified as Equityâ€ Subsequent Measurement. Pursuant to that guidance, the incremental fair value from the modification is recognized as an expense in the statements of operations to the extent the modified instrument has a higher fair value; however, in certain circumstances, such as when an entire class of warrants is modified, the measured increase in fair value may be more appropriately recorded as a deemed dividend, depending upon the nature of the warrant modification. The Company did not modify any equity-classified warrants for the three and nine months ended September 30, 2024 and 2023. In accounting for amendments to preferred stock, the Companyâ€™s policy is to measure the impact by analogy to ASC 470-50 in determining if such an amendment is an extinguishment or a modification. If the amendment results in an extinguishment, the Company follows the SEC staff guidance in ASC 260-10-S99-2, Earnings Per Shareâ€œOverallâ€ SEC Materials, and ASC 470-20, Debtâ€œD with Conversion and Other Options. If the amendment results in a modification, the Company follows the model in either ASC 718 or ASC 470-50, depending on the nature of the amendment. The Company did not modify any equity-classified preferred stock for the three and nine months ended September 30, 2024 and 2023. Stock-based Compensation The Company's Stock Incentive Plan (See Note 12) provides for the grant of stock options, restricted stock, and restricted stock unit awards. The Company measures stock awards granted to employees, non-employees, and directors at estimated fair value on the date of grant and recognizes the corresponding compensation expense of the awards, net of estimated forfeitures, over the requisite service periods, which correspond to the vesting periods of the awards. If necessary, forfeitures are estimated at the time of grant and revised in subsequent periods if actual forfeitures differ from those estimates. The Company issues stock awards with only service-based vesting conditions and records compensation expenses for these awards using the straight-line method. The Company uses its common stock's grant date fair market value to determine the grant date fair value of options granted to employees, non-employees, and directors. The Company measures and recognizes compensation expense for all stock options and RSUs granted to its employees and directors based on the estimated fair value of the award on the grant date. The Company uses the Black-Scholes valuation model to estimate the fair value of stock option awards. The fair value is recognized as an expense, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award, on a straight-line basis. The Company believes that the fair value of stock options granted to non-employees is more reliably measured than the fair value of the services received. The determination of the grant date fair value of options using an option pricing model is affected by the Companyâ€™s estimated common stock fair value and requires management to make a number of assumptions, including the expected life of the option, the volatility of the underlying stock, the risk-free interest rate and expected dividends. The Company estimates the fair value of stock options using the Black-Scholes option valuation model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair market value of common stock is based on the closing price of the Companyâ€™s common stock as reported on the date of the grant. A 19 Table of Contents A Income Taxes The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The Company has adopted the provisions of ASC 740, Income Taxes. Under these principles, tax positions are evaluated in a two-step process. The Company first determines whether it is more likely than not that a tax position will be sustained upon examination. If a tax position meets the more-likely-than-not recognition threshold, it is then measured to determine the amount of benefit to be recognized in the financial statements. The tax position is the most significant benefit, with a greater than 50 percent likelihood of being realized upon ultimate settlement. The Company files a consolidated tax return for its related entities. Foreign Currency Remeasurement and Translation The functional currency of Napo Therapeutics is the Euro. The Company follows ASC 830, Foreign Currency Matters (â€œASC 830â€). ASC 830 requires the assets, liabilities, and results of operations of a foreign operation to be measured using the functional currency of that foreign operation. Exchange gains or losses from remeasuring transactions and monetary accounts in a currency other than the functional currency are included in current earnings or losses. For certain subsidiaries, translation adjustments result from translating the functional currency of subsidiary financial statements into the U.S. Dollar reporting currency. These translation adjustments are reported separately and accumulated in the unaudited condensed consolidated balance sheets as a component of accumulated other comprehensive gain or loss. Comprehensive Loss The Company follows ASC 220, Income Statementâ€œReporting Comprehensive Income, which establishes standards for reporting and displaying comprehensive income and its components (revenue, expenses, gains, and losses) in a full set of general-purpose financial statements. For the three months ended September 30, 2024 and 2023, the other comprehensive losses from translation adjustments were \$164,000 and \$83,000, respectively. For the nine months ended September 30, 2024 and 2023, the other comprehensive losses from translation adjustments were \$40,000 and \$132,000, respectively. Basic and Diluted Net Loss Per Share of Common Stock Basic net loss per share of common stock is computed by dividing net loss attributable to common stockholders for the year by the weighted average number of common stock outstanding during the year. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders for the year by the weighted average number of common stock, including potential dilutive shares of common stock assuming the dilutive effect of potential dilutive securities. The Company uses the treasury stock method to calculate diluted net loss per share. For years in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share because their impact would be anti-dilutive to the calculation of net loss per share. For the three and nine months ended September 30, 2023, the Company reports a combined basic net loss and diluted loss per share of common stock. Diluted net loss per share of common stock is the same as basic net loss per share of common stock for the three and nine months ended September 30, 2024. Recent Accounting Pronouncements Recently Adopted Accounting Pronouncements Segment Reporting In November 2023, FASB issued ASU 2023-07, Segment Reporting â€œ Improvements to Reportable Segment Disclosures which amends Topic 280 by enhancing segment reporting by requiring more detailed expense information for each reportable segment. Under the guidance, public entities are required to disclose (1) significant expense categories and amounts as those regularly provided to the chief operating decision maker (â€œCODMâ€) for each reportable segment and how the CODM uses the reported measures of a segmentâ€œ profit or loss to assess segment performance and decide how to allocate resources (2) the amount and A 20 Table of Contents A composition of other segment items included in reported segment profit or loss, and (3) the CODMâ€s position and title. Additionally, multiple measures of a segmentâ€œ profit or loss may be reported, under certain conditions, and single reportable segment entities must apply Topic 280 in its entirety. The ASU requires all segment profit or loss and assets disclosures to be provided on an annual and interim basis. For each interim period, the total of the reportable segmentsâ€œ amount for the measures of profit or loss is to be reconciled to the public entity's consolidated income before income taxes and discontinued operations. The ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company early adopted the ASU on its interim period reporting as of and for the period ended September 30, 2024. Debt with Conversion and Other Options In August 2020, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2020-06, titled â€œDebtâ€œD with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedgingâ€œContracts in Entityâ€™s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entityâ€™s Own Equity.â€ This update simplifies the accounting for convertible instruments by removing the requirement to separate the debt and equity components of such instruments. This ASU has no impact in the Companyâ€™s financial statements. Recently Issued Accounting Pronouncements Not Yet Adopted Stock Compensation In March 2024, the FASB issued ASU 2024-01, Compensation â€œ Stock Compensation (Topic 718): Scope Application of Profit Interest and Similar Awards. This update clarifies how companies account for profit interest and similar awards given to employees or non-employees, which helps determine whether such award fall under stock compensation or general compensation accounting standards. The amendments in this update are effective for annual periods beginning after December 15, 2025, and interim periods within those annual periods for entities other than public business entities. The Company has elected not to early adopt but will monitor the effects of the additional disclosures. Joint Venture Formations (Subtopic 805-60): Recognition and Initial Measurement. This update outlines the recognition and initial measurement requirements for these joint ventures. The amendments are effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company has elected not to early adopt but will monitor the impact of the additional disclosures. 3. Fair Value Measurements ASC 820, Fair Value Measurements, defines fair value, establishes a framework for measuring fair value under U.S. GAAP and enhances disclosures about fair value measurements. Fair value is defined under ASC 820 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 under ASC 820 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following: A Level 1 â€œ Observable inputs such as quoted prices (unadjusted) for identical instruments in active markets. A Level 2 â€œ Observable inputs such as quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-derived valuations whose significant inputs are observable. A Level 3 â€œ Unobservable inputs that reflect the reporting entityâ€™s own assumptions. The following table set forth the fair value of the Companyâ€™s financial instruments that were measured at fair value on a recurring basis as of September 30, 2024 and December 31, 2023. A 21 Table of Contents A A A September 30, 2024 A A A (unaudited) A Level 1 A A Level 2 A A Level 3 A A Total A Iliad A \$ A â€œ A A \$ A â€œ A A \$ A 4,812 A A \$ A 4,812 A Uptown A A A â€œ A A A â€œ A A A 8,854 A A A 8,854 A Streeterville 2 A A A â€œ A A A â€œ A A A 7,994 A A A 7,994 A Streeterville Note A A A â€œ A A A â€œ A A A 11,131 A A A 11,131 A A A Total fair value A \$ A â€œ A A \$ A 32,791 A A A \$ A 32,791 A A A December 31, 2023





common stock at an exercise price of \$22.2 per share. Such warrants may be exercisable for cash or on a cashless basis at any time and from time to time during the period commencing on September 29, 2023 (the "Issuance Date") and ending on the five-year anniversary of the Issuance Date. Pursuant to an analysis of the indicators provided in ASC 470-60-55-8, Debt-to-Troubled Debt Restructurings by Debtors" Implementation Guidance and Illustrations (ASC 470-60-55-8), the Company is not deemed to be experiencing financial difficulty. The debt restructuring is, therefore, not considered a TDR. The cumulative effect of the exchanges to the October 2020 Royalty Interest resulted in significant modifications and was accounted for as extinguishment. The Company recorded an extinguishment gain in the unaudited condensed consolidated statements of operations amounting to \$2.0 million. The extinguishment triggered a remeasurement event under ASC 825-10 and created an election date on whether to account for the October 2020 Royalty Interest under the FVO. The Company irrevocably elected to initially and subsequently apply the FVO accounting to the entire royalty interest. The Company used the valuation report from an independent valuation service provided to measure the reporting date fair value of the royalty interest. On December 28, 2023, the Company entered into a privately negotiated exchange agreement with Iliad, pursuant to which the Company issued an aggregate of 81,250 shares of the Company's Common Stocks to Iliad in exchange for a \$789,000 reduction in the outstanding balance of the October 2020 Royalty Interest. The effect of the exchange was accounted for as a debt modification. On January 29, 2024, the Company entered into a privately negotiated exchange agreement with Iliad pursuant to which the Company issued an aggregate of 133,333 shares of the Company's common stock to Iliad in exchange for a \$836,000 reduction in the outstanding balance of the royalty interest dated October 8, 2020, Royalty Interest. The effect of the exchange was accounted for as a debt modification. A 32 Table of Contents A On June 7, 2024, the Company entered into an exchange agreement with Iliad, pursuant to which the parties agreed to partition \$1,500,000 from the outstanding balance of the royalty interest dated October 8, 2020. This reduced the outstanding balance of the original royalty interest. The partitioned royalty was exchanged for 6,562 shares of the Company's common stock. On July 15, 2024, the Company entered into a privately negotiated exchange agreement with Iliad pursuant to which the Company issued an aggregate of 455,000 shares of the Company's common stock to Iliad in exchange for a \$1.9 million reduction in the outstanding balance of the original royalty interest. The effect of the exchange was accounted for as a debt modification. On July 18, 2024, the Company entered into a privately negotiated exchange agreement with Iliad pursuant to which the Company issued an aggregate of 200,000 shares of the Company's common stock to Iliad in exchange for a \$819,000 reduction in the outstanding balance of the original royalty interest. The effect of the exchange was accounted for as a debt modification. On September 30, 2024 and December 31, 2023, the fair value of Iliad's royalty interests was determined to be \$4.8 million and \$6.9 million. For the three and nine months ended September 30, 2024, the net change in the fair value of Iliad's royalty interests was \$1.3 million and \$2.9 million, respectively. The net change in fair value was recorded in the changes in fair value of freestanding and hybrid financial instruments designated at FVO in the unaudited condensed consolidated statements of operations. December 2020 Purchase Agreement On December 22, 2020, the Company entered into a royalty interest purchase agreement (the "December 2020 Purchase Agreement") with Uptown Capital, LLC (f/k/a Irving Park Capital, LLC) (the "Uptown"), a company affiliated with CVP, pursuant to which the Company sold to Uptown a royalty interest entitling Uptown to receive \$12.0 million of future royalties on sales of Mytesi and certain up-front license fees and milestone payments from licensees and distributors (the "Royalty Repayment Amount") for an aggregate purchase price of \$6.0 million (the "December 2020 Royalty Interest"). Until such time as the Royalty Repayment Amount has been paid in full, the Company will pay Uptown 10% of the Company's Net Sales on Included Products and 10% of worldwide revenues related to upfront licensing fees and milestone payments from licensees and distributors, but specifically excluding licensing fees and milestone payments that are reimbursements of clinical trial expenses (the "Royalty Payments"). Beginning on the payment start date of March 8, 2024, and continuing until the 12-month anniversary of the Purchase Price Date, the monthly Royalty Payment shall be the greater of (a) \$750,000 and (b) the actual Royalty Payment amount Uptown is entitled to for such month. At initial recognition, the December 2020 Royalty Interest amount of \$12.0 million is classified as debt, net of a \$6.0 million discount. Under ASC 470-10-35-3, royalty payments to Uptown will be amortized under the interest method per ASC 835-30. Because there is no set interest rate and the royalty payments are variable, the discount rate is variable. After each royalty payment, the Company will use a prospective method to determine a new discount rate based on the revised estimate of remaining cash flows. The new rate is the discount rate that equates the present value of the revised estimate of remaining cash flows with the carrying amount of the debt, and it will be used to recognize interest expense for the remaining periods. At issuance, based on projected cash outflows from future revenue streams, the discount rate was 23.70%. On April 14, 2022, under the Royalty Interest Global Amendments, the Company was granted, at its sole discretion, the right to exchange, from time to time, all or any of the Royalty Interest under the original principal amount of \$12.0 million or any portion of the December 2020 Purchase Agreement for shares of the Company's common stock at a price per share equal to the Nasdaq Minimum Price (as defined in Nasdaq Listing Rule 5635(d)) as of date of the applicable exchange, subject to certain limitations. On February 8, 2023, the Company entered into an exchange agreement with Uptown, pursuant to which the parties agreed to partition \$675,000 from the outstanding balance of the royalty interest. The parties further agreed to exchange the partitioned royalty for 2,500 shares of the Company's stock. On May 8, 2023, the Company entered into an exchange agreement with Uptown to (i) partition a new royalty interest in the royalty repayment amount of \$1.1 million from the outstanding balance of the royalty interest and exchange for 31,811 shares of the Company's common stock. On the same date, the Company entered into the Standstill Agreement as described above, pursuant to which the Company may refrain from making royalty payments on the December 2020 Royalty Interest during the Standstill Period. On September 29, 2023, the Company entered into the Global Amendment No. 2 to the December 2020 Royalty Interest with Uptown, pursuant to which, beginning on January 1, 2026, the monthly Royalty Payment under the December 2020 Royalty Interest shall be the greater of (a) \$750,000.00, and (b) the actual Royalty Payment amount Uptown is entitled to for such month pursuant to A 33 Table of Contents A the terms of the December 2020 Royalty Interest. As a material consideration for Uptown's agreement to enter into this amendment, the Company agreed to issue to Uptown warrants to purchase up to 4,375 shares of the Company's common stock at an exercise price of \$22.2 per share. Such warrants may be exercisable for cash or on a cashless basis at any time and from time to time during the period commencing on September 29, 2023 (the "Issuance Date") and ending on the five-year anniversary of the Issuance Date. Pursuant to an analysis of the indicators provided in ASC 470-60-55-8, the Company is not deemed to be experiencing financial difficulty. The debt restructuring is, therefore, not considered a TDR. On the same date, the Company entered into a privately negotiated exchange agreement with Uptown (the "Exchange Agreement"), pursuant to which the Company issued an aggregate of 118 shares of the Company's newly authorized Series I Convertible Preferred Stock (the "Series I Preferred Stock" or "Preferred Stock") to Uptown, at an effective exchange price per share equal to the market price (defined as the Minimum Price under Nasdaq Listing Rule 5635(d)) as of the date of the Exchange Agreement, in exchange for a \$1,500,000.00 reduction in the outstanding balance of the December 2020 Royalty Interest (the "Partitioned Royalty") (the "Exchange Transaction"). Subject to the terms of the Series I Preferred Stock, each share of Series I Preferred Stock is convertible into shares of the Company's Common Stock (the "Conversion Shares"). The cumulative effect of the exchanges to the December 2020 Royalty Interest resulted in significant modifications and was accounted for as extinguishment. The Company recorded an extinguishment gain in the unaudited condensed consolidated statements of operations amounting to \$2.7 million. The extinguishment triggered a remeasurement event under ASC 825-10 and created an election date on whether to account for the December 2020 Royalty Interest under the FVO accounting. The Company irrevocably elected to initially and subsequently apply the FVO accounting to the entire royalty interest. The Company used the valuation report from an independent valuation service provided to measure the reporting date fair value of the royalty interest. On September 30, 2024 and December 31, 2023, the fair value of Uptown's royalty interests was determined to be \$8.9 million and \$7.5 million. For the three and nine months ended September 30, 2024, the net change in the fair value of Uptown's royalty interests was \$619,000 and \$1.4 million, respectively. The net change in fair value was recorded in the change in fair value of financial instruments and hybrid instruments designated at FVO in the unaudited condensed consolidated statements of operations. March 2021 Purchase Agreement On March 8, 2021, the Company entered into a purchase agreement (the "March 2021 Purchase Agreement") with Streeterville Capital, LLC (the "Streeterville"), a company affiliated with CVP, pursuant to which the Company sold a royalty interest entitling Streeterville to \$10.0 million and any interest, fees, and charges as royalty repayment amount for an aggregate purchase price of \$5.0 million (the "March 2021 Royalty Interest"). Interest will accrue on the royalty repayment amount at a rate of 5% per annum, compounding quarterly, and will increase to 10% per annum, compounding quarterly on the 12-month anniversary of the closing date. The Company will be obligated to make minimum royalty payments on a monthly basis beginning at the earlier of (a) 36 months following the closing date or (b) 30 days following the satisfaction of all existing royalties to Streeterville, and its affiliates namely Iliad and Uptown, but not earlier than 18 months following the closing date in an amount equal to the greater of (i) \$250,000 beginning on the royalty payment start date and continuing until either the royalty repayment amount has been paid in full or the 6-month anniversary of the royalty payment start date, \$400,000 beginning on the 6-month anniversary of the royalty payment start date and continuing until either the royalty repayment amount has been paid in full or the 12-month anniversary of the royalty payment start date, \$600,000 beginning on the 12-month anniversary of the royalty payment start date and continuing until either the royalty repayment amount has been paid in full or the 18-month anniversary of the royalty payment start date, \$750,000 beginning on the 18-month anniversary of the royalty payment start date and continuing until the royalty repayment amount has been paid in full, and (ii) 10% of the Company's net sales on included products, 10% of worldwide revenues related to upfront licensing fees and milestone payments from licensees and/or distributors but specifically excluding licensing fees and/or milestone payments that are reimbursements of clinical trial expenses or associated with the license of Included Products from the Company to Napo EU, including but not limited to the upfront fee payable by Napo EU to Napo for included products and Crofelemer for other indications; and 50% of royalties collected from licenses of the included products to third parties. At initial recognition, the March 2021 Royalty Interest amount of \$10.0 million is classified as debt, net of a \$5.0 million discount. Under ASC 470-10-35-3, royalty payments to Streeterville will be amortized under the interest method per ASC 835-30. Because there is no set interest rate and the royalty payments are variable, the discount rate is variable. After each royalty payment, the Company will use a prospective method to determine a new discount rate based on the revised estimate of remaining cash flows. The new rate is the discount rate that equates the present value of the revised estimate of remaining cash flows with the carrying amount of the debt, and it will be used to recognize interest expense for the remaining periods. At issuance, based on projected cash outflows from future revenue streams, the discount rate was 19.36%. A 34 Table of Contents A On April 14, 2022, under the Royalty Interest Global Amendments, the Company is granted, at its sole discretion, the right to exchange, from time to time, all or any of the Royalty Interest under the original principal amount of \$10.0 million of the March 2021 Purchase Agreement for shares of the Company's common stock at a price per share equal to the Nasdaq Minimum Price (as defined in Nasdaq Listing Rule 5635(d)) as of date of the applicable exchange, subject to certain limitations. The Company entered into several exchange agreements after the Royalty Interest Global Amendments from August 17, 2022, to September 30, 2022, whereby the Company agreed to partition \$5.4 million from the outstanding balance of the royalty interest and exchange for a total of 5,170 shares of the Company's common stock with a par value of \$0.0001 in accordance with the term of the Royalty Interest Exchange Agreement. These exchange agreements were collectively assessed and accounted for as debt modification. On March 1, 2024, the Company entered into a privately negotiated exchange agreement with Streeterville, pursuant to which the Company issued an aggregate of 179 shares of Series J Preferred Stock to Streeterville in exchange for the surrender of the March 2021 Royalty Interest by Streeterville. Upon completion of the CVP Exchange Transaction, all outstanding balance of the March 2021 Royalty Interest was fully paid, and the March 2021 Royalty Interest was terminated. The exchanges of Series J Preferred Stock were accounted for as extinguishment. Because the fair value of the common stock transferred is less than the carrying amount of the Series J Preferred Stock surrendered, the difference was credited to retained earnings and added to earnings available to common shareholders. Interest expenses were \$0 and \$448,000 for the three and nine months ended September 30, 2024, respectively. Interest expenses for the three and nine months ended September 30, 2023, were \$531,000 and \$1.5 million, respectively. As of September 30, 2024, and December 31, 2023, the carrying value of the debt was \$0 and \$4.6 million, respectively. August 2022 Purchase Agreement On August 24, 2022, the Company entered into another royalty interest purchase agreement (the "August 2022 Purchase Agreement") with Streeterville, pursuant to which the Company sold Streeterville a royalty interest to receive \$12.0 million (the "August 2022 Royalty Interest") of future royalties on sales of Mytesi® (crofelemer) for any indications that could cannibalize crofelemer indications or any other chronic indication and certain up-front license fees and milestone payments from licensees and/or distributors for an aggregate purchase price of \$4.0 million (the "Royalty Financing"). The Company will use the proceeds to support the ongoing pivotal Phase 3 clinical trial of crofelemer for prophylaxis of diarrhea in adults receiving targeted cancer therapy. Interest will accrue on the Royalty Repayment Amount at a rate of 5% per annum from the closing of the Royalty Financing until the one-year anniversary of such closing and 10% per annum thereafter, simple interest computed based on a 360-day year comprised of twelve 30-day months. The Company will be obligated to make minimum royalty payments on a monthly basis beginning on January 1, 2024 in an amount equal to the greater of (A) \$250,000 (which increases to \$400,000 beginning 6 months following the closing of the Royalty Financing, \$600,000 beginning 12 months following the closing of the Royalty Financing, and \$750,000 beginning 18 months following the closing of the Royalty Financing) and (B) the royalty payments to which Investor is entitled, consisting of (1) 10% of the Company's net sales of crofelemer for any indications that could cannibalize crofelemer indications or any other chronic indication (including any improvements, modifications and follow-on products, collectively referred to as "Included Products") (2) 10% of worldwide revenues related to upfront licensing fees and milestone payments from licensees and/or distributors, but specifically excluding licensing fees and/or milestone payments that are (A) reimbursements of clinical trial expenses or (B) associated with the license of the Included Products from the Company to Napo Therapeutics and (3) 50% of royalties collected from licenses of the Included Products to third parties. Pursuant to the terms of the August 2022 Royalty Interest, the Company has the right to exchange from time to time at the Company's sole discretion all or any portion of the Royalty Interest for shares of common stock at a price per share equal to the Nasdaq Minimum Price (as defined in Nasdaq Listing Rule 5635(d)) as of the date of the applicable exchange. At issuance, based on projected cash outflows from future revenue streams, the discount rate was 55.97%. On September 29, 2023, the Company entered into a Global Amendment No. 2 (the "Global Amendment") with the Investor as described further above, such that the Company issued Streeterville warrants to purchase 255,000 shares of the common stock the Global Amendment No. 1 and Global Amendment No. 2 to the August 2022 Royalty Interest with Streeterville, pursuant to which, (a) beginning on January 1, 2026, the monthly Royalty Payment under the August 2022 Royalty Interest shall be the greater of (x) \$750,000.00, and (y) the actual Royalty Payment amount Streeterville is entitled to for such month pursuant to the terms of the August 2022 Royalty Interest, and (b) the Company is prohibited from making prepayments of the Royalty Repayment Amount under the August 2022 Royalty Interest. As a material consideration for Streeterville's agreement to enter into these amendments, the Company agreed to issue Streeterville warrants to purchase up to 4,250 shares of the Company's common stock at an exercise price of \$22.20 A 35 Table of Contents A per share. Such warrants may be exercisable for cash or on a cashless basis at any time and from time to time during the period commencing on September 29, 2023 (the "Issuance Date") and ending on the five-year anniversary of the Issuance Date. Pursuant to an analysis of the indicators provided in ASC 470-60-55-8, the Company is not deemed to be experiencing financial difficulty. The debt restructuring is, therefore, not considered a TDR. The cumulative effect of the exchanges to the August 2022 Royalty Interest resulted in significant modifications, which were accounted for as extinguishment. The Company recorded an extinguishment loss in the unaudited condensed consolidated statements of operations amounting to \$1.0 million. The extinguishment triggered a remeasurement event under ASC 825-10 and created an election date on whether to account for the August 2022 Royalty Interest resulted under the FVO accounting. The Company irrevocably elected to initially and subsequently apply the FVO accounting to the entire royalty interest. The Company used the valuation report from an independent valuation service provided to measure the reporting date fair value of the royalty interest. On January 29, 2024, the Company entered into a privately negotiated exchange agreement with Streeterville pursuant to which the Company issued 26,461 shares of the Company's common stock, par value \$0.0001 to Streeterville in exchange for a \$165,000 reduction in the outstanding balance of the royalty interest dated August 24, 2022. On September 30, 2024 and December 31, 2023, the fair value of Streeterville's royalty interests was determined to be \$8.0 million and \$6.8 million, respectively. For the three and nine months ended September 30, 2024, the net change in the fair value of Streeterville's royalty interests was \$55,000 and \$1.3 million, respectively. The net change in fair value were recorded in the changes in fair value of freestanding and hybrid instruments designated at FVO in the unaudited condensed consolidated statements of operations. Streeterville Note On January 13, 2021, the Company issued a secured promissory note to Streeterville in the original principal amount of \$6.2 million for an aggregate purchase price of \$6.0 million. The Company will use the proceeds to fund the development of the Company's NP-300 drug product candidate for the indication of the symptomatic relief of diarrhea from cholera and general corporate purposes, including the Company's product pipeline activities. The note is due after four years and bears interest at 3.25% per annum. Interest on the note is payable annually in advance by adding the interest











financial instrument and hybrid instrument designated at FVO of \$3.4 million, amortization of debt discounts and debt issuance costs of \$11.5 million, stock-based compensation of \$1.5 million, depreciation and amortization expenses of \$1.5 million, amortization of operating lease right-of-use asset of \$286,000, shares issued in exchange of services of \$166,000, equity in a net loss in the joint venture of \$42,000, gain on extinguishment of debt of \$3.7 million and changes in operating assets and liabilities of \$7.8 million. A 62 Table of Contents A Cash Used in Investing Activities During the nine months ended September 30, 2024, net cash used in investing activities of \$16,000 consisted of a \$16,000 purchase of equipment. Cash outflows for investing activities were minimal at \$16,000 in 2024, dedicated solely to equipment purchases. This reflects management's commitment to maintaining liquidity, as there were no cash outflows for investing activities in the prior year. No cash is used in investing activities during the nine months ended September 30, 2023. Cash Provided by Financing Activities During the nine months ended September 30, 2024, net cash provided by financing activities of \$28.4 million consisted of \$27.8 million in net proceeds from shares issued in an At the Market offering, \$1.2 million proceeds from the issuance of common shares in exchange of License Agreement, offset by \$437,000 repayment of insurance financing, and \$100,000 in principal payments of the notes payable. Net cash provided by financing activities increased to \$28.4 million in 2024, primarily from an ATM offering and share issuance related to licensing agreement. This trend underscores the Company's ongoing necessity to leverage external financing to address cash flow shortfalls from operations. During the nine months ended September 30, 2023, net cash provided by financing activities of \$23.6 million consisted of \$20.8 million in net proceeds from shares issued in an At the Market offering, \$1.2 million net proceeds from issuance of warrants in PIPE financing, \$611,000 net proceeds from issuance of preferred shares in PIPE financing and noncontrolling interest of \$1.2 million, offset by \$293,000 repayment of insurance financing, and \$50,000 in principal payments of the notes payable. Item 3. Quantitative and Qualitative Disclosures About Market Risk Not applicable. Item 4. Controls and Procedures Disclosure Controls and Procedures Our management, Chief Executive Officer, and Principal Financial and Accounting Officer evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial and Accounting Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, our Chief Executive Officer and Principal Financial and Accounting Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2024. Internal Control over Financial Reporting Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(c) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of the effectiveness of internal control in future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our Chief Executive Officer and Principal Financial and Accounting Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of September 30, 2024, using the criteria established in Internal Control-Integrated Framework (2013 Framework) issued by the Committee of Sponsoring Organization of the Treadway Commission ("COSO"). Based on our evaluation using those criteria, our management has concluded that, as of September 30, 2024, our internal control over financial A 63 Table of Contents A reporting was effective in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP for the reasons discussed above. This Quarterly Report on Form 10-Q does not include an attestation report of our registered public accounting firm on our internal control over financial reporting because we are a smaller reporting company and are not subject to auditor attestation requirements under applicable SEC rules. There were no changes in our internal control over financial reporting that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting. A 64 Table of Contents A PART II. A" OTHER INFORMATION Item 1. Legal Proceedings From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Regardless of the outcome, litigation can have a material adverse effect on us due to defense and settlement costs, diversion of our management resources, and other factors. We are not currently subject to any material legal proceedings. Item 1A. Risk Factors The following discussion of risk factors contains forward-looking statements. These risk factors may be important to understanding other statements in this Quarterly Report on Form 10-Q, including Management's Discussion and Analysis of Financial Condition and Results of Operations and our unaudited condensed consolidated financial statements and related notes, before making a decision to invest in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. If any of the events or circumstances described in the following risk factors actually occur, our business, operating results, financial condition, cash flows, and prospects could be materially and adversely affected. In that event, the market price of our common stock could decline, and you could lose part or all of your investment. The business, financial condition, and operating results of the Company can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below, any one or more of which could, directly or indirectly, cause the Company's actual financial condition and operating results to vary materially from past, or from anticipated future, financial condition and operating results. Any of these factors, in whole or in part, could materially and adversely affect the Company's business, financial condition, operating results, and stock price. Because of the following factors and other factors affecting the Company's financial condition and operating results, past financial performance should not be considered a reliable indicator of future performance, and investors should not use historical trends to anticipate results or trends in future periods. Our royalty interests require us to make minimum royalty payments, even if we do not sell sufficient products to cover such. A Since March 2020, we have sold royalty interests to certain lenders that entitle such lenders to receive future royalties on sales of our products. These royalty interests require us to make minimum royalty payments beginning in 2021, even if we do not sell a sufficient amount of product to cover such payments, which may strain our cash resources. Total minimum royalty payments, approximately totaling \$36.0 million, will commence in 2026. Item 2. Unregistered Sales of Equity Securities and Use of Proceeds On July 15, 2024, the Company entered into a privately negotiated exchange agreement with a holder of royalty interest in the Company pursuant to which the Company issued 455,000 shares of the Company's common stock, par value \$0.0001 to such holder in exchange for a \$1,851,850 reduction in the outstanding balance of the royalty interest held by such holder. On July 18, 2024, the Company entered into a privately negotiated exchange agreement with Iliad pursuant to which the Company issued 200,000 shares of the Company's common stock, par value \$0.0001 to Iliad in exchange for a \$819,600 reduction in the outstanding balance of the royalty interest dated October 8, 2020. The shares of common stock that were issued in the exchange transactions described above were issued in reliance on the exemption from registration provided under Section 3(a)(9) of the Securities Act. Other than equity securities issued in transactions disclosed above and on our Current Reports on Form 8-K filed with the SEC on June 10, 2024, and July 16, 2024, there were no unregistered sales of equity securities during the period. Item 3. Defaults Upon Senior Securities None. Item 4. Mine Safety Disclosures Not applicable. A 65 Table of Contents A Item 5. Other Information None. A 66 Table of Contents A Item 6. Exhibits Exhibit No. A Description 3.1 A Certificate of Eighth Amendment of the Third Amended and Restated Certificate of Incorporation of Jaguar Health, Inc. (incorporated by reference to Exhibit 3.1 to the Form 8-K filed May 23, 2024, File No. 001-36714). 10.1 A Second Amendment to the At the Market Offering Agreement, dated May 23, 2024, by and between Jaguar Health, Inc. and Ladenburg Thalmann & Co. Inc. (incorporated by reference to Exhibit 10.1 to the Form 8-K filed May 23, 2024, File No. 001-36714). 10.2 A Third ATM Amendment, dated July 17, 2024, to ATM Agreement by and among Jaguar Health, Inc., Ladenburg Thalmann & Co. Inc. and Lucid Capital Markets, LLC (incorporated by reference to Exhibit 10.1 to the Form 8-K filed July 18, 2024, File No. 001-36714). 31.1\* A Principal Executive Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. 31.2\* A Principal Financial Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. 32.1\*\* A Certification Pursuant to 18 U.S.C. A§ 1350 (Section 906 of Sarbanes-Oxley Act of 2002). 32.2\*\* A Certification Pursuant to 18 U.S.C. A§ 1350 (Section 906 of Sarbanes-Oxley Act of 2002). 101.INS A Inline XBRL Instance Document A" the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document 101.SCH A Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents 104 A The cover page for the Company's Quarterly Report on Form 10-Q has been formatted in Inline XBRL and contained in Exhibit 101 A A A A A A A A A A \* Filed herewith. \*\* In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34 47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10 Q and will not be deemed A filed A for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933 except to the extent that the registrant specifically incorporates it by reference. A 67 Table of Contents A SIGNATURE Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized. A November 13, 2024 A A JAGUAR HEALTH, INC. A A A By: /s/ Carol R. Lizak A Principal Financial and Accounting Officer A A 68 EX-31.1 Exhibit 31.1 CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002 I, Lisa A. Conte, certify that: 1.I have reviewed this quarterly report on Form 10-Q of Jaguar Health, Inc. for the quarter ended September 30, 2024; 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(s) 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; and 5.The registrant's other certifying officer(s) 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. A Date:November 13, 2024 By: /s/ Lisa A. Conte Lisa A. Conte President and Chief Executive Officer A A EX-31.2 Exhibit 31.2 CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002 I, Carol Lizak, certify that: 1.I have reviewed this quarterly report on Form 10-Q of Jaguar Health, Inc. for the quarter ended September 30, 2024; 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(s) 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, 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; and 5.The registrant's other certifying officer(s) 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. A Date: November 13, 2024 By: /s/ Carol Lizak Carol Lizak Principal Financial and Accounting Officer A A EX-32.1 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 Quarterly Report of Jaguar Health, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. A§ 1350, as adopted pursuant to 906 of the Sarbanes-Oxley Act of 2002, that: (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 result of operations of the Company. A Date: November 13, 2024 By: /s/ Lisa A. Conte Lisa A. Conte President and Chief Executive Officer A A EX-32.2 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 Quarterly Report of Jaguar Health, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. A§ 1350, as adopted pursuant to 906 of the Sarbanes-Oxley Act of 2002, that: (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 result of operations of the Company. A Date: November 13, 2024 By: /s/ Carol Lizak Carol Lizak Principal Financial and Accounting Officer A A